AOAC Official Methods Board
June 22, 2016
Webconference

AOAC INTERNATIONAL
2275 Research Blvd, Suite 300
Rockville, MD 20850
1.301.924.7077

OFFICIAL METHODS BOARD MEETING

Wednesday and Thursday, June 22-23, 2016

10am ET / 9:00am CT (Day One) & 9:30am ET / 8:30am CT (Day Two)

Table of Contents

PRELIMINARY ITEMS

2014-2015 OMB Roster	3
Policy Documents/Terms of Reference	4
Draft OMB Meeting Agenda*	25
Draft OMB Meeting Minutes – February 29, 2016	26
AOAC Official Methods Board Update	28
AOAC Board of Directors – June Meeting Update	29

OFFICIAL METHODS BOARD WORKING GROUPS

OMB Working Group on Method Format	30
OMB Working Group on Vetting Stakeholder Panels & Expert Review Panels	31
OMB Working Group on Review of Candidate Methods	34
OMB Working Group on OMB New Member Selection	41
Committee on Safety and Committee on Statistics – Terms of Reference	145
OMB Working Group on OMB Terms of Reference	152

AOAC EXPERT REVIEW PANELS

ERP for SPDS – Aloin, Cinnamon, Tea, and Vitamin D	155
ERP Recommendation for Final Action	294

AOAC OFFICIAL METHODS BOARD AWARDS

AOAC OMB Awards Document	395
Award Candidates – AOAC Website	

AOAC ANNUAL MEETING PREVIEW OF ACTIVITIES

Annual Meeting Activities and OMB Meetings	401

Upcoming Meetings

AOAC ERP FOR SPDS – ALOIN, CINNAMON, TEA,
ROCKVILLE
AUGUST 2, 2016

AOAC SPADA MEETING
ROCKVILLE
AUGUST 30, 2016

AOAC STAKEHOLDER PANEL MEETINGS
DALLAS, TX
SEPTEMBER 16-18, 2016

AOAC ANNUAL MEETING
DALLAS, TX
SEPTEMBER 18-21, 2016

AOAC BOARD OF DIRECTORS MEETING
DALLAS, TX
SEPETMEBER 19, 2016

AOAC OMB MEETING
DALLAS, TX
SEPTEMBER 22, 2016

Calls for Methods

- *SPDS – Cinnamon, Aloin, Tea, & Vitamin D*
- *SPSFAM – Ethanol in Kombucha (fermented tea),*
- *SPSFAM - Select Food Allergens (Hazelnut, Milk, Peanut, Whole Egg)*

Calls for Experts

- *Ethanol in fermented teas*
- *Hazelnut, Milk, Peanut, and whole milk allergens and MS technology*
- *Solids in Syrups*

AOAC INTERNATIONAL
OFFICIAL METHODS BOARD

2015 – 2016

Chair	**Shauna Roman** Reckitt Benckiser, Inc. Shauna.Roman@reckittbenckiser.com Term 3: August 29, 2013 – September 21, 2016	*Member*	**Joe Boison** Canadian Food Inspection Agency Joe.Boison@inspection.gc.ca Term 1: August 29, 2013 – September 21, 2016
Member	**Doug Abbott** Independent Consultant douglas.abbott@gmail.com Term 2: September 11, 2014 - September 27, 2017	*Member*	**Don Gilliland** Abbott Nutrition don.gilliland@abbott.com Term 1: October 1, 2015 - September 29, 2018
Member	**Sneh Bhandari** Silliker, Inc. Sneh.Bhandari@Silliker.com Term 2: August 29, 2013 – September 21, 2016	*Member*	**Katerina Mastovska** Covance Laboratories Katerina.Mastovska@covance.com Term 1: October 1, 2015 - September 29, 2018
Member	**Jo Marie Cook** Florida Department of Agriculture and Consumer Services JoMarie.Cook@freshfromflorida.com Term 2: August 29, 2013 – September 21, 2016	*Member*	**Tom Phillips** Maryland Department of Agriculture phillitd@mda.state.md.us Term 2: August 29, 2013 – September 21, 2016
Member	**Erin Sutphin Crowley** Q Laboratories, Inc. ecrowley@qlaboratories.com Term 2: October 1, 2015 - September 29, 2018	*Member*	**Bradley Stawick** Microbac Laboratories, Inc. brad.stawick@microbac.com Term 2: October 1, 2015 - September 29, 2018
Member	**Qian Graves,** US FDA *AOAC Committee on Statistics, Chair* Qian.graves@fda.hhs.gov Term 2: August 29, 2013 – September 21, 2016	*Member*	**Yvonne Salfinger,** Independent Consultant *AOAC Committee on Safety, co-Chair* Yhale@aol.com Term 1: August 29, 2013 – September 21, 2016
Past Chair (Ex-officio Member)	**John Szpylka** Silliker, Inc. John.Szpylka@Silliker.com Term 4: August 29, 2013 – September 21, 2016		

AOAC Staff Liaisons

Deborah McKenzie Sr. Director- Standards Development Sr. Director- AOAC Research Institute dmckenzie@aoac.org	Delia Boyd Program Manager – Standards Development dboyd@aoac.org

AOAC INTENATIONAL Terms begin following the AOAC Business Meeting. Terms expire at the AOAC Business Meeting. Version 2

AOAC INTERNATIONAL
BYLAWS

As Amended September 26, 2010

ARTICLE I
Name

The name by which this Association shall be known is "AOAC INTERNATIONAL" (hereinafter referred to as the "Association").[1]

ARTICLE II
Purpose

The primary purpose of the Association is to promote methods validation and quality measurements in the analytical sciences.

ARTICLE III
Membership

Section 1. Types of Membership

There shall be three (3) types of membership in the Association: Individual Members, Sustaining Member Organizations, and Organizational Affiliates.

A. Individual Members

There shall be four (4) categories of Individual Members in the Association: Members, Retired Members, Student Members, and Honorary Members.

B. Sustaining Member Organizations

There shall be one (1) category of Sustaining Member Organizations.

C. Organizational Affiliate

There shall be one (1) category of Organizational Affiliate.

Section 2. Qualifications for Membership

A. Individual Members

[1] Members

Qualifications for Members shall be a degree in science, or equivalent as approved by the Board of Directors, and interest in supporting and furthering the purpose and goals of the Association. Such scientists shall be eligible for membership provided they are engaged, or have been engaged, directly or indirectly, in a field relevant to the purpose of the Association.

[2] Retired Members

[1] AOAC INTERNATIONAL was incorporated in the District of Columbia on January 20, 1932, as the Association of Official Agricultural Chemists. On November 10, 1965, the name of the corporation was changed to the Association of Official Analytical Chemists, and on September 12, 1991, the current name was adopted.

A current Member who is no longer actively engaged, directly or indirectly, in a field relevant to the purpose of the Association but who has served the Association as a Member for at least ten (10) years shall be eligible for Retired Member status upon written request and payment of the annual Retired Member dues. Any special benefits accorded Retired Members shall be determined by the Executive Director.

[3] Student Members

Any full-time student working toward an undergraduate or graduate degree in the areas of chemistry, microbiology, food science or other related science shall be eligible for Student Membership in AOAC INTERNATIONAL.

[4] Honorary Members

Honorary Members shall be persons recognized for their substantial contribution toward the achievement of the objectives of the Association. They shall be nominated by the Board of Directors and may be elected by a two-thirds vote of the Individual Members voting.

B. Sustaining Member Organizations

A Sustaining Member Organization shall be any agency of a local, state, provincial, national, or international government; a university, college, or academic department; or any firm, business, or organization with an interest in supporting and furthering the purpose of the Association. Every Sustaining Member Organization must have a designated representative(s). All such Sustaining Member Organization representatives must meet the qualifications for Members and become Individual Members with all the rights and privileges thereof.

C. Organizational Affiliate

An Organizational Affiliate Organization shall be any agency of a local, state, provincial, national, or international government; a university, college, or academic department; or any firm, business, or organization with an interest in supporting and furthering the purpose of the Association. Every Organizational Affiliate must have a designated representative(s). All such Organizational Affiliate representatives must meet the qualifications for Members and become Individual Members with all the rights and privileges thereof.

Section 3. Application for Membership

Applications or requests for membership shall be submitted to the Association's headquarters office. Membership shall become effective upon approval of the application or request, payment of any required membership dues, entry on the membership rolls, and assignment of a member number.

Section 4. Expulsion

The Board of Directors, at any duly called meeting of the Board, by a two-thirds vote of those holding office, may terminate the membership of any member who in its judgment has violated the Bylaws or has been guilty of conduct detrimental to the best interests of the Association. Any member convicted of a felony is subject to immediate expulsion from the Association. Expulsion of a member by the Board of Directors shall be final and shall cancel all rights, interest, or privileges of such member in the services or resources of the Association. Any member, for whom expulsion is proposed, for reasons other than conviction of a felony, shall be entitled to not less than 60 days advance notice of the charges, the date upon which a hearing will be scheduled, and the right to present evidence in defense. The date and place of any such hearing, if held other than at the headquarters or annual meeting site of the Association, must be reasonable with respect to the location of any individual so charged.

Section 5. Dues, Membership Year, and Waivers

A. Annual dues for membership in the Association shall be fixed by the Board of Directors, subject to approval by the majority of the Individual Members voting by ballot by any of the following means (whichever is deemed appropriate by the Board at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission.

B. Honorary Members of the Association shall be exempt from payment of dues and annual meeting registration fees.

C. The membership year and the delinquency date shall be determined by the Board of Directors.

D. The authority to grant waivers of membership dues rests with Executive Director.

E. Student Member dues shall be one-third of regular Member dues, rounded up to the nearest $5.00 increment.

Section 6. Members in Good Standing; Rights and Privileges

All Individual Members who maintain their membership by payment of dues as required under these Bylaws and who otherwise qualify shall be considered in good standing and entitled to full privileges of membership.

ARTICLE IV
Officers

Section 1. Elected Officers

The elected officers of the Association shall be Individual Members and shall consist of a President, President-Elect, Secretary, Treasurer, and Immediate Past President.

A. President

The President shall be the principal elected officer of the Association, shall preside at meetings of the Association and of the Board of Directors and of the Executive Committee, and shall be a member ex-officio, with right to vote, of all committees except the Nominating Committee. He or she shall also, at the annual meeting of the Association and at such other times as he or she shall deem proper, communicate to the Association or the Board of Directors such matters and make such suggestions as may in his or her opinion tend to promote the welfare and further the purpose of the Association and shall perform such other

duties as are necessarily incident to the office of President or as may be prescribed by the Board of Directors.

B. President-Elect

In the absence of the President, or in the event of the President's inability or refusal to act, the President-Elect shall perform the duties of the President, and, when so acting, shall have all the powers of and be subject to all the restrictions upon the President. The President-Elect shall perform such other duties as from time to time may be assigned to him or her by the President or by the Board of Directors.

C. Secretary

The Secretary shall give notice of all meetings of the Association, keep a record of all proceedings, attest documents, and, in general, perform such other duties as are usual of the office of Secretary and such other duties as may be assigned by the President or by the Board of Directors.

D. Treasurer

The Treasurer shall be responsible for the funds and securities of the Association; serve as financial officer of the organization and as Chairperson of the Finance Committee; manage the Board of Director's review of and action related to the Board of Director's financial responsibilities; serve as the chief Board liaison in overseeing and reviewing the annual audit, and in general, perform such other duties as are usual of the office of Treasurer and such other duties as may be assigned by the President or by the Board of Directors.

E. Immediate Past President

The Immediate Past President shall serve as advisor to the President and Directors and perform such other duties as may be assigned from time to time by the President or by the Board of Directors.

Section 2. Appointed Officers

The appointed officers shall include the Executive Director and such other appointed officers as may be designated by the Board of Directors from time to time.

A. Executive Director

The day-to-day administration and management of the Association's offices shall be vested in a salaried manager employed or appointed by, and directly responsible to, the Board of Directors. This manager shall have the title of Executive Director with responsibility for the management and direction of all operations, programs, activities, and affairs of the Association, as approved or delegated by the Board of Directors. The Executive Director shall have direct responsibility for employment and termination of employment and the determination of compensation for staff members within the budgetary framework determined by the Board of Directors. The Executive Director functions as the chief operating officer of the Association within the guidelines established by the policies and procedures of the Board of Directors and, as necessary, with the concurrence of the President. The Executive Director shall have such other duties as may be prescribed by the Board.

B. Other Appointed Officers

Other appointed officers shall have such duties as may be prescribed by the Board.

ARTICLE V
Nominations, Elections, Terms, and Appointments to the Board of Directors

Section 1. Nominating Committee

The Nominating Committee shall annually recommend to the Board of Directors a slate of Individual Members as potential nominees for the elected positions where vacancies will occur. The Nominating Committee shall consist of five (5) members who shall be three (3) immediate Past Presidents, as available, and two (2) Individual Members-at-Large of the Association. If three Past Presidents are not available to serve, other Individual Members-at-Large shall be appointed by the President to the extent necessary to form the five (5)-member committee.

Section 2. Elections and Terms of Office

The President-Elect, the Secretary, Treasurer, and the Directors of the Board of Directors shall be elected by a majority of Individual Members voting, from a slate of nominees recommended annually by the Board of Directors.

Terms of office for all Officers and Directors shall begin with the adjournment of the annual meeting following their election and shall end with the adjournment of the annual meeting occurring nearest the expiration of their term. The six (6) Directors shall be elected to staggered three-year terms with two Directors elected to full three-year terms each year, but not to more than two (2), consecutive, three-year terms. Appointment or election to fill an unexpired term shall not affect the eligibility of a person to subsequently be elected to two (2) full terms. The Secretary shall be elected to a one-year term and may be re-elected to successive one-year terms. The Treasurer shall be elected for a one-year term and may be re-elected to successive one-year terms. The President-Elect shall be elected to a one-year term; whereupon the current President-Elect shall become President and the current President shall become the Immediate Past President, each serving a one-year term.

Section 3. Appointments

Directors-at-Large are appointed by the Board in accordance with Article VI, Section 2. Directors-at-Large are appointed for one (1) year terms, renewable at the discretion of the elected Board.

ARTICLE VI
Board of Directors

Section 1. Composition

The Board of Directors shall consist of eleven (11) elected members to include the President, President-Elect, Secretary, Treasurer, Immediate Past President, six (6) Directors, and up to three (3) appointed Directors-at-Large, all of whom shall be Individual Members of the Association. The elected Board shall reflect the makeup of the Association membership and shall not be dominated by any single interest.

Section 2. Powers and Duties

The Board of Directors shall provide supervision, control, and direction of the affairs of the Association, shall determine the Association's policies or changes therein within the limits of the Bylaws, shall actively prosecute

its purpose, and shall have discretion in the disbursement of its funds. It may adopt such rules and procedures for the conduct of its business as shall be deemed advisable, and may, in the execution of the powers granted, appoint such agents as it may consider necessary. The Board of Directors may appoint up to three (3) Directors-at-Large, if, in their opinion, such appointments advance the purpose of the Association. Directors-at-Large shall be accorded the same voting privileges as elected Directors.

Section 3. Meetings

Except that the Board shall have a regular meeting at the time and place of the annual meeting, the Board shall meet, in person or via telephone conference call, upon call of the President at such times and places as he or she may designate within the policies adopted by the Board, and shall be called to meet upon demand of a majority of its members. Notice of all meetings of the Board of Directors shall be sent by any of the following means (whichever is deemed appropriate by the President at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission to each member of the Board at his or her last recorded address or number at least fourteen (14) days in advance of in-person meetings or forty-eight (48) hours in advance of conference call meetings.

Section 4. Quorum

A quorum for any meeting of the Board is six (6) Board members elected in accordance with Article V (1). Any less number may: (1) set a time to adjourn, (2) adjourn, (3) recess, or (4) take measures to obtain a quorum.

Section 5. Absence

Any member of the Board of Directors unable to attend a meeting of the Board shall notify the President and state the reason for his or her absence. If a member of the Board is absent from two (2) consecutive meetings, he or she may be removed by a two-thirds vote of the Board Members then in office.

Section 6. Compensation

Members of the Board of Directors, as such, shall not receive any compensation for their services as Board members, but the Board may, by resolution under policies it may adopt, authorize reimbursement of expenses incurred in the performance of members' duties. Such authorization may prescribe conditions and procedures for approval and payment of such expenses. Nothing herein shall preclude a Board member from serving the Association in any other capacity and receiving compensation for such services, if compensation is customarily paid for such services.

Section 7. Resignation or Removal

Any member of the Board may resign at any time by giving written notice to the President, Secretary, Treasurer, or to the Board of Directors. Such resignation shall take effect at the time specified therein, or, if no time is specified, at the time of acceptance thereof as determined by the President or the Board.

Any member of the Board may be removed by a three-fourths vote of the Board members then in office and present at any regular or special meeting of the Board.

Section 8. Vacancies: Members of the Board

If a vacancy should occur in the membership of the elected Board of Directors, any Past President may be appointed by action of the remaining members of the Board to temporarily fill such vacancy until the next

regularly scheduled election. At the next regularly scheduled election nominations will be presented to fill the vacancy for the unexpired portion of the term remaining.

Section 9. Vacancies: President and Other Officers

If the office of the President shall become vacant, the President-Elect shall thereupon become President of the Association for the unexpired term, followed by his or her duly elected term. In the event the office of President becomes vacant at a time when the office of President-Elect is also vacant, the Presidency shall be filled for the remainder of the term by the action of the Board of Directors. If any other officer position shall become vacant, the office may be filled for the remainder of the term by action of the Board.

ARTICLE VII
Committees

Section 1. Committee Formation

The Board of Directors shall form and adopt terms of reference for such standing or special boards, committees, subcommittees, task forces, or task groups as may be required by these Bylaws or as the Board may determine necessary to carry out the affairs of the Association.

Section 2. Committee Appointments

Subject to the requirements of these Bylaws and the specific terms of reference adopted by the Board, the President shall make the appointments to fill the vacancies occurring in the Association's standing or special boards, committees, subcommittees, task forces, or task groups.

ARTICLE VIII
Official Methods of Analysis

The Board of Directors (BoD) is empowered to develop written policies and procedures for the study, adoption, and change in status of the Official Methods of Analysis of AOAC INTERNATIONAL. Implementation of the policies and procedures shall be delegated to an Official Methods Board (OMB).

Section 1. Composition of the Official Methods Board

The Official Methods Board shall consist of a chair and a vice chair, and members who are recommended by the chair. The chair, vice chair and members are appointed by the President of AOAC INTERNATIONAL. The OMB shall be composed of members representing a balance of government, industry, and academia as appropriate to the scope of the group and shall not be dominated by any single interest.

Section 2. Purpose of the Official Methods Board

The OMB shall serve the Association in a scientific and advisory capacity on methods and the process of their adoption. The OMB shall be responsible for implementation of procedures adopted by the BoD, according to the principles in section 3 below.

Section 3. Principles of the Official Methods Program

A. Adequate records of technical data, discussions, and decisions on the study, adoption, and change of status of Official Methods of Analysis shall be maintained for a reasonable time.

B. Timely notice of proposed method studies, adoption, or change in status shall be published in an Association publication that is circulated to the members.

C. Opportunity shall be provided for materially interested parties to submit input during method study and adoption procedures and to submit comments on the adoption, use of, or change in status of specific methods.

D. Methods submitted to the OMB for inclusion in the OMA shall be thoroughly studied, scientifically reviewed, and available in published form prior to adoption as Final Action by the OMB.

E. The OMB shall adopt methods as Final Action.

ARTICLE IX
Meetings

Section 1. Annual Meeting

The annual business meeting of the Association shall be held at the time and place decided by the Board of Directors. A special meeting of the entire Association may be called by the Board of Directors; announcement thereof shall be made at least thirty (30) days prior to the time of said meeting.

Section 2. Quorum

One hundred Individual Members who are present in person or by proxy and entitled to vote shall constitute a quorum at any meeting of the Association which is duly called pursuant to the provisions of these Bylaws.

ARTICLE X
Voting

Section 1. Voting by Ballot

By direction of the Board of Directors, unless otherwise required by these Bylaws or conducted under alternative procedures established under these Bylaws, voting on any matter, including the election of officers and directors, the election of Honorary Members, amendment of the Bylaws, and the approval of dues, may be conducted by ballot of the voting membership by any of the following means (whichever is deemed appropriate at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission, and the question(s) thus presented shall be determined according to the votes received, provided in each case votes of at least five (5) percent of the voting membership shall be received. Any and all action taken in pursuance of a vote by any of the means indicated above (whichever the Board deemed appropriate at the time)

in each case shall be binding upon the Association in the same manner as would be action taken at a duly called meeting and shall become effective, unless otherwise provided for in these Bylaws or otherwise stated in the ballot, on the day following certification of the vote.

Section 2. Voting by Proxy

At any duly called meeting of Individual Members, a member-of-record, as determined thirty (30) days prior to any meeting and who is entitled to vote, may vote by proxy executed in writing by the Individual Member or his or her duly authorized attorney-in-fact. No proxy shall be valid for more than eleven (11) months after the date of its execution unless otherwise provided in the proxy.

ARTICLE XI
Earnings and Assets

Section 1. Non-Profit Status

A. Regardless of any provision of the Bylaws which may be construed otherwise:

[1] No part of the net earnings of the Association shall under any circumstances inure to the benefit of any member or individual.

[2] The Association shall not be operated for a private profit.

B. On lawful dissolution of the Association and after settlement of all just obligations of the Association, the Board of Directors shall distribute all remaining assets of the Association to one (1) or more organizations selected by the Board of Directors which have been held exempt from Federal Income Tax as organizations described in section 501(c)(3) of the Internal Revenue Code of 1954.

Section 2. Political Activities

A. No substantial part of the Association's activities shall consist of carrying on propaganda or otherwise attempting to influence local, state, or national legislation. All activities of the Association shall be determined by the Board of Directors.

B. The Association shall not participate or intervene in any manner in any campaign on behalf of any candidate for a political office.

ARTICLE XII
Sections

Section 1. Sections

The Board of Directors shall set geographic limits and grant authority to groups of Individual Members of the Association residing or working in the same geographical areas for the establishment of Sections.

Section 2. Purpose of Sections

The purpose of Sections shall be to promote and further the purpose of the Association.

Section 3. Membership in Sections

Individuals interested in the purpose of the Section shall be eligible for Section membership. Only Individual Members of the Association shall be eligible for election to the Executive Committee of the Section.

Section 4. Bylaws of Sections

Subject to approval of the Board of Directors, each Section shall adopt, for its own governance, bylaws not inconsistent with these Bylaws.

Section 5. Dissolution of Sections

When any Section shall cease to function as a Section for a period of more than one year, or if its membership shall be less than ten (10) Individual Members of the Association for a period of one (1) year, the Board of Directors may terminate the existence of such Section.

Section 6. Actions of Sections

No act of a Section or its members shall be considered an act of the Association unless expressly authorized, ratified, or affirmed by the Board of Directors.

ARTICLE XIII
Technical Divisions

Section 1. Purpose

Technical Divisions shall represent communities of interest within the Association which have the purpose of furthering the purpose of the Association through the development of the analytical sciences either in a commodity-based or scientific discipline-based field. Their activities shall not duplicate the organizational structure nor conflict with the policies or procedures for the adoption of official methods of analysis by the Association.

Section 2. Creation, Combination, Discontinuance, or Change

Technical Divisions may be created, existing Technical Divisions may be combined or discontinued, or the name of a Technical Division may be changed under policies and procedures adopted by the Board of Directors. Each Technical Division shall adopt bylaws not inconsistent with these Bylaws. The jurisdiction of each Technical Division shall be described in its bylaws. No act of any Technical Division or its members shall be considered an act of the Association unless expressly authorized, ratified, or affirmed by the Board of Directors.

ARTICLE XIV
Indemnification

The Association shall have the power to pay, by indemnity, reimbursement, or otherwise, to or for the use of any person designated by resolution of the Board of Directors who was or is a party or is threatened to be made a party to any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative (other than an action by or on behalf of the Association), by reason of the fact he or she is or was a director, officer, committee member, employee or agent of the Association, or was serving as such for another at the request of the Association, against expenses (including legal, accounting, witness and other), judgments, fines, and amounts paid in settlement so long as such person was not found by a court of competent jurisdiction to have been willfully negligent of the interests of the Association or such person had reasonable cause to believe that his or her conduct was lawful.

ARTICLE XV
Parliamentary Authority

The rules contained in the current edition of *Robert's Rules of Order Newly Revised* shall govern the Association in all cases in which they are applicable and in which they are not inconsistent with these Bylaws or any special rules of order the Association may adopt.

ARTICLE XVI
Amendments to the Bylaws

These Bylaws may be amended, repealed, or altered, in whole or in part, by a three-fourths vote: (a) of the Individual Members at any annual business or duly called special meeting of the Association, provided notice of any amendment proposed for consideration shall be sent by any of the following means (whichever may be deemed appropriate at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission to the last recorded address or number of each Individual Member at least thirty (30) days prior to the date of the meeting; or (b) by approval of the Individual Members through ballot sent by any means indicated above in accordance with the provisions of Article X, Voting.

All proposed amendments of these Bylaws shall be presented in writing to the Board of Directors. The Board shall present the proposals to the Association membership, with recommendations. All amendments to the Bylaws, unless otherwise stated, will become effective at the adjournment of the meeting where action is taken or on the day following the certification of a vote by mail ballot.

AOAC INTERNATIONAL
POLICY ON THE USE OF THE
ASSOCIATION NAME, INITIALS,
IDENTIFYING INSIGNIA, LETTERHEAD, AND BUSINESS CARDS

Introduction

The following policy and guidelines for the use of the name, initials, and other identifying insignia of AOAC INTERNATIONAL have been developed in order to protect the reputation, image, legal integrity and property of the Association.

The name of the Association, as stated in its bylaws, is "AOAC INTERNATIONAL". The Association is also known by its initials, AOAC, and by its logo, illustrated below, which incorporates the Association name and a representation of a microscope, book, and flask. The AOAC logo is owned by the Association and is registered with the U.S. Patent and Trademark Office.

AOAC INTERNATIONAL

The full Association insignia, illustrated below, is comprised of the logo and the tagline, "The Scientific Association Dedicated to Analytical Excellence," shown below. The typeface used is Largo. The AOAC tagline is owned by the Association and is registered with the U.S. Patent and Trademark office.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

Policy

Policy on the use of the Association's name and logo is established by the AOAC Board of Directors as follows:

> "The Board approves and encourages reference to the Association by name, either as AOAC INTERNATIONAL or as AOAC; or reference to our registered trademark, AOAC®, in appropriate settings to describe our programs, products, etc., in scientific literature and other instances so long as the reference is fair, accurate, complete and truthful and does not indicate or imply unauthorized endorsement of any kind.
>
> The insignia (logo) of AOAC INTERNATIONAL is a registered trade and service mark and shall not be reproduced or used by any person or organization other than the Association, its elected and appointed officers, sections, or committees, without the prior written permission of the Association. Those authorized to use the AOAC INTERNATIONAL insignia shall use it only for the purposes for which permission has been specifically granted.
>
> The name and insignia of the Association shall not be used by any person or organization in any way which indicates, tends to indicate, or implies AOAC official endorsement of any product, service, program, company, organization, event or person, endorsement of which, has not been authorized by the Association, or which suggests that membership in the Association is available to any organization."

The Executive Director, in accordance with the above stated policy, is authorized to process, approve, fix rules, and make available materials containing the Association name and insignia.

It should be noted that neither the Association's name nor its insignia nor part of its insignia may be incorporated into any personal, company, organization, or any other stationery other than that of the Association; nor may any statement be included in the printed portion of such stationery which states or implies that an individual, company, or other organization is a Member of the Association.

Instructions

1. Reproduction or use of the Association name or insignia requires prior approval by the Executive Director or his designate.

2. Association insignia should not be altered in any manner without approval of the Executive Director or his designate, except to be enlarged or reduced in their entirety.

3. Artwork for reproducing the Association name or insignia, including those incorporating approved alterations, will be provided on request to those authorized to use them (make such requests to the AOAC Marketing Department). Examples of the types of alterations that would be approved are inclusion of a section name in or the addition of an officer's name and address to the letterhead insignia.

4. When the Association name is used without other text as a heading, it should, when possible, be set in the Largo typeface.

5. Although other colors may be used, AOAC blue, PMS 287, is the preferred color when printing the AOAC insignia, especially in formal and official documents. It is, of course, often necessary and acceptable to reproduce the insignia in black.

6. Do not print one part of the logo or insignia in one color and other parts in another color.

7. The letterhead of AOAC INTERNATIONAL shall not be used by any person or organization other than the Association, its elected and appointed officers, staff, sections, or committees; except by special permission.

   Correspondence of AOAC official business should be conducted using AOAC letterhead. However, those authorized to use AOAC letterhead shall use it for official AOAC business only.

   Copies of all correspondence using AOAC letterhead or conducting AOAC official business, whether on AOAC letterhead or not, must be sent to the appropriate office at AOAC headquarters.

8. AOAC INTERNATIONAL business cards shall not be used by any person or organization other than the Association, its staff, and elected officials, except by special permission.

   Those authorized to use AOAC business cards shall use them for official AOAC business only and shall not represent themselves as having authority to bind the Association beyond that authorized.

Sanctions

1. Upon learning of any violation of the above policy, the Executive Director or a designate will notify the individual or organization that they are in violation of AOAC policy and will ask them to refrain from further misuse of the AOAC name or insignia.

2. If the misuse is by an Individual Member or Sustaining Member of the Association, and the misuse continues after notification, the Board of Directors will take appropriate action.

3. If continued misuse is by a nonmember of the Association or if a member continues misuse in spite of notification and Board action, ultimately, the Association will take legal action to protect its property, legal integrity, reputation, and image.

* * * * * *

Adopted by the AOAC Board of Directors: September 24, 1989
Revised: June 13, 1991; February 26, 1992; March 21, 1995; October 1996

AOAC INTERNATIONAL
ANTITRUST POLICY
STATEMENT AND GUIDELINES

Introduction

It is the policy of AOAC INTERNATIONAL (AOAC) and its members to comply strictly with all laws applicable to AOAC activities. Because AOAC activities frequently involve cooperative undertakings and meetings where competitors may be present, it is important to emphasize the on_going commitment of our members and the Association to full compliance with national and other antitrust laws. This statement is a reminder of that commitment and should be used as a general guide for AOAC and related individual activities and meetings.

Responsibility for Antitrust Compliance

The Association's structure is fashioned and its programs are carried out in conformance with antitrust standards. However, an equal responsibility for antitrust compliance __ which includes avoidance of even an appearance of improper activity __ belongs to the individual. Even the appearance of improper activity must be avoided because the courts have taken the position that actual proof of misconduct is not required under the law. All that is required is whether misconduct can be inferred from the individual's activities.

Employers and AOAC depend on individual good judgment to avoid all discussions and activities which may involve improper subject matter and improper procedures. AOAC staff members work conscientiously to avoid subject matter or discussion which may have unintended implications, and counsel for the Association can provide guidance with regard to these matters. It is important for the individual to realize, however, that the competitive significance of a particular conduct or communication probably is evident only to the individual who is directly involved in such matters.

Antitrust Guidelines

In general, the U.S. antitrust laws seek to preserve a free, competitive economy and trade in the United States and in commerce with foreign countries. Laws in other countries have similar objectives. Competitors (including individuals) may not restrain competition among themselves with reference to the price, quality, or distribution of their products, and they may not act in concert to restrict the competitive capabilities or opportunities of competitors, suppliers, or customers.

Although the Justice Department and Federal Trade Commission generally enforce the U.S. antitrust laws, private parties can bring their own lawsuits.

Penalties for violating the U.S. and other antitrust laws are severe: corporations are subject to heavy fines and injunctive decrees, and may have to pay substantial damage judgments to injured competitors, suppliers, or customers. Individuals are subject to criminal prosecution, and will be punished by fines and imprisonment.
Under current U.S. federal sentencing guidelines, individuals found guilty of bid rigging, price fixing, or market allocation must be sent to jail for at least 4 to 10 months and must pay substantial minimum fines.

Since the individual has an important responsibility in ensuring antitrust compliance in AOAC activities, everyone should read and heed the following guidelines.

1. Don't make any effort to bring about or prevent the standardization of any method or product for the purpose or intent of preventing the manufacture or sale of any method or product not conforming to a specified standard.

2. Don't discuss with competitors your own or the competitors' prices, or anything that might affect prices such as costs, discounts, terms of sale, distribution, volume of production, profit margins, territories, or customers.

3. Don't make announcements or statements at AOAC functions, outside leased exhibit space, about your own prices or those of competitors.

4. Don't disclose to others at meetings or otherwise any competitively sensitive information.

5. Don't attempt to use the Association to restrict the economic activities of any firm or any individual.

6. Don't stay at a meeting where any such price or anti_competitive talk occurs.

7. Do conduct all AOAC business meetings in accordance with AOAC rules. These rules require that an AOAC staff member be present or available, the meeting be conducted by a knowledgeable chair, the agenda be followed, and minutes be kept.

8. Do confer with counsel before raising any topic or making any statement with competitive ramifications.

9. Do send copies of meeting minutes and all AOAC_related correspondence to the staff member involved in the activity.

10. Do alert the AOAC staff to any inaccuracies in proposed or existing methods and statements issued, or to be issued, by AOAC and to any conduct not in conformance with these guidelines.

Conclusion

Compliance with these guidelines involves not only avoidance of antitrust violations, but avoidance of any behavior which might be so construed. Bear in mind, however, that the above antitrust laws are stated in general terms, and that this statement is not a summary of applicable laws. It is intended only to highlight and emphasize the principal antitrust standards which are relevant to AOAC programs. You must, therefore, seek the guidance of either AOAC counsel or your own counsel if antitrust questions arise.

* * * * *

Adopted by the AOAC Board of Directors: September 24, 1989
Revised: March 11, 1991
Revised October 1996

AOAC INTERNATIONAL

POLICY AND PROCEDURES ON

VOLUNTEER CONFLICT OF INTEREST

Statement of Policy

While it is not the intention of AOAC INTERNATIONAL (AOAC) to restrict the personal, professional, or proprietary activities of AOAC members nor to preclude or restrict participation in Association affairs solely by reason of such activities, it is the sense of AOAC that conflicts of interest or even the appearance of conflicts of interest on the part of AOAC volunteers should be avoided. Where this is not possible or practical under the circumstances, there shall be written disclosure by the volunteers of actual or potential conflicts of interest in order to ensure the credibility and integrity of AOAC. Such written disclosure shall be made to any individual or group within the Association which is reviewing a recommendation which the volunteer had a part in formulating and in which the volunteer has a material interest causing an actual or potential conflict of interest.

AOAC requires disclosure of actual or potential conflicts of interest as a condition of active participation in the business of the Association. The burden of disclosure of conflicts of interest or the appearance of conflicts of interest falls upon the volunteer.

A disclosed conflict of interest will not in itself bar an AOAC member from participation in Association activities, but a three-fourths majority of the AOAC group reviewing the issue presenting the conflict must concur by secret ballot that the volunteer's continued participation is necessary and will not unreasonably jeopardize the integrity of the decision-making process.

Employees of AOAC are governed by the provision of the AOAC policy on conflict of interest by staff. If that policy is in disagreement with or mute on matters covered by this policy, the provisions of this policy shall prevail and apply to staff as well.

Illustrations of Conflicts of Interest

1. A volunteer who is serving as a committee member or referee engaged in the evaluation of a method or device; who is also an employee of or receiving a fee from the firm which is manufacturing or distributing the method or device or is an employee of or receiving a fee from a competing firm.

2. A volunteer who is requested to evaluate a proposed method or a related collaborative study in which data are presented that appear detrimental (or favorable) to a product distributed or a position supported by the volunteer's employer.

3. A referee who is conducting a study and evaluating the results of an instrument, a kit, or a piece of equipment which will be provided gratis by the manufacturer or distributor to one or more of the participating laboratories, including his or her own laboratory, at the conclusion of the study.

4. Sponsorship of a collaborative study by an interest (which may include the referee) which stands to profit from the results; such sponsorship usually involving the privilege granted by the investigator to permit the sponsor to review and comment upon the results prior to AOAC evaluation.

5. A volunteer asked to review a manuscript submitted for publication when the manuscript contains information which is critical of a proprietary or other interest of the reviewer.

The foregoing are intended as illustrative and should not be interpreted to be all-inclusive examples of conflicts of interest AOAC volunteers may find themselves involved in.

Do's and Don'ts

Do avoid the appearance as well as the fact of a conflict of interest.

Do make written disclosure of any material interest which may constitute a conflict of interest or the appearance of a conflict of interest.

Do not accept payment or gifts for services rendered as a volunteer of the Association without disclosing such payment or gifts.

Do not vote on any issue before an AOAC decision-making body where you have the appearance of or an actual conflict of interest regarding the recommendation or decision before that body.

Do not participate in an AOAC decision-making body without written disclosure of actual or potential conflicts of interest in the issues before that body.

Do not accept a position of responsibility as an AOAC volunteer, without disclosure, where the discharge of the accepted responsibility will be or may appear to be influenced by proprietary or other conflicting interests.

Procedures

Each volunteer elected or appointed to an AOAC position of responsibility shall be sent, at the time of election or appointment, a copy of this policy and shall be advised of the requirement to adhere to the provisions herein as a condition for active participation in the business of the Association. Each volunteer, at the time of his or her election or appointment, shall indicate, in writing, on a form provided for this purpose by AOAC, that he or she has read and accepts this policy.

Each year, at the spring meeting of the AOAC Board of Directors, the Executive Director shall submit a report certifying the requirements of this policy have been met; including the names and positions of any elected or appointed volunteers who have not at that time indicated in writing that they have accepted the policy.

Anyone with knowledge of specific instances in which the provisions of this policy have not been complied with shall report these instances to the Board of Directors, via the Office of the Executive Director, as soon as discovered.

* * * * * *

Adopted: March 2, 1989
Revised: March 28, 1990
Revised: October 1996

The Scientific Association Dedicated to Analytical Excellence®

AOAC INTERNATIONAL

TERMS OF REFERENCE

I. NAME:

OFFICIAL METHODS BOARD (OMB)

II. MISSION:

To serve the Association in a scientific and advisory capacity on standards and methods with ethical, timely, open and independent scientific oversight for the implementation of standards development and conformity assessment policies and procedures of AOAC INTERNATIONAL.

III. RESPONSIBILITIES:

To provide ethical, timely, open and independent scientific oversight for the policies and procedures of AOAC INTERNATIONAL.

To approve "Final Action" status for First Action Methods (new and revised) following a proactive review;

To repeal methods, if necessary, in accordance with established policies and procedures;

To participate in addressing appeals and requests for action or guidance, and in resolving disputes;

To endorse and monitor all voluntary consensus panels for appropriate representation and balance of stakeholders' perspectives;

To endorse and monitor all volunteer subject matter experts for volunteer conformity assessment activities;

To adopt and monitor scientific and technical guidance and references;

To acknowledge outstanding scientific and technical volunteer activity and achievement within AOAC;

To actively participate in AOAC standards development activities and maintain and communicate explicit knowledge of AOAC standards development and conformity assessment;

IV. COMPOSITION AND ORGANIZATION:

The Official Methods Board shall consist of up to 13 voting members including a Chair, a Vice-chair, the Chair of the Committee on Safety and the Chair of the Committee on Statistics. The Committee on Safety and the Committee on Statistics may contain co-chairs. The co-chairs for these committees represent one vote on the OMB. Members of the OMB may serve in multiple volunteer roles for the benefit of the Association. The Chair of the Official Methods Board shall have previously served as a member of the Official Methods Board. The Chair, Vice-chair, and members of the Official Methods Board including the chairs of standing committees shall be appointed for a term of three years. A member of the OMB may be reappointed upon the recommendation of the Chair of the Official Methods Board with a maximum term of service of six (6) years. Exceptions may be made at the discretion of the President. The Chair of the Official Methods Board is eligible to serve an additional post chair term of up to three (3) years as an *ex-officio* member. Members of the Official Methods Board must be members of AOAC.

All members of the Official Methods Board are recommended by the Chair and appointed by the President. All Official Methods Board members serve at the pleasure of the President.

The Official Methods Board represents the membership of AOAC INTERNATIONAL. It shall be composed of members representing a balance of scientific expertise, government, industry, and academia as appropriate to the scope of the Board. Every effort should be made to include international representation on the Board.

Additional working groups, task forces, and other appropriate subgroups shall be appointed as needs arise by the Chair of the Official Methods Board.

V. STAFF LIAISON:

The Executive Director shall assign a member of the staff to serve as staff liaison.

VI. REVIEW SCHEDULE:

Every three years.

VII. DATE ESTABLISHED:

Renamed in 1981

VIII. DATES REVIEWED

01/08,

IX. DATES REVISED:

9/89; 5/90; 1/91; 8/06;
02/07; 07/07; 2/08; 4/13; 8/13

OFFICIAL METHODS BOARD MEETING & WEBCONFERENCE

Wednesday and Thursday, June 22-23, 2016
10:00am – 6:00pm ET/ 9:00am - 5:00pm CT (Day One)
9:30am – 5:00pm ET / 8:30am – 4:00pm CT (Day Two)
AOAC Headquarters (Rockville, MD) & Mérieux NutriSciences (Chicago, IL)

DRAFT MEETING AGENDA

I. PRELIMINARY ITEMS
a. Welcome
b. Call to Order /Introductions/Announcements *(Roman)*
c. Review of Policy Documents/Terms of Reference *(Roman)*
d. Review of Draft Agenda* *(Roman)*
e. Review of May 12, 2016 OMB Teleconference Minutes* *(Roman)*
f. Update on OMB Report to the AOAC Board of Directors *(Roman)*
g. June Board of Directors Meeting Update *(Meiklejohn)*

II. OFFICIAL METHODS BOARD WORKING GROUPS
a. Working Group on Method Format & Revision to SMPR Guidelines *(Roman/Coates)*
b. Working Group on Vetting Stakeholder Panels and Expert Review Panels* *(Roman/ McKenzie)*
c. Working Group on Review of Candidate Methods* *(Roman/McKenzie)*
d. Working Group on OMB New Member Selection* *(Szpylka/Roman/McKenzie)*
e. Committee on Safety TOR* *(Salfinger/Roman/McKenzie)*
f. Committee on Statistics TOR* *(Graves/Roman/McKenzie)*
g. Working Group on OMB Terms of Reference* *(Roman/McKenzie)*

III. EXPERT REVIEW PANELS
a. ERP for SPDS Aloin, Cinnamon, Tea, & Vitamin D* *(Roman/Coates/McKenzie)*
b. ERP Recommendation for Final Action* *(Gilliland/Roman/McKenzie)*
   i. AOAC 2012.22 (Vitamin C in Infant Formula)

IV. AOAC OFFICIAL METHODS BOARD AWARDS
a. Team Awards *(Roman/McKenzie)*
   i. Award for Technical and Scientific Excellence*
   ii. ERP of the Year*
b. Individual Awards *(Roman/McKenzie)*
   i. Technical Service Award*
   ii. Method of the Year*

V. ANNUAL MEETING PREVIEW OF ACTIVITIES
a. Stakeholder Panel Meetings *(Roman/McKenzie)*
b. Expert Review Panel Meetings *(Roman/McKenzie)*
c. OMB Meetings *(Roman/Crowley/McKenzie)*
   i. 2016
   ii. 2017

VI. ADJOURNMENT

**** Items that require or may require a vote***

Upcoming Meetings

AOAC ERP FOR SPDS – ALOIN, CINNAMON, TEA, ROCKVILLE
AUGUST 2, 2016

AOAC SPADA MEETING
ROCKVILLE
AUGUST 30, 2016

AOAC STAKEHOLDER PANEL MEETINGS
DALLAS, TX
SEPTEMBER 16-18, 2016

AOAC ANNUAL MEETING
DALLAS, TX
SEPTEMBER 18-21, 2016

AOAC BOARD OF DIRECTORS MEETING
DALLAS, TX
SEPETMEBER 19, 2016

AOAC OMB MEETING
DALLAS, TX
SEPTEMBER 22, 2016

Calls for Methods
- *SPDS – Cinnamon, Aloin, Tea, & Vitamin D*
- *SPSFAM – Ethanol in Kombucha (fermented tea),*
- *SPSFAM - Select Food Allergens (Hazelnut, Milk, Peanut, Whole Egg)*

Calls for Experts
- *Ethanol in fermented teas*
- *Hazelnut, Milk, Peanut, and whole milk allergens and MS technology*
- *Solids in Syrups*

AOAC OFFICIAL METHODS BOARD
Teleconference
May 12, 2016
1:00pm ET – 2:30pm ET

DRAFT MEETING MINUTES

OMB MEMBERS *(present during all or part of the meeting)*

Shauna Roman	Reckitt Benckiser	Chair
Erin Crowley	Q Laboratories	Vice Chair
Douglas Abbott	Independent Consultant	Member
Joe Boison	Canadian Food Inspection Agency	Member
Jo Marie Cook	Florida Dept. of Agriculture and Consumer Services	Member
Don Gilliland	Abbott Nutrition	Member
Qian Graves	US FDA	Member
Katerina Mastovska (proxy)	Covance	Member
Tom Phillips	Maryland State Dept. of Agriculture	Member
Yvonne Salfinger	Independent Consultant	Member
Brad Stawick	Microbac	Member
John Szpylka	Mérieux NutriSciences	Past Chair-Ex-Officio

OMB MEMBERS ABSENT *(without proxy)*

Sneh Bhandari	Mérieux NutriSciences	Member

BOARD OF DIRECTORS *(present during all or part of the meeting)*

Darryl Sullivan	Covance Laboratories	Board Secretary

AOAC STAFF *(present during all or part of the meeting)*

Delia Boyd Deborah McKenzie

I. INTRODUCTORY ITEMS

a. Call to Order/Introductions/Announcements
Roman called the meeting to order at 1:05pm ET.

b. Roman called OMB's attention to the AOAC policy documents and reminded all attendees to review the documents and that the meeting will be held according to these policies.

c. Review and Approval of Draft Meeting Agenda
MOTION: For OMB to approve the agenda as amended.
Stawick moved and Crowley seconded. Consensus: Unanimous.

d. Review and Approval of April 14, 2016 OMB teleconference minutes.
MOTION: For OMB to approve the April 14, 2016 OMB meeting minutes
Boison moved and Abbott seconded. Consensus: Unanimous.

II. AOAC OMB AWARDS UPDATE

a. McKenzie reviewed a list of the OMB award candidates and nominees for the 2016 OMB awards. She informed OMB that they will have an opportunity to review the electronically. McKenzie mentioned that recommendations for nominations for Method of the Year were solicited from ERP

chairs. Roman reminded OMB that they have reviewed all eligible methods in the past. McKenzie and Roman reminded OMB members to provide nominations for the Technical and Scientific Award.

ACTION ITEMS:

1. Roman to coordinate method review assignments to OMB members.
2. Staff to coordinate online access to award information.
3. Staff to include discussion of the awards on the June meeting agenda..

VI. UPDATE ON AOAC OMB SUMMER MEETING – JUNE 22-23, 2016

a. Roman clarified attendance of OMB members at the June OMB meeting.

VII. AOAC OMB WORKING GROUP UPDATES

a. Working Group on Method Format & Revision to SMPR Guidelines
ACTION ITEM: Add to June Meeting agenda for Coates to provide update.

b. Working Group on OMB TOR
ACTION ITEM: Add to June Meeting agenda for OMB to discuss.

c. Working Group on Review of Candidate Methods
ACTION ITEM: Add to June Meeting agenda for OMB to discuss.

d. Working group on OMB New Member Selection
ACTION ITEM:
- OMB to send in nominations and Szpylka to send list of nominees with CVs to Roman a couple weeks ahead of June meeting.
- Staff to add to June Meeting agenda for OMB to discuss and recommend.

e. Working Group on Vetting of SPs and ERPs
ACTION ITEM: Add to June Meeting agenda for OMB to discuss.

VIII. ADJOURNMENT

MOTION: To adjourn the meeting.
Cook moved. Meeting adjourned at 1:53pm.

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MEMORANDUM

Date: 07 June 2016
To: AOAC INTERNATIONAL Board of Directors
From: Shauna Roman – Chair, Official Methods Board
Subject: AOAC Official Methods Board Update

STANDARDS DEVELOPMENT AND CONFORMITY ASSESSMENT

OMB Participation in Standards Development

- At least one OMB member participated in stakeholder panel meetings and affiliated working groups during the March 2016 Mid-Year Meeting. The Mid-Year Meeting activities were discussed during the April 14, 2016 OMB conference call.

- OMB was informed of the impact of multiple cycles of method reviews for methods purported to meet the SMPR and the impact of low response to some calls for methods. OMB initiated a working group to discuss and evaluate any gaps in the process. This will be discussed during the OMB meeting later this month.

Recommendation from OMB: None at this time.

OTHER DECISIONS AND ACTIONS OF THE AOAC OMB

OMB Meetings and Teleconferences

- April 14, 2016- OMB Teleconference
- May 12, 2016- OMB Teleconference
- The next in-person OMB meeting will be June 22& 23, 2016, Rockville, MD and Chicago, IL.

AOAC INTERNATIONAL
The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 22, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item Ig. - AOAC Board of Directors June Meeting Update**

Alicia Meiklejohn will provide a verbal update.

RECOMMENDATIONS: None.

ENCLOSURES: None.

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 22, 2016

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: Item IIa. – Working Group on Method Format & Revision to SMPR Guidelines

There is no update at this time.

RECOMMENDATIONS: None.

ENCLOSURES: None.

AOAC INTERNATIONAL
The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 22, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item IIb. – Working Group on Vetting Stakeholder Panels and Expert Review Panels**

The working group had a meeting that had to be postponed pending McKenzie drafting some language. Enclosed are two documents: one that describes OMB vetting process for stakeholder panels and the second is a document that describes the OMB vetting process for Expert Review Panels.

RECOMMENDATIONS: For OMB to review, modify if needed, and accept the documents.

ENCLOSURES: Operation Process for Vetting Stakeholder Panels
Operation Process for Vetting Expert Review Panels

OFFICIAL METHODS BOARD

Operating Procedures: Vetting AOAC Stakeholder Panels

Role of OMB:

1. To vet proposed stakeholder panel chair(s)
2. To vet proposed representative voting members

Definitions:

Advisory Panel	One or more stakeholder(s) and project sponsors, who define the priorities under which AOAC initiates project with a stakeholder panel.
Stakeholder Panel	AOAC community based volunteer consensus body that develops and establishes voluntary consensus standards.
Working Group	Subset of stakeholders that develops draft standards for the stakeholder panel for stakeholder community
Stakeholder Panel Chair	Vetted lead champion and moderates/facilitates discussions and deliberations for both the stakeholder panel and advisory panel
Voting Members (Panel)	Vetted balanced representative subset of the stakeholder panel that demonstrates the consensus of the stakeholder panel during meetings

Vetting Stakeholder Panel Chair:

1. AOAC Executive Office identifies potential chair for the stakeholder panel and forwards recommendation and rationale/credentials to OMB
2. OMB reviews and deliberates on recommendation and renders consensus decision
3. OMB approval is forwarded to AOAC President for volunteer appointment
4. OMB reviews stakeholder panel chair as needed based on Executive Office recommendation

Vetting Voting Members or Panel:

1. AOAC Standards Development provides a proposal that includes a list of organizational meeting registrants, categorization of organizational registrants into various perspectives, and a list proposed of voting member organizations for each meeting
2. OMB reviews, deliberates on proposal and renders consensus decision on a final list of balanced representative voting members for each panel
3. OMB approval is forwarded to AOAC project leads and coordinators for each meeting
4. OMB reviews voting member proposal for each stakeholder panel meeting during which stakeholder consensus decisions will be made.

OFFICIAL METHODS BOARD

Operating Procedures: Vetting AOAC Expert Review Panels

Role of OMB:

1. To vet proposed Expert Review Panel members and chair
2. To modify Expert Review Panel roster with additions or subtraction of members

Definitions:

Expert Review Panel	One or more stakeholder(s) and project sponsors, who define the priorities under which AOAC initiates project with a stakeholder panel.

Vetting Expert Review Panels (ERP):

1. AOAC identifies potential ERP members based on issued Call for Experts and other recruiting methods.
2. AOAC Chief Science Officer (CSO) reviews credentials and a recommendation is made to OMB
3. OMB reviews candidate expertise, credentials, and balance of overall ERP
4. OMB reviews, deliberates, and modifies slate of ERP members as needed and reaches a consensus decision on the ERP roster and ERP chair
5. OMB approved roster is forwarded to AOAC President for AOAC volunteer appointment
6. OMB reviews Expert Review Panel members as needed based on recommendations from AOAC staff, ERP chair and CSO recommendation

AOAC INTERNATIONAL
The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 22, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – Deborah McKenzie**

Subject: **OMB Working Group on Review of Candidate Methods**

AOAC's pathway to Official Methods of Analysis does not guarantee *Official Methods of Analysis*. However, trying to demonstrate due diligence has led to repetitive calls for methods for the same analytes/matrices with the results being either, few to no methods submitted, to methods being reviewed by the ERP and deemed to require further optimization and/or development with subsequent cycles of review prior to adoption.

AOAC is investigating ways to increase the number of methods that will likely meet the SMPR submitted for identified stakeholder priorities, and ways of end potential open cycles of review of methods that ERPs determine do not meet the SMPRs sufficiently for adoption as *Official Methods of Analysis*.

AOAC OMB formed a working group that held its initial meeting on Wednesday, May 11, 2016 and led by Shauna Roman, with working group members including Erin Crowley, Don Gilliland, Kate Mastovska, and Tom Phillips along with Delia Boyd and Deborah McKenzie. Absent with regrets was ERP chair, Darryl Sullivan.

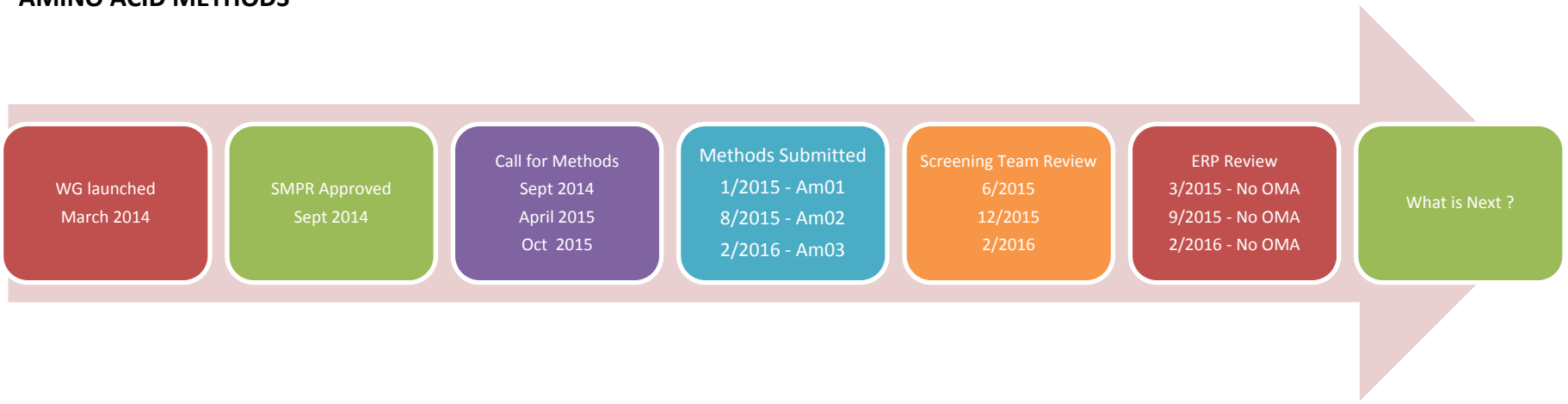
McKenzie provided examples from both SPIFAN and SPDS. Roman provided a flowchart of what the process should include. The working group agreed that there was no need for any changes in policy at this time, but rather:

- More focus could be on more explicit training for ERP chairs
- Additional communications with potential method authors regarding ERP comments
- Reinforcement of deadlines and timelines for submission

These measures will also coincide with additional communications measures earlier in the process at the Advisory Panel and Stakeholder Panel meetings pre-SMPR formation.

Attachments: Examples (McKenzie) and Flowchart (Roman)

AMINO ACID METHODS

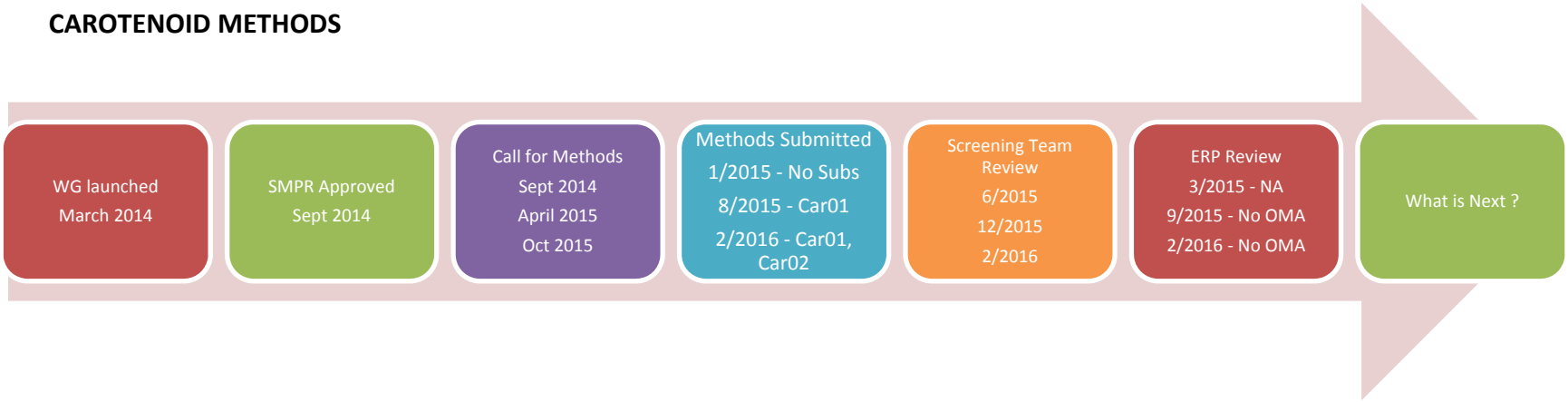


Screening Team Review: Consists of a preliminary review by Working Group Chair, ERP Chair, and CSO

ERP Reviews Comments

Am-01 – 3/2015	Am-02 – 9/2015	Am-03 – 2/2016
▪ Method is well written; sound methodology ▪ Study author should use all AOAC SPIFAN samples and provided the information ▪ Analytical range; LOQ ▪ Lysteine has limited range ▪ Title change – total amino acid ▪ Does not capture tryptophan ▪ Proprietary technique ▪ Recovery over 110% ▪ Method has potential; needs optimization	▪ The amino acid profile only measures tryptophan ▪ For chosen samples the method showed good precision and accuracy. ▪ Data for NIST SRM 1849a is presented for 2 laboratories and accuracy for this matrix meets SMPR. ▪ The sample prep takes less time ▪ Sample size is too small/precision ▪ No SPIFAN matrices were used for validation. Limited data for 3 matrices are presented – NIST SRM 1849a, soy formula and Hypoallergenic formula. o Method needs more data on SPIFAN materials ▪ Method uses 3-point calibration instead of recommended 6-point and no information on the range is given. ▪ Actual levels of Tryptophan in studied matrices (except for NIST SRM 1849a) and spike levels used for accuracy studies are not listed. ▪ Background Tryptophan from self-digest of enzymes in the absence of the sample is a concern since this can affect accuracy of analysis at low levels. ▪ One weakness is the limit of quantitation range ▪ Provide additional information on the following: o Analytical range o wide calibration range o system suitability	▪ Method is three (3) methods in one (1); uses three (3) separate digestions ▪ It is hard to determine how many samples were completed and in how many days ▪ The intermediate precision was completed over two (2) days and six (6) replicates daily; the information should be presented clearer. ▪ Method is promising, but lacks SLV data ▪ One weakness is optimizing the method ▪ Internal standards should be brought in earlier; internal standard is added after hydrolysis o No tryptophan in the internal standards; should investigate and correct ▪ Full SPIFAN SLV study should be completed ▪ Follow instructions in the use of the AOAC SPIFAN samples ▪ Suitability step should be built in the method to check the column for separation suitability

CAROTENOID METHODS

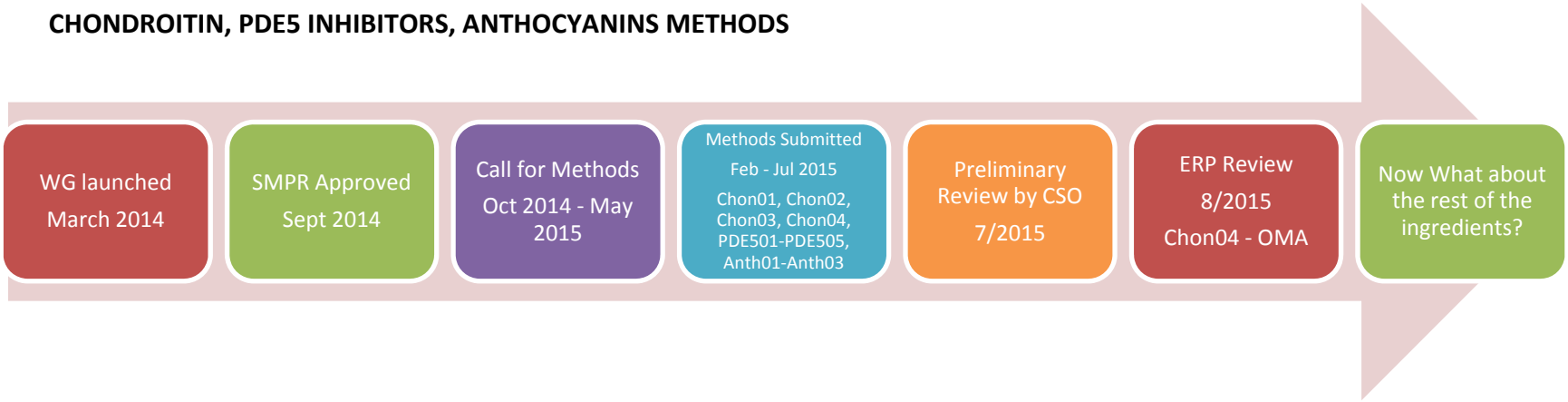


Screening Team Review: Consists of a preliminary review by Working Group Chair, ERP Chair, and CSO

ERP Reviews Comments

Car-01 – 9/2015	Car-01 – 2/2016	Car-02 – 2/2016
▪ Method uses best of the technology available for Carotenoids ▪ Use of internal standards & PKB columns could improve ▪ Need safety comments for the isopropyl ether/ peroxides ▪ determination of the beta carotene stock solution needs a second step ▪ Mobil phase D has to be stirred constantly ▪ A working standard injection is specified, but nothing on how to prepare or any chromatograms o Information provided on six (6) samples and one (1) lab o Awaiting additional data ▪ Good method, but needs additional work and clarification on standards (include control sample) and purity checks ▪ Need to see a standard chromatogram (including reference) ▪ Method needs enough samples of Carotenoids to do an SLV Temperature is very high (85˚)	▪ Method uses sound methodology ▪ It is clearly written and should be easy to follow ▪ Has description of spectrophotometric as well as chromatographic determination of standards purity ▪ Uses internal standard (Apocarotenal) ▪ Saponification step is short and done at room temperature ▪ No details about how to make up a-carotene, lutein, lycopene standards, or mixed calibration standards. ▪ Clear equations describing how the standards and samples are quantitated is required. ▪ No data are presented for alpha-carotene and Lycopene – doesn't meet the scope specified in SMPR ▪ Not enough validation data: o Accuracy by spike recovery of SRM1849a at 2 levels of all-trans lutein and all-trans b-carotene – meet SMPR for recoveries and repeatability (no reference or certified carotenoid values is available from NIST) o Repeatability determined for only 2 SPIFAN matrices for cis and trans lutein and cis and trans b-carotene –data meet SMPR ▪ No safety concerns are noted by the authors ▪ Not all carotenoids specified by SMPR are determined by this method ▪ Only SRM 1849a and 2 SPIFAN (?) matrices were analyzed ▪ No details on System Suitability	▪ Method has issues with lycopene and alpha carotene ▪ Method is clearly written and has sound methodology, but doesn't meet the scope o Expand scope to include α-carotene and lycopene ▪ No data provided on alpha carotene ▪ No safety concerns ▪ Method has the potential to meet the SMPR® ▪ Method only analyzed three (3) matrices ▪ Reassemble the working group to review the comments for the SMPR® ▪ This nutrient may require four (4) SMPRs® or some variation ▪ Set order of priority ▪ SLV may be requirement for beta carotene and lutein

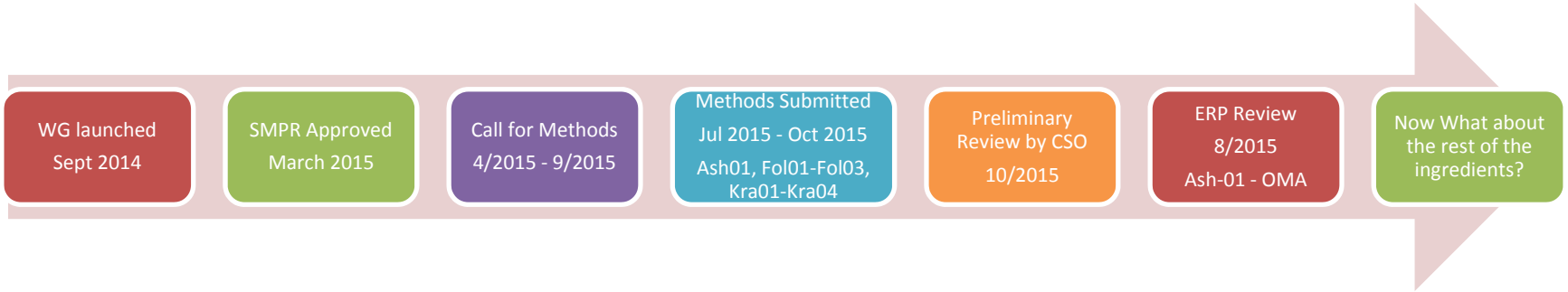
CHONDROITIN, PDE5 INHIBITORS, ANTHOCYANINS METHODS



ERP Reviews Comments

Chon-01: method author should submit probability of detection (POD) data at the minimum detection level for the compounds listed in Annex I of AOAC SMPR 2014.008.	PDE5-01: ERP finds this method intriguing and would like to see a further submission of data demonstrating applicability towards the SMPR 2014.012.	Anth-01: no further action
Chon-02: No comments	PDE5-02: ERP finds this method valuable for screening and would like to see a further submission of data demonstrating applicability towards the SMPR 2014.012.	Anth-02: no further action
Chon-03: method author whether they can provide additional data regarding the interfering compounds that are listed on the SMPR008 and if they have additional data for system suitability / all validation data.	PDE5-03: method should: 1. Supply single lab validation data related to LOD. 2. Supply LIB data if available, and any other data that exists in support of this method's applicability to the SMPR 2014.012 or 2014.010.	Anth-03: no further action
	PDE5-04: ERP finds this method valuable for screening and would like to see a further submission of data demonstrating applicability towards the SMPR 2014.012.	

ASHWAGANDHA, FOLIN C, KRATOM, CINNAMON METHODS



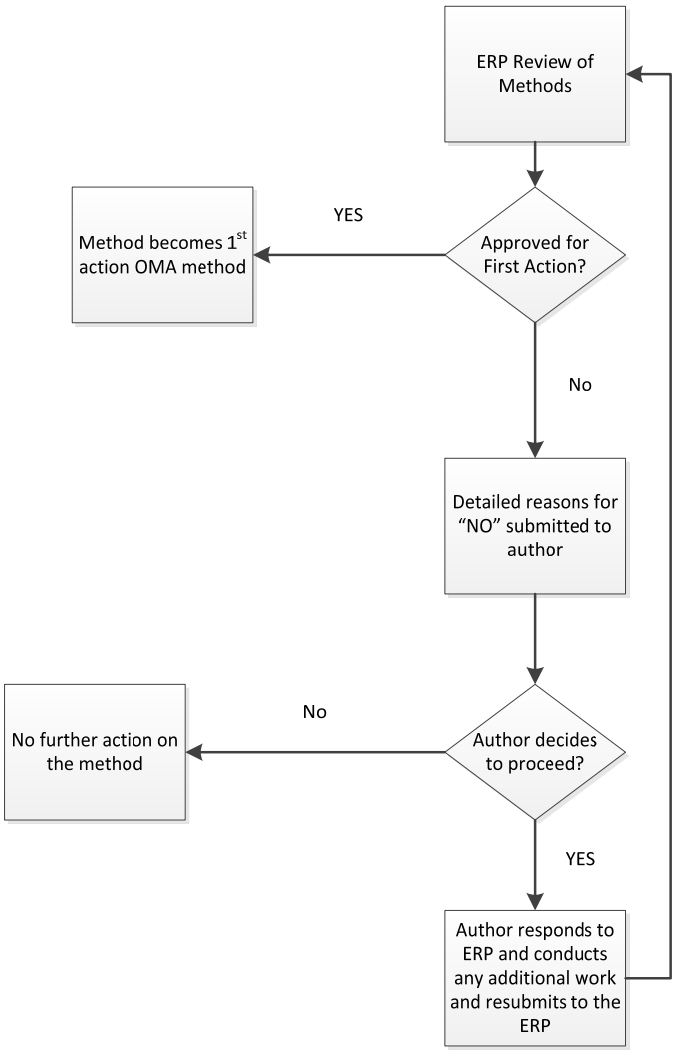
ERP Reviews Comments

Fol-01: • Clarify benefits of single vs. dual; ask which of the two is being submitted • Clarification on purpose of the cleanup steps • Clarify the major differences in the data between the two methods. • Ask if there is data on sample matrices addressed in SMPR • Need data on reference materials (available from Kate Rimmer, NIST) • Use Gallic Acid for calibrant • Provide raw data	Kra-01: • Commercially available standards from Chromadex for 7 OH • Need to see recovery data • Include 7 OH data • Range of quantification must cover whole range from SMPR • Precision and accuracy data is needed across entire range of quantification • Interest from ERP is in the tandem MS method
Fol-02: • Need data on reference materials (available from Catherine Rimmer, NIST) • Ask if there is data on sample matrices addressed in SMPR • Expand analytical range • Data not completely clear • More supporting data for recovery and LOQ	Kra-02: • LOD and LOQ information for 7-OH required. • Repeatability must be improved • More accuracy and recovery data • Peak purity PDA • Examine additional wavelength data
Fol-03: • Need more data to meet SMPR • Need data on reference materials (available from Catherine Rimmer, NIST) • Ask if there is data on sample matrices addressed in SMPR • Express as Gallic Acid equivalent Comparative data between traditional folin and modified folin between a range of matrices is required.	Kra-04: • Feedback on recoveries outside the SMPR • Demonstration of precision data • Additional details around sample preparation • Clarification of ability to measure 7-OH • Clarify the procedure used to gather accuracy data • Calibration curve range needs to be defined.
	Kra-03: Need precision and accuracy to demonstrate compliance with the SMPR.

CONCERNS AND ISSUES:

1. After subsequent method submissions and reviews of same method or method reviews of various method, not able to achieve First Action status without significant method development in some cases
2. Methods process implicitly allows for a continuous unending cycle without a stop for justifiable due diligence
3. Methods process implicitly allows for a continuous unending cycle without a stop for needed method development
    a. For unanswered *Call for Methods*
    b. For cycling ERP method reviews

Is there a step that allows AOAC to push the issue back to the community for further or addition consideration, such as potential method development or other, with AOAC's effort completed?


ERP Review of Methods
Approved for First Action?
YES
Method becomes 1st action OMA method
No
Detailed reasons for "NO" submitted to author
Author decides to proceed?
No
No further action on the method
YES
Author responds to ERP and conducts any additional work and resubmits to the ERP

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 22, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item IId. OMB New Member Selection**

There a maximum of seven (7) positions open on the OMB for 2016-2017 term, including the chair positions for the Committees on Statistics and Safety. Of current OMB members who will have completed two three year terms, two OMB members are eligible to serve and have agreed to serve a second three year term. This leaves five potential positions that can be filled.

The AOAC OMB New Member Selection Working Group has solicited nominations for potential OMB membership. Using last year's list, the working group also reached out to interested candidates from 2015 to gauge their continued interest to remain under consideration for OMB membership. The working group has compiled a list of interested candidates and all have been contacted by the OMB chair.

RECOMMENDATIONS: For OMB to deliberate on candidates and reach a consensus on a propose OMB slate for 2016-2017.

ENCLOSURES: List of candidates and Candidate CVs/resumes.
OMB breakdown

Additionally, the working group was invited to review the Selection of New OMB Members document and the Selection of OMB Vice-Chair document to provide OMB with suggestions for revisions for OMB's consideration.

RECOMMENDATIONS: For OMB to deliberate on the documents

ENCLOSURES: Selection of New OMB Members
Selection of OMB Vice-Chair

	1st Contact	Nominee	Contact Information	Affiliation	Background	Nominator (s)	Region	Expertise	Perspective	
	yes/no - GET CV									
no reply this year	Erin	Daniel Klein	(314) 290-4777 daniel_klein@steris.com	Steris Corp.	Chair Committee M, Micro	Jim Agin (2013)	MO	Microbiologist	Industry/ASTM	AOAC Methods Process Knowledge
would be 2nd Covance member	John	John Austad	(608) 242-2712 x2065 John.Austad@covance.com	Covance	Lots of chem method development experience, SPs and MMC chair	Darryl Sullivan (2013)	WI	Chemist	Industry / Lab	chair Vit D for DS. WG chair for many groups / RI ERP / ERP chais / Elanco project
no reply	Erin	Philip Bronstein	philip.bronstein@fsis.usda.gov	USDA-FSIS	Microbiology	Erin Crowley	DC	Microbiologist	Govt	ISP WG9 / ISPAM / Build relationships with govts expertice in all aspects
Yes (CV collected)	John/Erin	Dawn Mettler	d_mettler@yahoo.com	Rockbridge Labs	Micro/Chem	Erin Crowley	OH	Micro/Chem	Consultant	ALACC / ISPAM / MU knowledge
Yes	Jo Marie	Eric Verdon	Eric.VERDON@anses.fr	ANSES	Chemistry	Jo Marie Cook	EU	Chemistry	Govt lab	Vet drugs chair/ long history
Yes (CV sent in 2015)	Jo Marie	Jon Wong	Jon.Wong@fda.hhs.gov	FDA	Chemistry	Jo Marie Cook	MD	Chemistry	Chem/Pesticides	Pesticide chair / 1080 ERP & WG / botanicals / Pest in Teas
online/call yes. Needs funding for ftf - Yes (CV collected)	Jo Marie	Jane Weitzel	mljweitzel@msn.com	Ind	Chemistry	Deborah McKenzie	Canada	Chemistry	Independent	Stats/TDLM/Quality/wide range of areas/1 ftf per yr/USP stats committee
Yes (CV collected)	Erin	Adrianne Klijn	Adrianne.klijn@rdls.nestle.com / 0041 78 839 22	Nestle	Microbiology	Erik Konings (2015); David Fornes	EU	Microbiology	Industry	SPSFAM, ISO,
No	John	M. Sarita Cardozo	513-684-3401 maria.cardozo@ttb.gov	TTB	Chem, Nutrition	Norma Hill (2013)		Chemistry	Gov't lab	
Yes (CV collected)	John	Wendy McMahon	wendy.mcmahon@mxns.com	Merieux NS	Micro	John Szpylka (2013)	IL	Microbiology	Lab	
Yes (CV collected)	John	Kate Rimmer	catherine.rimmer@nist.gov	NIST	Chemistry		DC	Chemistry	Govt	reference materials
Yes	Jo Marie	Gabriel Giancaspro	GiG@usp.org	USP	Dietary Supps			Chemistry	USP	reference materials
Yes (CV collected)	John	Melissa Phillips	melissa.phillips@nist.gov	NIST	Chemistry		DC	Chemistry	Govt	reference materials
Yes (CV collected)	John	Esther Campos Giménez	esther.campos-gimenez@rdls.nestle.com	Nestle	infant formula, nutriceuticals	Eric Koening	Switz	Chemistry	Industry	
Yes (CV sent in 2015)	Jo Marie	Amy Brown	amy.brown@freshfromflorida.com	Florida Dept of Agriculture & Consumer Services	Chemical Contaminants, Chemistry	Jo Marie Cook	FL	Chemistry	State Gov't	
No	Jo Marie	Michelle Briscoe	Michelle@brooksrand.com	Brooks Applied Labs	Chemistry, Heavy Metals, ERP member, Method author	Jo Marie Cook	WA	Chemistry	Industry	

NOMINATIONS FOR NEW OMB MEMBERS – 2016-2017 TERM

Last Name	First Name	Affiliation	Region	General Scientific Expertise	CV?	Current AOAC Member?	AOAC Standards/Methods Activity *(Last 5+ Years)*
Austad	**John**	Covance	USA	Chemistry	Yes	Yes	1. Expert Review Panel for Proprietary Vitamin Methods - Member 2. Expert Review Panel for SPIFAN Nutrient Methods – Member 3. Stakeholder Panel on Dietary Supplements - Member 4. SPDS Vitamin D Working Group - Chair 5. Stakeholder Panel on Infant Formula and Adult Nutritionals – Member and Working Group Member for all 26 Nutrients 6. SPIFAN Working Group on Carnitine – Working Group Chair 7. Stakeholder Panel on Strategic Food Analytical Methods – Member 8. SPSFAM Working Group on Ingredients – Working Group Chair 9. TDLM - Technical Division for Laboratory Management - Member
Brown	**Amy**	Florida Dept. of Agriculture	USA	Chemistry	Yes	Yes	1. Expert Review Panel for Pesticide Residues - Member 2. International Stakeholder Panel on Alternative Methodology - Member 3. Southern Section - Member
Campos Gimenez	**Esther**	Nestle	Switzerland	Chemistry	Yes	Yes	1. Stakeholder Panel on Infant Formula and Adult Nutritionals – Member 2. SPIFAN Working Group on Vitamin B12 – Working Group Chair 3. SPIFAN Working Group on Pantothenic Acid - Member 4. Stakeholder Panel on Strategic Food Analytical Methods - Member 5. Expert Review Panel for SPIFAN Nutrient

							Methods – Member
Giancaspro	**Gabriel**	USP	USA	Chemistry	Yes	Yes	1. Editorial Board - Member 2. Stakeholder Panel on Dietary Supplements Advisory Panel - Member 3. Stakeholder Panel on Dietary Supplements - Member 4. Anthocyanins Working Group - Member 5. Chondroitin Working Group - Member 6. Ingredient Ranking Subgroup - Member 7. PDE 5 Working Group - Member 8. SPDS Working Group for Kratom – Member 9. Mid-Atlantic Section - Member
Klijn	**Adrianne**	Nestle	Switzerland	Microbiology	Yes	No	
McMahon	**Wendy**	Merieux NutriSciences	USA	Microbiology	Yes	Yes	1. AOAC Fellow (2014) 2. Committee on Fellows - Member 3. ERP for Microbiology in Food - Co-Chair 4. International Stakeholder Panel on Alternative Methods - Member 5. ISPAM Fresh Produce (Stakeholders) - Member 6. ISPAM Fresh Produce WG Method Performance - Member 7. ISPAM Fresh Produce WG Sampling - Member 8. ISPAM Harmonized Salmonella Methods WG - Member 9. Research Institute Expert Reviewers - RI Expert Reviewer 10. Research Institute Laboratories - RI Independant Lab 11. Midwest Section - Member
Mettler	**Dawn**	Rockbridge Labs	USA	Chemistry; Microbiology	Yes	Yes	1. ALACC Microbiology Subcommittee – Member 2. Central Section Executive Committee – Member-at-Large
Phillips	**Melissa**	NIST	USA	Chemistry	Yes	Yes	1. Editorial Board - Member 2. Stakeholder Panel on Dietary Supplements - Member

							3. SPDS Protein Working Group - Member 4. Anthocyanians Working Group - Member 5. Chondroitin Working Group - Member 6. Mid-Atlantic Section - Member 7. PDE 5 Working Group - Member 8. SPDS Aloin Working Group - Member 9. SPDS Lutein Working Group - Member 10. SPDS Set 1 Ingredients ERP - Member 11. SPDS Tea Working Group - Member 12. SPDS Turmeric Working Group - Member 13. SPDS Vitamin B12 - Member 14. SPDS Vitamin D Working Group - Member 15. Stakeholder Panel on Infant Formula and Adult Nutritionals - Member 16. SPIFAN Working Groups - Member for all 26 17. Stakeholder Panel on Strategic Food Analytical Methods - Member 18. SPSFAM - Allergens Working Group - Member 19. SPSFAM - Kombucha Working Group - Member 20. TDLM - Technical Division for Laboratory Management - Member 21. TDRM - Technical Division on Reference Materials - Member 22. Technical Division on Reference Materials - Newsletter Editor
Rimmer	**Catherine (Kate)**	NIST	USA	Chemistry	Yes	Yes	1. Stakeholder Panel on Dietary Supplements - Member 2. SPDS Aloe Vera Working Group - Member 3. SPDS Protein Working Group - Member 4. SPDS Anthocyanians Working Group - Member 5. SPDS Chondroitin Working Group – Co-Chair 6. SPDS PDE 5 Working Group - Member 7. SPDS Aloin Working Group - Member 8. SPDS Lutein Working Group - Member 9. SPDS Tea Working Group - Member

							10. SPDS Turmeric Working Group - Member 11. SPDS Vitamin B12 - Member 12. SPDS Vitamin D Working Group - Member 13. ERP for SPDS Methods – Ashwagandha, Folin C, and Kratom - Member 14. SPSFAM - Allergens Working Group - Member 15. SPSFAM - Kombucha Working Group - Member 16. Stakeholder Panel on Infant Formula and Adult Nutritionals - Member 17. Stakeholder Panel on Strategic Food Analytical Methods - Member 18. Mid-Atlantic Section - Member 19. TDLM - Technical Division for Laboratory Management - Member 20. TDRM - Technical Division on Reference Materials - Member 21. Technical Division on Reference Materials - Member 22. Vitamin K - Member
Verdon	**Eric**	ANSES	France	Chemistry	No	No	1. Chemical Contaminants Community Vet Drugs Subgroup Chair
Weitzel	**Jane**	Independent	Canada	Laboratory Quality; Statistics; Reference Materials	Yes	Yes	1. AOAC Fellow (2012) 2. LPTP Advisory Committee - Member 3. Pacific Southwest Section - Member 4. Statistics Committee - Member 5. TDLM - Technical Division for Laboratory Management - Member 6. TDRM - Technical Division on Reference Materials - Member 7. Technical Programming Council - Member
Wong	**Jon**	FDA	USA	Chemistry	Yes	Yes	1. Mid-Atlantic Section - Member 2. Technical Programming Council - Member

Nominees Who Respectfully Declined in 2016

Last Name	First Name	Affiliation	Comments
Cardozo	M. Sarita		
Briscoe	Michelle		

Nominees From Whom There Is No Response in 2016

Last Name	First Name	Affiliation	Comments
Klein	Daniel	Steris	
Bronstein	Philip	USDA	

Criteria for Member of the OMB:

1. Must provide a current Curriculum Vitae;
2. Must be a member of AOAC INTERATIONAL in good standing;
3. Must have a letter of support from the sponsoring organization [employer/supervisor];
4. Must have an executed AOAC Volunteer Acceptance Form;
5. Must provide two letters of recommendation from someone other than an employee, employer or supervisor;
6. Should be willing and capable of acting as a Liaison with the Communities, Technical Divisions, Research Institute, and other major Stakeholders;
7. Should possess the minimum of a Bachelor's degree in chemistry, biology, mathematics or a related scientific field;
8. Should demonstrate technically competent written and oral communication and networking skills;
9. Should demonstrate leadership capabilities through documentation of project management, supervisory experience, or leadership positions within AOAC;
10. Should have experience in the AOAC collaborative study process;
11. Should be familiar with the AOAC Program Manual and the Official Methods of Analysis appendices; and
12. Should have successfully completed OMB training in the method validation process, demonstrate ability to perform adequate review of AOAC collaborative studies, and agree to appropriate retraining at least every three ears.

Nominees	CV?	AOAC Member	Employer Support	AOAC VAF	2 Recs – Other	Liaison Ready?	Science based Degree?	Communication & Networking	Leadership Abilility?	Experience in AOAC	Familiarity AOAC Info	Training?
Austad, John	Y	Y					BS					
Brown, Amy	Y	Y					BS					
Campos-Gimenez, Esther	Y	Y					MS					
Giancaspro, Gabriel	Y	Y					Ph.D.					
Klijn, Adrianne	Y	N					Ph.D.					
McMahon, Wendy	Y	Y					MS					
Mettler, Dawn	Y	Y					BS					
Phillips, Melissa	Y	Y					Ph.D.					
Rimmer, Catherine	Y	Y					Ph.D.					
Verdon, Eric	N	N										
Weitzel, M.L. Jane	Y	Y					BS					
Wong, Jon	Y	Y					Ph.D.					

COVANCE
THE DEVELOPMENT SERVICES COMPANY

CURRICULUM VITAE: JOHN W. AUSTAD

CURRENT POSITION

Title:	Manager I
Department:	Nutritional Chemistry and Food Safety Covance Laboratories Inc. Madison, Wisconsin

EDUCATION

BS Chemistry, University of Wisconsin-Stevens Point, Stevens Point, Wisconsin, 2001

Additional Training

Covance Quality Systems Training, Covance Laboratories Inc., Madison, Wisconsin, 2001
Rees Monitoring System Training, Covance Laboratories Inc., Madison Wisconsin 2002
Pre-Management Training Program, Covance Laboratories Inc., Madison Wisconsin 2002-2003
Targeted Selection Training Program, Covance Laboratories Inc., Madison, Wisconsin, 2003
Six-Sigma Greenbelt Training Program, Covance Laboratories Inc., Vienna Virginia, 2005
Spill Responder Training Program, Covance Laboratories Inc., Madison Wisconsin, 2006

PROFESSIONAL EXPERIENCE

03/2009 - Present: Manager I, Nutritional Chemistry and Food Safety

Mr. Austad is directly responsible for overseeing the several chemistry groups at the Madison location. He is responsible for all aspects of these group's, including the quality of results, assay turn-around time, productivity, profitability and the technical guidance of analytical activities. He ensures that each group's processes comply with Good Laboratory Practices (GLPs) guidelines. In addition, he is responsible for the hiring and training of new personnel as well as the performance evaluation for each employee.

10/2007 – 03/2009: Supervisor III, Food and Drug Analysis, Technical Development

As supervisor of the Technical Development group, Mr. Austad was responsible for working with client service personnel, client managers and study directors in scheduling client specific methods and also working with management in scheduling the validation and implementation of new methods. Mr. Austad also worked with area supervisors to schedule his staff to resolve technical issues with existing assays. Mr. Austad was responsible for the review of all requests of the Technical Development group and scheduling them according the objectives set forth by management. Mr. Austad also conducts performance evaluations, hires new personnel and serves as a back-up for several routine analysis groups.

COVANCE
THE DEVELOPMENT SERVICES COMPANY

CURRICULUM VITAE: JOHN W. AUSTAD

PROFESSIONAL EXPERIENCE (Continued)

1/2007 – 10/2007: Supervisor II, Food and Drug Analysis, Technical Development

As supervisor of the Technical Development group, Mr. Austad was responsible for the review of new methods and scheduling staff to conduct the validation of new methods. Mr. Austad was also responsible for working with other departments and scheduling his staff to work on any technical issues with existing methods currently performed in Nutritional Chemistry. Mr. Austad also conducted performance evaluations and hired new personnel. He had overall responsibility for client interaction and the technical conduct of new methodology as well as for the interpretation, analysis, documentation, and reporting of results.

12/2004 – 1/2007: Supervisor II, Food and Drug Analysis, Vitamin Chemistry

As supervisor of the Vitamin Chemistry group, Mr. Austad was responsible for scheduling and reviewing analytical work performed by members of the group. This work included routine and non-routine analysis of fat-soluble vitamins in foods, food supplements, and feeds. Mr. Austad also conducted performance evaluations and hired new personnel. He also acted as a study director and or Principal Investigator for Food and Drug Analysis studies. He had overall responsibility for client interaction and the technical conduct of a study as well as for the interpretation, analysis, documentation, and reporting of results

4/2003 – 12/2004: Supervisor I, Food and Drug Analysis, Second Shift

Mr. Austad was responsible for scheduling work and reviewing results for the evening shift. He was responsible for all aspects of these groups; including the quality of results, assay turn-around time, productivity, profitability and the technical guidance of analytical activities. In addition, he hired and trained new personnel and conducted the performance evaluation for each employee.

6/2001 – 4/2003: Analyst, Food and Drug Analysis

Mr. Austad was responsible for the analysis of heavy metals using graphite furnace atomic absorption spectrometry. His duties included processing samples for analysis, preparation of standards, operation of spectrometer, calculating, and reporting data. Mr. Austad was responsible for the routine maintenance of the spectrometer, microwave and other equipment while maintaining a clean and safe laboratory work environment. In addition to above duties, Mr. Austad was trained to set Inductively Coupled Plasma (ICP), Selenium, Silicon, and Mercury samples for digestion, perform Karl Fischer Moisture assays, and respond to Rees System alarms.

Amy N. Brown

Contact Information

Division of Food Safety, Chemical Residue Laboratory
Florida Department of Agriculture and Consumer Services
3125 Conner Blvd. Lab 3
Tallahassee, Florida 32399
(850) 617-7510
Amy.Brown@FreshFromFlorida.com

EMPLOYMENT

Environmental Manager **June 2005-Present**
DEPT. OF AGRICULTURE, DIV. OF FOOD SAFETY, CHEMICAL RESIDUE LABORATORY TALLAHASSEE, FL

Assist the Bureau Chief of the Chemical Residue Laboratory by acting as technical manager of the State Pesticide Residue Regulatory Program which is responsible for ensuring a safe food supply under Florida Statue 500. This includes assuring that violations are identified accurately and appropriate regulatory actions are taken in a timely manner. Manages deliverables for all pesticide regulatory actions including preparation and maintenance of records (e-mail and phone instructions, audit trail of these communications, summary tables, timely updates to Bureau, Division, Department and FDA managers, etc.) in a manner that assures all affected parties are accurately informed.

Assists the Bureau Chief with special projects such as Deep Horizon Oil spill analysis of seafood samples for PAHs and Dispersants.

Supervises chemists assigned to the Sample Preparation section and the Standard's section, including leave approval, performance counseling and appraisal.

Manages the daily operations and sample analysis schedule for the Laboratory, including sample collection, receipt, preparation, extractions and data entry. Conducts technical review of completed results. Reviews and approves all instrumental data in support of the State Pesticide Residue Regulatory Program. Analysis instruments include GC-Triple Quadrupole (GC-MS/MS), LC-Triple Quadrupole (LC-MS/MS) and LC-High Resolution Mass Spectrometry (LC/HRMS). Ensures that the laboratory adheres to strict ISO 17025 procedures to uphold accreditation.

Working knowledge of QA and ISO 17025 principles and how they relate to trace level analysis, and assurance that the laboratory adheres to strict laboratory QA ISO 17025 procedures. The lab received accreditation from the A2LA ISO/IEC 17025:2005 to perform Multiresidue Screening of Pesticide Data Program Samples and Multiresidue Pesticides in State Program Fruits and Vegetables (A2LA certificate # 2534.03).

Acts as the laboratory database administrator. This includes updating and maintaining the laboratory information management system (LIMS).

Chemist Administrator **November 2002-June 2005**
DEPT. OF AGRICULTURE, DIV. OF FOOD SAFETY, CHEMICAL RESIDUE LABORATORY TALLAHASSEE, FL

Assists the Quality Assurance Officer with the development and implementation of Quality Assurance/Quality Control procedures in the Chemical Residue Laboratory.

Supervises chemists assigned to the Quality Assurance/Methods Development Section, including leave approval, performance counseling and appraisal.

Performs formal Quality Assurance reviews for all USDA Pesticide Data Program (PDP) samples and is responsible for transmitting the laboratory results to PDP headquarters.

Administers and/or coordinates Method Development and Method Validation projects. Assembles method validation data and prepares appropriate forms and summaries. Submits validation data to the USDA Pesticide Data Program (PDP). Provides training in methodology to laboratory personnel.

Chemist III **March 2001-November 2002**
DEPT. OF AGRICULTURE, DIV. OF FOOD SAFETY, CHEMICAL RESIDUE LABORATORY TALLAHASSEE, FL

Assists the Quality Assurance Officer with the development and implementation of Quality Assurance/Quality Control procedures in the Chemical Residue Laboratory.

Maintains the analytical standard inventory utilizing an Access data base. Ensures appropriate neat pesticides are ordered and available.

Operates and maintains instrumentation for the QA/Methods Development Sub-section. Performs routine maintenance of gas chromatograph and Liquid chromatograph instrumentation. Evaluates new instrumentation as part of methods development

Conducts method development work using a variety of preparative, GC, and LC techniques in support of other laboratory sections. Performs method validation for new methods. Provides training in methodology to laboratory personnel.

Chemist II **June 1999-March 2001**
DEPT. OF AGRICULTURE, DIV. OF FOOD SAFETY, CHEMICAL RESIDUE LABORATORY TALLAHASSEE, FL

Prepares analytical standard solutions including stock solutions, working concentrations, various mixed standards and all needed dilutions from neat pesticides for the Chemical Residue Laboratory.

Maintains the analytical standard inventory utilizing an Access data base. Ensures appropriate neat pesticides are ordered and available. Responsible for distribution of all pesticide standards to all subsections including the Winter Haven Laboratory.

Operates and maintains instrumentation for the QA/Methods Development Sub-section

Assists with method validation and with the development of new and improved analytical methods.

Chemist I **January 1998- June 1999**
DEPT. OF AGRICULTURE, DIV. OF FOOD SAFETY, CHEMICAL RESIDUE LABORATORY TALLAHASSEE, FL

Prepares analytical standard solutions including stock solutions, working concentrations, various mixed standards and all needed dilutions from neat pesticides for the Chemical Residue Laboratory.

Maintains the analytical standard inventory. Ensures appropriate neat pesticides are ordered and available. Responsible for distribution of all pesticide standards to all subsections including the Winter Haven Laboratory.

Operates and maintains instrumentation for the QA/Methods Development Sub-section.

Lab Technician II **March 1997- January 1998**
STATE OF FLORIDA, BUREAU OF PETROLEUM TALLAHASSEE, FL

Analyzed gasoline's octane by testing the gasoline in the Bureau of Petroleum on research and motor Waukesha engines following ASTM procedures. Utilized infrared spectroscopy to analyze the octane content. Prepared gasoline standard and reference fuels. Prepared octane results utilizing Lotus 123 and Microsoft Excel. Assembled octane reports.

Assisted in distillation lab to determine boiling points of gasoline utilizing manual stills, automatic stills and gas chromatograph following ASTM procedures. Used Chem Station and Simdis to generate data. Assembled distillation reports.

Assisted in diesel lab analyzing sulfur, viscosity and flash points of diesel fuel following ASTM procedures.

Assisted in shipping and receiving, sample preparation and sample distribution.

Performed monthly quality assurance checks of equipment by testing diesel fuels and gasoline to ensure precision and accuracy.

Clerical Assistant II **October 1996-March 1997**
CITY OF TALLAHASSEE, DEPT. OF GENERAL SERVICES, ADMINISTRATION TALLAHASSEE, FL

Assisted the Department Director, Administrative Supervisor and the Executive Secretary in the office by answering phones, scheduling meetings, maintaining filing system and typing correspondence utilizing Microsoft Word.

Responsible for the organizing, writing, editing and distribution of the department monthly newsletter.

Lab Assistant **June 1996- October 1996**
STATE OF FLORIDA, FLORIDA DEPARTMENT OF LAW ENFORCEMENT TALLAHASSEE, FL

Worked in the Chemistry Laboratory assisting the Crime Lab Analyst in the analysis of suspected illegal drugs. Analysis included various color tests, solubility tests, use of microscope and use of the gas chromatograph.

Collated all test results and chromatographic data. Ensured data was with appropriate evidence package.

Clerical Assistant III **December 1990-August 1995**
CITY OF TALLAHASSEE, DEPT. OF GENERAL SERVICES, MAINTENANCE DIVISION TALLAHASSEE, FL

Scheduled conference rooms and pool cars. Maintained filing system. Assembled plans, typed memos and letters utilizing Microsoft Word.

Processed purchase orders for the division, answered telephones, greeted visitors, updated I.D. badges and monitored parking gate.

Received work order requests and assigned the duties to the custodial workers or maintenance repair workers.

Acted as furniture liaison for City hall, ordering furniture, receiving furniture and designing work spaces.

EDUCATION

Bachelors of Science Degree **December 1997**
FLORIDA STATE UNIVERSITY TALLAHASSEE, FL
Major: Chemistry, A.C.S. Certified Degree

Activities: Assisted in the research lab in the Florida State University Physics Department running crystalline surface experiments by way of Helium Atom Scattering (HAS), Low Energy Electron Diffraction (LEED), and Auger Electron Spectroscopy. Also assisted in the design of a UHV Evaporator used in Thin-Film Deposition.

Certified Public Management **May 2005**
FLORIDA STATE UNIVERSITY TALLAHASSEE, FL
Certification: Certified Public Manager (CPM)

Society of Government Meeting Professionals **May 2009**
GRADUATE SCHOOL, USDA
Certification: Certified Government Meeting Professional (CGMP)

PROFESSIONAL MEMBERSHIPS AND COMMITTES

AOAC International
Member, 2010 – present
Pesticide Expert Review Panelist

Southern USA Regional Section of AOAC International
President, 2012-2013
President elect, 2011-2012
Secretary, 2010-2011
Executive Committee Member, 2008 - present

Florida Capital Chapter of The Society of Government Meeting Professionals
President, 2009-2013
Vice President, 2008-2009
Member, 2006 - present

Planning Committee, North American Chemical Residue Workshop (Formally Florida Pesticide Residue Workshop), Planning Committee, 1999 – present

AWARDS

Davis Productivity Award Winner 2009
Citrus Method Development Team of the Chemical Residue Laboratories

AOAC International Expert Review Panel Member of the Year 2014-2015
Expert Review Panel for Pesticide Residues

Anant Jain Founders Award 2015
Southern USA Regional Section of AOAC International

Doug Hite Honorarium 2016
Southern USA Regional Section of AOAC International

PUBLICATIONS

Brown, et.al., JAOAC, 2011; 94(3): 931-941, "Analysis of Pesticides Residues in Fresh Produce Using Buffered Acetonitrile Extraction and Aminopropyl Cleanup with GC/Triple Quad MS, LC/Triple Quad MS, GC Ion Trap MS, and GC with a Halogen-Specific Detector"

Schenck, Brown, Podhorniak, Parker, Reliford and Wong, JAOAC, 2008; 91(2): 422-438, “A Rapid Multiresidue Method for Determination of Pesticides in Fruits and Vegetables by Using Acetonitrile Extraction/Partitioning and Solid Phase Extraction Column Cleanup”

Schenck et.al, FDA LIB #4442, “Two Modified QuEChERS Methods for the Multiresidue Determination of Pesticides in Produce Samples: An Interlaboratory Study”

Schenck et.al, FDA LIB #4390, “Multiresidue Analysis of Pesticides in Fruits and Vegetables Using a Modified QuEChERS method”

ESTHER CAMPOS GIMENEZ
e-mail address esther.campos-gimenez@rdls.nestle.com

EDUCATION

BS Biology (Biochemistry) University of Valencia, Spain
MS Food Science and Engineering Polytechnic University of Valencia, Spain

WORK EXPERIENCE

August 2005- Present
Research Scientist
Nestlé Research Center, Lausanne, Switzerland
Lead Scientist – Vitamins Team
- Development and validation of analytical methods for vitamins in foodstuffs
- Highly involved in international officialization projects
- Active member of CEN Working Group on Vitamins and Carotenoids
- Active participation to AOAC SPIFAN activities – Chair of Working Group on vitamin B12

October 99-August 2005
Research Scientist
Nestlé Research Center, Lausanne, Switzerland
- Development and validation of analytical methods related with amino acids (HPLC, UPLC, AAA, HPAEC-PAD) and proteins (classical Nitrogen determination, SDS-PAGE)
- Assistance to Regional Laboratories in methodology related to amino acids analysis
- Member of CEN Working Group on Vitamins and Carotenoids since 2005

August 97-September 99
Laboratory Chemist II
Nestlé Quality Assurance Laboratory, Dublin, Ohio
- Review analytical data and provide reports for factory sample release
- Organize and supervise departmental analytical workload
- Train other chemists in analytical methodologies, new software applications and LIMS
- Assure quality of results by assisting with the establishment and maintenance of QA plan.
- Write up, review and provide proper documentation for methods
- Modify methods to solve complex problems
- Perform chemical analyses and determinations on a variety of non-routine samples
- Research and undertake method development for special projects
- Assure equipment is maintained in reliable working order, make repairs within capability

February 96-July 97
Laboratory Chemist I
Nestlé Quality Assurance Laboratory, Dublin, Ohio
- Perform routine sample analyses per NQAL methods
- Document QA data and report to section manager
- Assure quality of results by following QA plan and Internal Control Plan
- Ensure safety regulations are followed
- Review data and provide initial draft reports
- Resolve analytical methodology problems

April 95-October 95
Research Laboratory Chemist
Nestlé Research Center, Lausanne, Switzerland
- Develop and optimize methods for a variety of analyses of drug residues in animal products
- Write up draft analytical methods for different antibiotics and matrixes
- Resolve analytical or instrumental problems under minimal supervision
- Conduct literature searches as required to maintain awareness of current publications relating to work area

June 93-June 94
Research Training Position

Nestlé Research Center, Lausanne Switzerland

- Develop analytical method for analysis of sulfonamides residues in pork meat and final meat products
- Compare methods and generate technical reports
- Work with higher level chemist to modify and adapt methods to different matrixes

July 89-July 91 **Research Student**

Microbiology department

University of Valencia, Spain

- Assisted Ph.D. dissertation research
- Develop project in yeast fermentation and its influence on wine flavor
- Perform wine flavor extraction
- Analyze flavor extract and provide chromatography results

SKILLS

Highly knowledgeable with HPLC technique, instrumentation and software packages
Quick study and strong desire for knowledge
Good interpersonal skills
Experienced and productive in a team as well as independent work environment

LANGUAGES

Spanish, mother tongue
English, speak, read and write
French, speak, read and write
Catalán, speak and read
German, basic knowledge

PUBLICATIONS

- J.J. Mateo, M. Jiménez, J.V. Gil, E. Campos, T. Huerta, A. Pastor, “Análisis de la fracción volátil de vinos de la variedad de uva Monastrell (D.O. Alicante). Puesta a punto del método.” Semana Vitivinícola, 2313/14,5713-5721.

- J.V. Gil, E. Campos, M. Jiménez, T. Huerta, J.J. Mateo. “Efectos de la congelación sobre la población levaduriforme en mosto de uva” Revista Española de Ciencia y Tecnología de Alimentos 1992,32(2) pp. 213-219

- F. Fenaille, E. Campos Giménez, P.A. Guy, C. Schmitt, F. Morgan, "Monitoring of ß-lactoglobulin dry-state glycation using various analytical techniques". *Analytical Biochemistry* 320 (2003) 144-148

- Campos Giménez, E., Spack, L., Meyer, L., Perrin, C. & Acheson-Shalom, R. Measurement uncertainty of the caffeine determination in soluble coffee by HPLC. *Mitteilungen aus Lebensmitteluntersuchung und Hygiene* **95**, 240-250 (2004).

- Spack, L., Royer, D., Campos Giménez, E., Acheson-Shalom, R. & Stadler, R. Measurement uncertainty of chloramphenicol in food products by LC-MS/MS. *Mitteilungen aus Lebensmitteluntersuchung und Hygiene* **95**, 223-239 (2004).

- E. Campos Giménez, T. Bénet, L. Spack. The uncertainty in the calculation of the amount of blocked and reactive lysine in milk products, as determined by the furosine method. *Accred. Qual. Assur*. **9**, 605-614 (2004)

- S. Populaire, E. Campos Giménez. Use of validation data for fast and simple estimation of measurement uncertainty in Liquid Chromatography methods. Journal of *Liquid Chromatography and Related Technologies*, 28, 1-9 (2005)

- E. Campos Giménez, S.Populaire. A simplified approach to the estimation of analytical measurement uncertainty. Accred. Qual. Assur. Jan 2006, 1-9

- K. A. Cooper, E. Campos Giménez, D. Jiménez Alvarez, K. Nagy, J. L. Donovan & G. Williamson. Rapid Reversed Phase-Ultra Performance Liquid Chromatography Analysis of the Major Cocoa Polyphenols and Inter-relationships of their Concentrations in Chocolate J. Agric. Food Chem.; 2007; 55(8) pp 2841 – 2847

- K. A. Cooper, E. Campos Giménez, D. Jiménez Alvarez, K. Nagy, J. L. Donovan & G. Williamson Predictive relationship between polyphenol and non-fat cocoa solids content of chocolate J. Agric. Food Chem. , 56, 260-265

- E. Campos Giménez, P. Fontannaz, M.J. Trisconi, T. Kilinc, C. Gimenez, P. Andrieux Determination of vitamin B12 in food products by LC-UV with immunoaffinity extraction. Single Laboratory Validation J. AOAC Int.; 2008, 91 (4), 786-793

- P. Andrieux*, T. Kilinc, C. Perrin, and E. Campos Giménez Simultaneous determination of free carnitine and total choline by liquid chromatography-mass spectrometry in infant formula and healthcare products: Single Laboratory Validation J. AOAC Int.; 2008, 91 (4), 777-785

- E. Campos Giménez, M.J. Trisconi, T. Kilinc, P. Andrieux Optimisation and validation of a LC-FLD method for biotin in infant formula, infant cereals, cocoa-malt beverages and clinical nutrition products J AOAC Int. Vol 93 (5) 1494-1502 (2010)

- Lutter, P. Savoy-Perroud, M.C., Campos Giménez, E., Meyer, L., Goldmann, T. Bertholet, M.C., Mottier, P. Desmarchelier, A., Monard, F., Perrin, C., Robert, F., Delatour, T., “Screening and confirmatory methods for the determination of melamine in cow’s milk and milk-based powdered infant formula. Validation and proficiency tests of ELISA, HPLC-UV, GC-Ms and LC-MS/MS” Food Control, vol 22, 903-913 (2011)

- Andrieux,P. Fontannaz, P., Kilinc, T, E. Campos Giménez « Pantothenic acid (vitamin B5) in fortified foods. A comparison between a novel UPLC-MS/MS method and classical microbiological assay » J. AOAC Int, Vol 95 (1) (2012)

- M.J. Trisconi, E. Campos Giménez, G. Jaudzems, D. Dowell “Determination of Vitamin A in Infant Formula and Adult Nutritionals by UPLC-UV: First Action 2011.07” J. AOAC Int. Vol. 95 (2) (2012)

- E. Campos Giménez, P. Fontannaz, M.J. Trisconi, T. Kilinc, C. Gimenez, P. Andrieux, M. Nelson, « Determination of Vitamin B12 in Infant Formula and Adult Nutritionals by Liquid Chromatography/UV Detection with Immunoaffinity Extraction : First Action 2011.08 » J. AOAC Int. Vol. 95 (2) (2012)

June 13th, 2005

GABRIEL IGNACIO GIANCASPRO
Associate Director for Dietary Supplements
Department of Standards Development
United States Pharmacopeia
Phone: 301-816-8343
e-mail: gig@usp.org

Personal Languages: **Spanish, Native**
English, Fluent
Portuguese

Education:

Primary Studies: **(March 1967 to December 1972)**
Instituto San Jose, San Martin 319, (1708) Morón,
Provincia de Buenos Aires Argentina.
Phone: 54-11-4629-0419

Secondary Studies: **(March 1973 to December 1978)**
Colegio Nacional José Hernández,
Aristobulo del Valle 995, (1712) Castelar,
Provincia de Buenos Aires. Argentina.

Bachelor in Science: **(March 1979 to March 1984)**
School of Pharmacy and Biochemistry
(Pharmacy) **University of Buenos Aires, Argentina.**
Junin 956, (1113) Buenos Aires Argentina.

Ph. D. **(June 1985 October 1997)**
School of Pharmacy and Biochemistry
University of Buenos Aires, Argentina.
Junin 956, (1113) Buenos Aires Argentina.

Thesis: Synthesis and Antidepressant and Trypanocidal Activities of Disubstituted 1,2,3,4-Tetrahydrocarbazoles
Advisor: Dr. María Teresa Pizzorno

Other Training:

Organic Synthesis, Organic Chemistry B.
School of Exact and Natural Sciences, University of Buenos Aires, Argentina.

Topics in Nuclear Magnetic Resonance and Mass Spectroscopy.
School of Exact and Natural Sciences University of Buenos Aires, Argentina.

Stereo selectivity in Organic Synthesis.
School of Pharmacy and Biochemistry, University of Buenos Aires, Argentina.

Free Radicals and Biological Oxidations.
School of Pharmacy and Biochemistry, University of Buenos Aires, Argentina.

Computer Aid in Drugs Design.
School of Pharmacy and Biochemistry, University of Buenos Aires, Argentina

Instrumental Methods In Drug Analyses
School of Pharmacy and Biochemistry, University of Buenos Aires, Argentina

Teaching Experience:

Lecturer and developer of courses of Pharmacopeial Education for USP:

Validation of Analytical Methods. (Puerto Rico-July 2003, Mexico DF April 2004 and August 2004, Rockville, December 2004.)

Titration (Amgen, Dec 2003)

USP Dissolution tests (USP headquarters 2001)

From April 1981 to July 1998 in the Faculty of Pharmacy and Biochemistry, University of Buenos Aires. Argentina. Junin 956, (1113) Buenos Aires Argentina.

1997-1998 Sabbatical to Assistant Professor Quality Control in Pharmaceutical Industry. Faculty of Pharmacy and Biochemistry, University of Buenos Aires, Argentina.

1996-1997 Assistant Professor (Interim), Quality Control in Pharmaceutical Industry. Faculty of Pharmacy and Biochemistry, University of Buenos Aires, Argentina.

1994-1997. Assistant Professor (Interim), Drugs and Pharmaceutical Products Stability. Faculty of Pharmacy and Biochemistry, University of Buenos Aires, Argentina.

1989-1994. Teaching Assistant (Tenure), Quality Control in Pharmaceutical Industry. Faculty of Pharmacy and Biochemistry, University of Buenos Aires, Argentina.

1984-1989. Teaching Assistant (Tenure), Analytical Chemistry and Stability of Drugs. Faculty of Pharmacy and Biochemistry, University of Buenos Aires, Argentina.

1981-1984. Teaching Assistant. Organic Chemistry II. Faculty of Pharmacy and Biochemistry, University of Buenos Aires, Argentina.

1982, 1983, 1984. Chemistry Instructor, Summer Preparatory Course. School of Medicine. University of Buenos Aires, Argentina.

NON ACADEMIC POSITIONS

July 2004 to date

Associate Director for Dietary Supplements
United States Pharmacopeia, Department of Standards Development

July 2002 to July 2004

Senior Scientist/Latin-American Specialist
United States Pharmacopeia. Division of Dietary Supplements, Information and Standards Development

July 1999 to July 2002

Scientist/Latin-American Specialist
United States Pharmacopeia. Division of Dietary Supplements, Information and Standards Development

July 1997 to July 1999

Senior Scientific Associate/Latin-American Specialist
United States Pharmacopeia. Drug Standards Division.

July 1996- June 1997

Scientific Consultant for Latin-American Issues.
United States Pharmacopeia. Drug Standards Division.

Jan 1995 to May 1995

Visiting Scientist
United States Pharmacopeia. Drug Standards Division.

March 1993 to June 1997

General Factory Manager
Laboratory Kampel Martian SA
Av. Cordoba 4694
Buenos Aires Argentina
Phone 54-11-4772-3788

May 1992 to March 1993

Quality Control Manager
Laboratorio Asofarma, Callao 853
Buenos Aires, Argentina.

June 1990 to December 1991

Technical Director
Laboratorio Schwabe, Montevideo 174.
Buenos Aires, Argentina

May 1988 to June 1990

Technical Director
Rigecin Labs. Cachi 1204
Buenos Aires, Argentina

December 1984 to May 1988

Registered Pharmacist
Farmacia Pararruso, Paraguay 2145
Buenos Aires, Argentina

PROFESSIONAL EXPERIENCE

As Scientist in USP. Development of Public Standards, General Chapters and New Monographs for Dietary Supplements: Botanicals, Vitamins, Minerals,

and other Natural Products included in the US legislation as Dietary Supplements. Evaluation of analytical methods validation reports. Management and design of the project for New Spanish Translation of USP 29-NF 25. Management of scientific staff in the development of drug and dietary supplements standards.

As Senior Scientific Associate in USP. Development of Standards for Drugs and its Dosage forms, both in English and Spanish languages. Translation of USP 24 into Spanish.

As Technical Director and General Factory Manager, (Rigecin Labs, Schwabe and Kampel Martian SA) wide experience in regulatory issues and GMP certification. Development of new generic formulations and their manufacturing processes (lyophilization, injections, ointments and tablets). Development of more than 50 products for Laboratorio Kampel Martian (mostly for oncology, AIDS and pain management). Development of Botanical formulations and their methods of analysis for Lab. Schwabe Argentina (Ginseng, Milk Thistle and others).

As Quality Control Manager (Kampel, Asofarma) and Quality Control Professor (University of Buenos Aires) wide experience in Analytical Methods of Pharmaceutical Analyses, Development of New Methods for Quality Control, and Stability follow up.

AWARDS

Scientific and Technical Research National Council. (CONICET) Argentina. Initiation in Research Fellowship.
Medicinal Chemistry and Drug's Metabolism Institute. University of Buenos Aires, 1985-1987

Scientific and Technical Research National Council. (CONICET) Argentina. Advanced Research Fellowship.
Medicinal Chemistry and Drug's Metabolism Institute. University of Buenos Aires, 1987-1989

Scientific and Technical Research National Council. (CONICET) Argentina. Advanced Research Fellowship. (extension)
Medicinal Chemistry and Drug's Metabolism Institute. University of Buenos Aires, 1990-1991

Abstracts, Symposia and Congress Presentations

1.- Giancaspro, G.I., Albónico S.M., Pizzorno M.T., Zeichen R., Bindstein E., *Synthesis and Antidepressant Activity of dialkylamine-tetrahydrocarbazolyl-2-propanols.* **II Simposio Nacional de Química Orgánica, San Luis, Argentina, 1985.**

2.- Giancaspro, G.I., Albónico S.M., Pizzorno M.T., Zeichen R., Bindstein E., *Potential Antidepressant Activity of New dialkylamine-tetrahydrocarbazolyl-2-propanols.* **XII Congreso Panamericano de Farmacia y Bioquímica. San José, Costa Rica, 1985.**

3.- Giancaspro, G.I., Albónico S.M., Pizzorno M.T., *Stereoselective Synthesis of R and S dialkylamine-tetrahydrocarbazolyl-2-propanols.* **. III Simposio Nacional de Química Orgánica, Córdoba, Argentina, 1986.**

4.- Giancaspro, G.I., Orecchia E., Pizzorno M.T. *Cinnarizine and Procetofene Determination by Protonic Magnetic Resonance.* **III Reunión Latinoamericana de Ciencias Farmacéuticas. Montevideo, Uruguay, Dec 1986.**

5.- Giancaspro, G.I., Albónico S.M., Pizzorno M.T., Zeichen R., Bindstein E., *Synthesis and Antidepressant Activity of dialkylamine-tetrahydrocarbazolyl-2-propanols. Part II.* **III Reunión Latinoamericana de Ciencias Farmacéuticas. Montevideo, Uruguay, Dec 1986.**

6.- Giancaspro, G.I., Tombazzi J.L., Pizzorno M.T., *Identification of the Active Isomer of Procaterol by Protonic Magnetic Resonance.* **IV Congreso Argentino de Farmacia y Bioquímica Industrial., Buenos Aires Argentina.**

7.- Giancaspro, G.I., Casaubon R.E., Pizzorno M.T., *Synthesis and Trypanocidal Activity of Disubstituted 1,2,3,4.tetrahydrocarbazols.* **II Jornadas Nacionales de Farmacoquímica, Villa Carlos Paz, Argentina, Aug. 1988.**

8.-Machalinski C., Giancaspro, G.I, Pizzorno M.T., Ercolano I. *Famotidine: Polymorphic Crystalline Forms.* **Primeras Jornadas de Farmacia y Bioquímica Industrial, Buenos Aires, Argentina. Oct. 1988.**

9. Machalinski C., Giancaspro, G.I, Pizzorno M.T. : *Stability of Cinnarizine: Identification of Benzophenone and Cinnarizine N-oxide as Oxidative degradation products.* **Primeras Jornadas de Farmacia y Bioquímica Industrial, Buenos Aires, Argentina. Oct. 1988.**

10.- Giancaspro, G.I., Casaubon R.E., Pizzorno M.T., *Design and Synthesis of Disubstituted 1,2,3,4.tetrahydrocarbazols with Trypanocidal Activity.* **Primeras Jornadas de Farmacia y Bioquímica Industrial, Buenos Aires, Argentina. Oct. 1988.**

11.- Giancaspro G.I., Colombari V.D., Albónico S.M., Pizzorno M.T., Minio E., Frasca R., *Synthesis and Trypanocydal Activity of 10-Methoxy-5,6-Dihydro-Benzo-[a]-carbazols.* **V Simposio Nacional de Química Orgánica, Córdoba, Argentina, 1988.**

12.- Rivas M.C., Cardoni R.L., Giancaspro G. I., Pizzorno M.T., *In vitro Trypanocidal Activity of Substituted 1,2,3,4-tetrahydrocarbazols.* **XXXIII Reunión Anual de la Sociedad Argentina de Investigación Clínica, Mar del Plata, Argentina, Nov 1989**.

13.-Giancaspro G.I., Dolberg R., Pizzorno M.T., *New HPLC Method for Ondansetron Determination, A Case of Chemically Inert Carbonyl Group To Amino Packing***. IV Congreso Argentino de Farmacia y Bioquímica Industrial, Buenos Aires, Argentina. Jun 1993.**

14.-Radice M., Amoroso A., Gutkind G., Pappa H.N., Segall A., Colombari D., Giancaspro G.I., *Antimicrobial Activity of 5,6-Dihydro-Benzo-[a]-carbazols. Part V.* **XII Congreso Farmacéutico Argentino, Mar del Plata, Argentina, May 1994.**

15.-Giancaspro G.I., Palacios M.L., Pizzorno M.T., *Simultaneous Determination of Two Solar Filters by Derivative UV Spectroscopy.* **XV Congreso Panamericano de Farmacia y Bioquímica., Buenos Aires, Argentina Nov 1994.**

16.-Segal A., Ricci R., Giancaspro G., Pizzorno M.T., *New HPLC method for Sodium Cromoglicate Determination.* **V Congreso de Farmacia y Bioquímica Industrial, Buenos Aires, Argentina, Jun 1996.**

Lectures

1.- *The USP 23 NF 18 Spanish Translation Process*.
II Congreso de la Federación Farmacéutica Sudamericana. **Santiago de Chile, Chile** Oct. 1995.

2.- *The USP Revision Process*
First Meeting for the Elimination of Technical Barriers to Bilateral Trading Between USA and Argentina. **Buenos Aires, Argentina** Dec. 1995.

3.- *The USP Revision Process*
First Meeting for the Elimination of Technical Barriers to Bilateral Trading Between USA and Brazil. **Rio de Janeiro, Brazil** Dec. 1995.

4.- *The USP 23 NF 18 Spanish Translation Process.*
Primer Seminario Sobre la Farmacopea de los Estados Unidos.
Colegio de Farmacéuticos de **Córdoba. Argentina**. May 1996.

5.- *Reference Standards in the Certification Process.* CPhI Latinoamericana **Sao Paulo, Brazil,** Nov 1996.

6.- *The Importance of Reference Standards in Pharmaceutical Analyses* II Fenafarma. **Sao Paulo, Brazil**, April 1997.

7.- *The USP Reference Standard Program,* II Symposium of Latin America and Caribe of AOAC International. **Buenos Aires, Argentina**, June 1997.

8.- *The USP Reference Standards Program*. Medsul I. **Sao Paulo, Brazil**, Nov. 1997.

9.-*Validation of Analytical Methods for Compendial Purposes*. Proquifa Seminar. **Mexico City. Mexico** Feb 1998.

10.-*The USP Reference Standard Program.* Proquifa Seminar. **Mexico City. Mexico.** Feb 1998.

11.-*A Importanca dos Padroes de Referenca.* Medsul II. **Sao Paulo, Brazil**, Aug. 1998

12.- *Los Programas de Estándares de Referencia.* Safybi Seminar. **Buenos Aires, Argentina**. Oct. 1998.

13.- *Waters for Pharmaceutical Purposes*. V Congresso da Federacao Farmaceutica Sul-Americana, **Goiania, Brazil**, Nov. 1998.

14.- *Problems in the Analyses and Production of Formulations with low Concentration of Active Ingredients to meet Pharmacopeial Standards.* Medsul III. **Sao Paulo, Brazil,** July 1999.

15.- *Reference Standards in the GMP Compliance and Certification Process.* Instituto Adolpho Lutz, **Sao Paulo, Brazil,** July 1999.

16. *Panel Discussion on Analysis of Herbal Products.* Scientific Forum on Natural Products, October 26, 1999. Knowledge Foundation, **Baltimore, Maryland**.

17. *Development of Botanical Monographs in USP*. ETIF-Costa Salguero. October 2000, Buenos Aires, Argentina.

18. *Challenges in the Standardization of Botanicals,* AOAC International, Montevideo Uruguay, November 2001.

19. *USP Dissolution Procedures. Update and Their Relation with BE/BA Studies.* Course on Bioavailability and Bioequivalence. Pontific Catholic University of Chile, Santiago de Chile, April 2002.

20. *USP Approaches to Botanical Reference Standards*, V Forum Debates on Phytomedicines and Natural Products**,** Febrafarma, Sao Paulo, Brazil August 2002.

21. *Standards for Botanicals: The USP Perspective,* Drug Information Association, Washington DC. July 2004.

22. *New Monographs for Botanicals in USP, Scientific Approaches to Quality Assessment of Botanical Products,* University of Mississippi, Oxford MS, September 2004

23. *The New USP-NF Spanish Edition,* EXPOFARMA, Mexico DF, March 2005.

24. *USP Approach to System Suitability for Peak Identification of Botanical Markers,* Chemical Society of Washington-Washington Chromatography Discussion Group, Round Table on Food Chemistry, May 2005, Rockville MD.

Bibliography

Giancaspro, G.I., Albónico S.M., Pizzorno M.T., Garofalo A., Zeichen R., Bindstein E., **Synthesis of Disubstituted Tetrahydrocarbazols with Potential Antidepressant Activity**. *Il Farmaco Ed. Sci.* 1989, 44(5), 484- 489.

Giancaspro, G.I., Colombari V.D., Albónico S.M., Rivas C., Cardoni R., Pizzorno M.T, **Synthesis and Trypanocidal Activity of Tetrahydrocarbazols.** *Rev. Microbiol.* (Sao Paulo) 1994, 25(3), 201-205.

Segal A., Ricci R., Giancaspro G., Pizzorno M.T**. HPLC Determination of Sodium Cromoglycate**. *Drug Development and Industrial Pharmacy.* 1997, 23(8).

Name: **ADRIANNE KLIJN**
Address: Chemin de la Cabuse 3
1073 Savigny
Switzerland
Tel: 0041 78 839 22 41 (mobile)
E-mail: Adrianne.klijn@rdls.nestle.com
Details: Dutch, born in 1974, single, full driving licence

EMPLOYMENT HISTORY

2013-Present Group Leader Microbial and Molecular Analytics Group
Nestlé Research Centre, Vers-chez-les-Blanc, Switzerland
2010-2013 Senior microbiologist / Lead scientist
Nestlé Research Centre, Vers-chez-les-Blanc, Switzerland
2005-2010 Microbiology Services Manager
Nestlé Quality Assurance laboratory York, United Kingdom
1999 Inactivation of pathogens in dairy spreads
Traineeship at Unilever Research, Vlaardingen, the Netherlands (6 months)
1998 Toxin production of *Bacillus cereus* in food products
Traineeship at Hannah Research Centre, Ayr, Scotland (6 months)
1996-98 Part-time postal worker with the royal Dutch Mail Service
1991-94 Various catering related jobs

EDUCATION

2001-2005 Ph.D. at Nestlé Research Centre, Vers-chez-les-Blanc, Switzerland
In cooperation with University College Cork, Ireland
1999-2001 M.Sc in Food Microbiology
University College Cork, Cork, Ireland
1995-1999 B.Sc in Food Science and Technology
1997 Specialisation in Product Development
Larenstein International Agricultural College, Velp, the Netherlands
1991-1995 Diploma in Cooking, Serving, Beverages, Economics, Marketing, English, German
Senior Hotel and Catering Education, Wageningen, the Netherlands

CERTIFICATES

2012 Effective presentations - Story board approach **(Nestlé)**
2012 Skill based recruitment course **(AK partners)**
2011 Project management course **(Nestlé)**
2011 Basic DMAIC for sponsors **(Nestlé)**
2011 Training course on SAP LIMS as end user **(Nestlé)**
2009 ISO 22000 lead auditor **(CCFRA)**
2009 Management of microbiological hazards in foods **(Wageningen university)**
2008-09 Lead to Win **(Nestlé/Lane 4)**
2008 Management of food safety & hygiene **(Chartered Institute of Environmental Health)**
2008 OSTAS COSHH assessors course **(OSTAS)**
2008 Level 2 HACCP course **(Nestlé)**
2007 NEBOSH level 3 certificate in occupational health and safety **(NEBOSH)**
2007 Statistics for microbiologist **(Statistics for industry)**
2006 Practical training for BAX system **(Dupont Qualicon)**
2006 Recruitment skills **(Nestlé)**
2006 bioMerieux API training **(bioMerieux)**
2006 Transia© plate salmonella gold **(Biocontrol)**
2006 Labware LIMS administration course **(Labware)**
2006 UKAS internal auditing course **(UKAS)**
2006 Nestlé line managers course **(Nestlé)**

2006 Appraisal skills **(Nestlé)**
1994 NIMA A in Marketing **(Dutch Marketing Society)**

ACQUIRED SKILLS AND TECHNIQUES

- Leadership
  - Recruitment of team members.
  - Monitoring performance and addressing issues.
  - Through objectives (projects, courses, factory/ research secondments) coach and develop people so that they reach their full potential.
  - Ensuring that the lab operated within budget.
- Managing workload
  - The lab provided a high level of service to the business.
  - Turn around time were 99% despite a 30% increase in samples from 2004 to 2008.
  - Good balance between testing samples and developing people.
- Quality systems
  - Maintained UKAS and DEFRA accreditation.
  - Extension of scope for new methods.
  - Ensured compliance to Nestlé quality standard (only high performing microbiology lab in Nestlé).
  - Audit external laboratories in UK, Ireland, Belgium and Holland.
  - Audit Nestlé Quality Assurance Centres in North America and Thailand.
- Food safety:
  - Familiar with key Nestlé documents (e.g. manufacturing instructions) regarding food safety.
  - Knowledge of food safety management systems, ISO 22000 and HACCP (courses).
- Methods:
  - Setting a strategy for the establishing and revising laboratory instructions for Nestlé Quality Assurance Centres.
  - Writing laboratory standards that are used by Nestlé Quality Assurance Centres worldwide.
  - Ensuring that methods are verified at local level before implementation.
  - Ongoing method verification in the form of IQA.
  - Implementation of a way to determine the measurement of uncertainty for enumeration methods.
- Networking:
  - Attend ISO working group on standards such as sample preparation (ISO 6887 series), detection of Salmonella (ISO 6579) and media quality assurance (ISO 11133).
  - Attend general committee meetings from MicroVal.
  - Attended the UKAMA meetings.
  - Part of the Campden QA/QC working party.
  - From 2006-2010 Organised Northern Regional Association of Microbiologist, a group of 30 people that meet every 4 months to discuss microbiology and accreditation topics.
- Health and Safety
  - Implementation of a health and safety team.
  - Designed COSHH and general risk assessments forms.
- General microbial techniques:
  - Routine enumeration (spot-, spread-, pour-, and automatic plating).
  - Identification techniques.
  - Fermentation technology (small/medium scale, batch/continues systems).
- Protein related techniques:
  - General protein isolation, quantification, purification techniques.
- DNA related techniques:
  - General DNA isolation, quantification, purification techniques.
- RNA transcription related techniques:
  - General RNA isolation, quantification, purification techniques.
  - Competent in setting up hybridisation using DNA – ORF based micro arrays.
  - Real-Time PCR.

LANGUAGES

Dutch:	Mother tongue
English:	Fluent, native speaker
German:	Fluent
French:	Spoken

ACTIVITIES / INTEREST

My hobbies are reading, walking, agility and flybal with my dogs. Founding member of the Entlebucher Swiss Mountain Dog club in the UK.

REFERENCE

Available on request.

PUBLICATIONS

Han Joosten, John Marugg, Roger Stephan, Adrianne Klijn, Tim Jackson, Carol Iversen. A rapid and reliable alternative to ISO 21528-1:2004 for detection of *Enterobacteriaceae.* 2008. *International Journal of Food Microbiology*. 125, 344-346.

A. Klijn, D. Moine, M. Delly, A. Mercenier, F. Arigoni. Construction of a reporter vector for the analysis of *Bifidobacterium longum* promoters. 2006. *Applied and Environmental Microbiology*. 72, 7401-7405.

Adrianne Klijn, Annick Mercenier, Fabrizio Arigoni. Lessons from the genomes of Bifidobacteria. 2005. *FEMS Microbiology Reviews*. 29, 491-509.

E. Ananta, S.-E. Birkeland, B. Corcoran, G. Fitzgerald, S. Hinz, A. Klijn, J. Mättö, A. Mercenier, U. Nilsson, M. Nyman, E. O'Sullivan, S. Parche, N. Rautonen, P. Ross, M. Saarela, C. Stanton, U. Stahl, T. Suomalainen, J.-P. Vincken, I. Virkajärvi, F. Voragen, J. Wesenfeld, R. Wouters and D. Knorr. 2004. Processing Effects on the nutritional advancement of probiotics and prebiotics. *Microbial Ecology in Health and Disease*. 16, 113-124.

BIOGRAPHICAL SKETCH
Wendy A. McMahon

EMPLOYMENT HISTORY
Silliker, Inc.

2004-present, Microbiology Operations Manager, Chicago Heights, Illinois
Manage ISO 17025 contract microbiology laboratory.

1999-2004, Research Program Manager, South Holland, Illinois
Managed contract research programs including thermal process validation studies, method validation studies, and proficiency testing programs.

1995-1999, Manager of Laboratory Products, South Holland, Illinois
Developed and managed proficiency testing programs in food microbiology and chemistry.

1994-1995, Education Supervisor, Homewood, Illinois
Developed, updated and presented Silliker's technical short courses as well as customized seminars for industry companies.

1992-1994, Technical Education Specialist, Homewood, Illinois
Updated and presented technical short courses for food industry.

1990-1992, Research Microbiologist, Chicago Heights, Illinois
Executed food microbiology research projects including shelf-life and challenge studies and AOAC method validations.

EDUCATION
Master of Science, 1999, Food Science, University of Illinois, Urbana-Champaign, IL. Thesis: "Evaluation of Cooking Procedures to Destroy *Escherichia coli* O157:H7 in Whole Muscle Cuts of Beef".

Bachelor of Science, 1990. Biology, University of Illinois, Urbana-Champaign, IL.

MEMBERSHIPS
AOAC International and International Association of Food Protection

PUBLICATIONS

McMahon, W.A., A.M. Schultz, R.L. Johnson. 2004. Evaluation of VIDAS® *Salmonella* (SLM) Immunoassay Method with Rappaport-Vassiliadis (RV) Medium for Detection of *Salmonella* in Foods: Collaborative Study. J. AOAC Inter. 87 (4): 867-883.

McMahon, W.A., V.A. Aleo, A.M. Schultz, B.L. Horter, K.G. Lindberg. 2003. 3M™ Petrifilm™ Staph Express Count Plate Method for the Enumeration of *Staphylococcus aureus* in Selected Types of Meat, Seafood, and Poultry: Collaborative Study. J. AOAC Inter. 86 (5): 947-953.

Lepper, W.A., A.M. Schultz, M.S. Curiale, and R.L. Johnson. 2002. Evaluation of VIDAS Immuno-concentration *Salmonella*/VIDAS *Salmonella* Immunoassay Method for Detection of *Salmonella* in Selected Foods: Collaborative Study. J. AOAC Inter. 85 (3): 609-625.

Lepper, W.A., A.M. Schultz, M.S. Curiale, and R.L. Johnson. 2002. *Salmonella* in Selected Foods by VIDAS Immuno-concentration *Salmonella* Plus Selective Plate Method (Hektoen Enteric, Xylose Lysine Desoxycholate, Bismuth Sulfite): Collaborative Study. J. AOAC Inter. 85 (3): 593-608.

Lepper, W.A., A.M. Schultz, M.S. Curiale, and R.L. Johnson. 2002. *Salmonella* in Selected Foods by VIDAS Immuno-concentration *Salmonella* Plus Selective Plate Method (Hektoen Enteric, Bismuth Sulfite, *Salmonella* Identification): Collaborative Study. J. AOAC Inter. 85 (3): 576-592.

Lepper, W.A. 2001. Thermal Validation Studies Reduce Risks. SCOPE Technical Bulletin. 17 (1): 5-7.

Curiale, M.S., W. Lepper, and B. Robison. 1994. Enzyme-linked Immunoassay for Detection of *Listeria monocytogenes* in Dairy Products, Seafoods, and Meats: Collaborative Study. J. AOAC Inter. 77 (6): 1472-1489.

Curiale, M.S., T. Sons, L. Fanning, W. Lepper, D. McIver, S. Garramone, and M. Mozola. 1994. Deoxyribonucleic Acid Hybridization Method for the Detection of *Listeria* in Dairy Products, Seafoods, and Meats: Collaborative Study. J. AOAC Inter. 77 (3): 602-617.

Eckner, K.F., D. McIver, W.A. Lepper, L. Fanning, M.S. Curiale, R.S. Flowers, and B. Robison. 1992. Use of an Elevated Temperature and Novobiocin in a Modified Enzyme-linked Immunosorbant Assay for the Improved Recovery of *Salmonella* from Foods. J. Food Prot. 55 (10): 758-762.

PRESENTATIONS

2005. IAFP Annual Meeting. Baltimore, Maryland. Validation of the Use of Composite Sampling for the Detection of *Listeria monocytogenes* in a Variety of Food Products. Poster Presentation.

2004. IAFP Annual Meeting. Phoenix, Arizona. Evaluation of VIDAS Staph Enterotoxin II (VIDAS SET 2) Method. Poster Presentation.

2004. IAFP Annual Meeting. Phoenix, Arizona. Validation of Composite Sampling for Detection of *Escherichia coli* O157:H7 in Raw Beef Trims and Raw Ground Beef. Presented by Dr. Ann Marie McNamara.

2004. AOAC Annual Meeting. St. Louis, Missouri. VIDAS® *E. coli* O157 (ECO) and O157:H7 Plate Method Pre-collaborative Study Report: AOAC *Performance Tested Method*^{SM} . Poster Presentation.

2003. IAFP Annual Meeting. New Orleans, Louisiana. Evaluation of Second Generation VIDAS Listeria monocytogenes and Automated BAX Methods for Detection of Listeria monocytogenes in Ready-to-Eat Meat and Poultry. Presented by Dr. Ann Marie McNamara.

2002. Institute for Thermal Processing Specialists. Symposium on Advances in Extended Shelf-Life. Kissimmee, Florida. Advances in Rapid Microbial Detection. Presentation.

2002. AOAC Annual Meeting. Los Angeles, California. Evaluation of VIDAS® *Salmonella* (SLM) Immunoassay Method with Rappaport-Vassiliadis for Detection of *Salmonella* in Foods: Collaborative Study. Poster Presentation.

2002. International Ice Cream Association. Ice Cream Technology Conference. San Antonio, Texas. Rapid Methods for Pathogen Detection. Presentation.

2001. AOAC Annual Meeting. Kansas City, Missouri. Evaluation of VIDAS® Immuno-concentration *Salmonella* (ICS) / VIDAS *Salmonella* (SLM) Immunoassay Method for Detection of *Salmonella* in Selected Foods: Collaborative Study. Poster Presentation.

2001. AOAC Annual Meeting. Kansas City, Missouri. Evaluation of VIDAS® *Salmonella* (SLM) Immunoassay Method with Rappaport-Vassiliadis for Detection of *Salmonella* in Foods: Precollaborative Study. Poster Presentation.

2001. IAFP Annual Meeting. Minneapolis, Minnesota. Comparison of Methods for the Isolation of *Escherichia coli* O157:H7 from Ground Beef. Poster Presentation.

2000. AOAC International Annual Meeting. Philadelphia, Pennsylvania. Evaluation of VIDAS® Immuno-concentration *Salmonella* (ICS) / VIDAS *Salmonella* (SLM) Immunoassay Method for Detection of *Salmonella* in Selected Foods: Precollaborative Study. Poster Presentation.

1994. National Live Stock and Meat Board Demand Strategies/Annual Meeting. Chicago, Illinois. Evaluation of Cooking Procedures to Destroy *E. coli* O157:H7 in Whole Muscle Cuts of Beef. Technical Presentation.

Dawn M. Mettler
4816 Refugee Road
Baltimore, OH 43105
740-400-7509

EDUCATION

The Ohio State University, Columbus, OH

1/94-5/97 Enrolled in the Masters program in the Food Science & Technology department. Masters thesis was evaluating significance of mycotoxins in food products. Completed coursework in advanced food microbiology, industry problem-solving, and food law.

9/82-6/86 Earned Bachelor of Science degree in Agriculture. Coursework included chemistry (both organic and inorganic), microbiology, management, pathology, physics, communications (both group and individual speech), horticulture and computer science.

AFFILIATIONS & COMMITTEES

3/14 AOAC Central Division, Member-At-Large (to current)
8/13 Analytical Laboratory Accreditation Criteria Committee (ALACC) member (to current)
12/14 A2LA Life Sciences Modified Methods Subcommittee
4/10 A2LA TASARC Committee Chair – development of Threat Agent Program Criteria
11/08 Trainer for ISO/IEC 17025, 17043 and Guide 34 training courses (public and in-house), A2LA (to current)
4/08 A2LA Life Sciences Subcommittee on Proficiency Testing – Biological Scopes
1/08 AOAC Method Verification Technical Committee Co-Chair for 9/08 meeting and Chair for 9/09 meeting
3/07 A2LA Life Sciences Subcommittee on Development of Traceability Criteria for Chemical, Biological and Environmental Testing Laboratories (to current)
5/06 AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals Revision Committee member (to current)
3/06 Measurement Uncertainty for Microbiological Testing Subcommittee, A2LA (presented paper 9/07 AOAC Meeting, A2LA published 10/07)
11/13 ISO/IEC 17020 Assessor, A2LA (to current)
12/08 ISO/IEC 17065 Assessor, A2LA (to current)
1/06 ISO Guide 34 Assessor, A2LA (to current)
1/06 ISO/IEC 17043 Assessor, A2LA (to current)
4/05 World Anti-Doping Agency (WADA) Assessor, A2LA & WADA (to current)
5/99 ISO/IEC 17025 Assessor, A2LA (to current)
4/99 Registered Lead Auditor, NATA (IRCA)
3/05 Best Practices in Microbiological Methods, Statistics Committee member, AOAC
8/04 Measurement Uncertainty for Microbiological Testing Ad-Hoc Committee, A2LA (to current)
3/01 Accreditation Council, A2LA (to current)
3/01 Criteria Council, A2LA (to current)
1/97 American Society for Microbiologists, member (to current)
1/97 AOAC International, member (to current)
4/93 CPR Instructor certification American Heart Association, Instructor-Trainer, Training Center Faculty, affiliated with Grant Medical Center Lifelink & Grant Hospitals, Columbus, OH; renewed 3/95, 3/97, 3/99, 3/01, 3/03, 3/05, 3/07, 3/09, 3/11
7/03 BLS Regional Faculty, Ohio Region, American Heart Association, reappointed 7/05, 7/07, 7/09, 7/11

WORK EXPERIENCE

Rockbridge Laboratory Services, Baltimore, OH

8/99-present: Quality Systems Consultant

Independent consultant and assessor for the testing industry, with expertise in quality systems, microbiological, analytical, diagnostic and environmental assessment, including evaluation of environmental, microbiological and chemical proficiency testing providers, reference material producers, certification bodies, and inspection bodies. Additional expertise in pathology, microbiology (including both conventional pathogen isolation and rapid method detection such as PCR, genetic sequencing and enzyme linked immunoassay), analytical chemistry, serology, fluorescent

antibody testing, virus isolation, tissue culture, veterinary diagnostics and biodefense (select agents, toxins and pathogens of interest). Contracted assessor for ISO/IEC 17025, WADA, Veterinary Diagnostics, Animal Drug Testing, 17043, Guide 34, NELAC/TNI, 17020 and 17065. Contracted Trainer for A2LA public training courses and in-house customized courses (17025, G34, 17043, Internal Audits, Measurement Uncertainty, Corrective Actions & RCA). Develop and present customized training courses, including microbiological & chemical technical courses.

8/99-present: Laboratory Director

Customized testing laboratory that performs micropropagation of plant materials, plant pathology and tissue culture, sterility testing for local hospitals, and isolation and identification of contaminants in these hospitals.

Anheuser-Busch, Columbus, OH

11/00-10/01: Plant Microbiologist

Responsible for ensuring product testing was performed in accordance with company requirements, appropriate methodology was used, and results were reported properly. Supervised quality assurance department staff performing microbiology analyses, provided technical support to department staff, as well as plant staff, including the Brewmaster and Assistant Brewmaster. Worked closely with plant personnel during the brewhouse expansion, providing technical support to sanitation crews and brewing staff. Liaison to corporate quality assurance in St. Louis on microbiological quality of the products produced.

IDEXX Laboratories, Inc., Westbrook, ME

8/99-1/00: Technical Specialist, Special Projects

Provided technical assistance and training to clients regarding IDEXX product lines, including Lightning (ATP), Colilert, Colisure, Quanti-tray, SimPlate. Work with project managers in the Research & Development department to develop and validate new products. Perform quality audits in testing laboratories and food plants.

IDEXX Food Safety Net™ Services, Inc.; IDEXX Laboratories, Inc., Westbrook, ME

6/98-8/99: Quality Assurance Manager/Consultant/Laboratory Specialist

Consulted with customers (internal and external) on quality issues, Hazard Analysis Critical Control Point (HACCP) requirements and questions, methodology, SOPs, sanitation SOPs, GMPs, GLPs, and safety issues. Performed on site quality system audits in processing plants. Developed, implemented and documented laboratory quality systems and processes, and performed internal audits at each site. Assisted other departments within IDEXX on special projects as needed.

IDEXX Food Safety Net™ Services, Inc.; IDEXX Laboratories, Inc., Westbrook, ME

5/97-6/98: Laboratory Supervisor

Supervised laboratory operations for both microbiology and chemistry departments. Developed and implemented quality systems and processes for the IDEXX Food Safety Net™ laboratory in Elmhurst, IL. Identified and incorporated standard testing methodology for microbiological and analytical processes and ordered equipment and reagents to perform analyses. Consulted with customers (internal and external) on quality issues, HACCP requirements and questions, methodology, SOPs, SSOPs, and safety issues. Performed on site quality audits in processing plants. Addressed safety concerns, evaluated safety issues and chemical hazards, and developed policies to create a safe working environment. Served as Site Supervisor and First Responder for chemical spills in the laboratory. Performed laboratory tests as needed.

Silliker Laboratories of Ohio, Inc., Columbus, OH

4/96-5/97: Operations Manager, Microbiology

Managed all aspects of the department, including scheduling, budgeting, auditing, evaluating. Provided technical assistance to the clients regarding Good Manufacturing Practices (GMP), Hazard Analysis Critical Control Point (HACCP) and International Organization for Standardization (ISO). Interpreted data and evaluated manufacturing and sanitation practices for clients. Ensured testing was completed according to internal SOPs, FDA BAM, AOAC, AACC and ISO requirements. Reviewed methods and current technology to determine application to the lab. Prepared lab for 17025 accreditation audit. Served as facilitator for the TQM process.

5/92-5/97: Safety Officer

Developed and implemented the Chemical Hygiene Plan. Addressed safety concerns, evaluated safety issues and chemical hazards, and developed policies to create a safe working environment. Served as First Responder for chemical spills in the laboratory. Created a safety training program and arranged for safety demonstrations and training sessions from outside companies. Conducted CPR training for the entire lab.

12/93-4/96: Operations Supervisor, Microbiology Department

Supervised quantitative and qualitative microbiology department, which isolates, identifies and quantifies human pathogens from food substances and environmental samples. Ensured all assays were completed in a timely manner and reported correctly to the client. Worked with clients to address their needs and satisfy their requirements. Was recognized by AOAC for participation in the interlaboratory validation of AOAC Official Method 995.20, *Salmonella in Raw, Highly Contaminated Foods and Animal Feeds, Detection*. Utilized the Total Quality Management system to solve problems in the department.

8/91-12/93: Operations Supervisor, Qualitative Microbiology Department

Supervised the qualitative microbiology department. Ensured qualitative assays were completed in a timely manner and reported correctly to the client.

American Selected Products, Inc., Westerville, OH

11/90-8/91: Director, Laboratory Services

Maintained and supervised laboratory operations, performed laboratory tests (virus isolation, bacterial cultures, serology) and assisted the staff veterinarian with pathology. Represented the company in meetings with state veterinarians, National Poultry Improvement Plan officials and representatives of other laboratories concerning flock health status areas of the company. Administered the Flock Sanitation Program, which encompassed 5 states and 98 flocks. Maintained records and advised hatchery managers and field personnel about health-related issues.

1/90-11/90: Coordination Manager

Finalized schedules for hatchery managers, arranged deliveries to customers, solved problems between managers and customers, and performed special projects for other department managers.

Ohio Department of Agriculture Diagnostic Laboratories/Division of Animal Industry, Reynoldsburg, OH

6/86-12/89: Avian Microbiologist

Responsible for all aspects of the avian serology department. Organized paperwork and logged in samples, reported results and maintained monitoring programs on poultry flocks. Performed serological and bacteriological tests, virus isolation, tissue culture, serum neutralization and fluorescent antibody tests. Prepared specimens for histological examination. Formulated and synthesized antigens and reagents. Maintained operations of the leptospirosis department as required.

Greenmeadows Veterinary Hospital, Westerville, OH

3/83-1/94: Veterinary Technician

Responsible for caring for patients in the hospital, administering treatments, performing laboratory diagnostic tests, assisting the veterinarians with patient visit treatments, with radiographing and in surgery. Performed front office tasks as needed.

Melissa Meaney Phillips

3907 Joliet Street
Silver Spring, MD 20906
Phone: (517) 214-6967
Email: melmphillips@gmail.com

EDUCATION

Postdoctoral Research Chemist **January 2008 – January 2010**
Organic Chemical Metrology Group, Analytical Chemistry Division, National Institute of Standards and Technology, Gaithersburg, MD
Project: Determination of Marker Compounds in *Vaccinium* Berries
Advisor: Dr. Lane C. Sander

PhD in Chemistry (Analytical) **December 2007**
Department of Chemistry, Michigan State University, East Lansing, MI
Project: Analytical Applications of Fluorescence Quenching
Advisor: Dr. Victoria L. McGuffin

MS in Forensic Chemistry **October 2007**
School of Criminal Justice, Michigan State University, East Lansing, MI
Project: Quantitation of Nitrated Explosives by Fluorescence Quenching following Thin-Layer Chromatography
Advisors: Dr. Victoria L. McGuffin, Dr. Jay A. Siegel, Dr. Ruth J.H. Waddell

BS in Lyman Briggs School – Chemistry, *cum laude* **May 2002**
Michigan State University, East Lansing, MI

RESEARCH EXPERIENCE

Program Coordinator, Food & Nutrition **2013 – present**
Organic Chemical Metrology Group, Chemical Sciences Division, National Institute of Standards and Technology, Gaithersburg, MD
- Responsible for development of food Standard Reference Materials (SRMs), including identification and acquisition of materials, coordination of analytical measurements, and documentation of results
- Responsible for oversight of food and nutrition-related research projects

Research Chemist **2008 – present**
Organic Chemical Measurement Science Group, Chemical Sciences Division, National Institute of Standards and Technology, Gaithersburg, MD
- Evaluated various approaches for integration of data from two-dimensional liquid chromatography (LCxLC) for purposes of comparing quantitative data.
- Certified concentrations for water-soluble vitamins in food and dietary supplement SRMs (e.g., infant formula, baby food, whole milk powder, whole egg powder, soy flour, fortified breakfast cereal, soy milk, pet food, protein drink mix) using various extraction techniques and analytical methods such as liquid chromatography with isotope-dilution mass spectrometric detection (LC-ID-MS and LC-ID-MS/MS).
- Developed a method for high-precision determination and certified concentrations of choline and carnitine in food-matrix SRMs using microwave digestion and LC-ID-MS.
- Developed methods for high accuracy and high precision determination of ammonium and phosphate in a fertilizer SRM by ion chromatography with conductivity detection (IC-CD).
- Developed methods and certified concentrations of relevant active and marker compounds in botanical dietary supplement and natural product SRMs (e.g. *Vaccinium* berries, soy, St. John's wort) using various

extraction techniques and analytical methods such as liquid chromatography with absorbance (LC-Abs), gas chromatography with ID-MS, IC-CD, and LC-ID-MS.
Developed methods for separation of biomarker isomers by LC-Abs.
Administered a quality assurance program for dietary supplement laboratories, including selection and shipment of samples, communication with participants, collection and analysis of data, and formulation and distribution of final reports.
Tested and catalogued the performance (e.g. selectivity, number of theoretical plates, pressure) of over 300 liquid chromatography (LC) columns.

Research Assistant **2002 – 2007**
Department of Chemistry, Michigan State University
Investigated fluorescence quenching-based methods for detection of nitrated explosives by screening fluorophores based on sensitivity and incorporating them into potential field-ready devices for explosives detection.
Utilized the pH-dependent fluorescence of fluorescein for determination of acids in solution and applied this method to analysis of foods and beverages (juices, wines, and vinegars) and drugs of abuse (γ-hydroxybutyric acid or GHB) by HPLC.
Developed a less toxic method for the separation of explosives by thin-layer chromatography and quantitation based on CCD camera imaging.

TEACHING EXPERIENCE

Teaching Assistant **2002 – 2007**
Department of Chemistry, Michigan State University
Introductory Physical Chemistry I (Recitation Instructor) Physical chemistry of macroscopic systems including gases, liquids, phase diagrams, classic thermodynamics, chemical equilibrium, kinetics, electrolytic solutions and electrochemistry. Fall 2007. Instructor: Dr. John L. McCracken, enrollment: 280.
Advanced Analytical Chemistry (Teaching Assistant) Basic electronics and data acquisition/analysis, electrochemistry, and statistics for chemists. Fall 2006. Instructors: Dr. Merlin L. Bruening and Dr. Gary J. Blanchard, enrollment: 20.
Advanced Analytical Chemistry (Teaching Assistant) Principles of equilibria and applications in analytical methodology including acid-base, complexation, redox reactions, potentiometry and conductometry, solute partitioning in extraction and chromatography, and kinetic methods of analysis. Fall 2005. Instructor: Dr. Victoria L. McGuffin, enrollment: 12.
Quantitative Analysis (Recitation and Laboratory Instructor) Preparation and quantitative analysis of chemical compounds, including solution descriptions, solution chemistry (acid/base, solubility, complexation, oxidation-reduction reactions), titrimetry, volumetric calculations, statistics, chemical equilibrium, activity, buffers, indicators, gravimetric analysis, equilibrium, introductory spectroscopy, and calibration curves. Summer 2003, 2004, 2005, 2006, 2007. Instructor: Dr. Kathryn G. Severin, enrollment: 30.
Analytical Laboratory (Laboratory Instructor) A project-based capstone course in which students solve analytical chemical problems including chromatographic separations (GCMS or HPLC), spectroscopic (AA or XRF) and electrochemical methods (potentiometry or stripping voltammetry), deformulation of a household product using available techniques, computer programming using Labview, and surface and interface analysis. Spring 2003, 2004, 2005, 2006, 2007. Instructors: Dr. Merlin L. Bruening and Dr. Kathryn G. Severin, enrollment: 15-30.
Introductory Physical Chemistry I (Recitation Instructor) Physical chemistry of macroscopic systems including gases, liquids, phase diagrams, classic thermodynamics, chemical equilibrium, kinetics, electrolytic solutions and electrochemistry, and statistical mechanics. Fall 2002, 2003, 2004. Instructor: Dr. Paul F. Mantica, enrollment: 280.

Undergraduate Research Mentor **2004 – 2007**
Department of Chemistry, Michigan State University
Heidi L. Bonta, Michigan State University: Incorporation of Selected Fluorophores into Field-Ready Devices for the Detection of Nitrated Explosives. Fall 2006-Fall 2007.

Jenny M. Borowitz, Michigan State University: Quantitation of Nitrated Explosives by Fluorescence Quenching following Thin-Layer Chromatography. Summer 2005-Spring 2006.
Victoria J. Hall, Huntington University: Selectivity of Fluorescein Quenching by Nitroaromatic Compounds. Summer 2004.

Guest Lecturer **2005**
Forensic Science Workshop, Portage Northern High School, Portage, MI
Developed and presented forensic science-based laboratory experiments to 25 high school science teachers interested in incorporation of such materials into the classroom. Experiments included determination of blood alcohol content using visible spectrophotometry following reaction with a chromophore as well as comparison of soil composition (e.g. limestone, chloride, iron) using observation and visible spectrophotometry following addition of appropriate indicator solutions.

Guest Lecturer **2004**
School of Criminal Justice, Michigan State University
Survey of Forensic Science. Scientific analysis of physical evidence. Four major aspects of physical evidence using real criminal and civil cases: generation of physical evidence by criminal activity; collection and preservation of physical evidence; analysis of physical evidence by forensic science laboratory; presentation of scientific expert testimony in court. Topics covered: Fire/arson and explosives analysis. Fall 2004. Instructor: Dr. David R. Foran, enrollment: 15.

Tutor **2003 – 2005**
Department of Chemistry, Michigan State University
General Chemistry II and Introductory Physical Chemistry.

Undergraduate Teaching Assistant **2001**
Department of Mathematics, Michigan State University
Multivariable Calculus (Recitation Instructor) Vectors in space, functions of several variables and partial differentiation, multiple integrals, line and surface integrals, and Green's and Stokes's theorems. Spring 2001. Instructor: Dr. Khodr M. Shamseddine, enrollment: 600.

PROFESSIONAL AFFILIATIONS

American Chemical Society (ACS)	2004-present
ACS Subdivision on Chromatography and Separations Chemistry	2009-present
AOAC International	2008-present
AOAC International Technical Division on Reference Materials	2011-present
Washington Chromatography Discussion Group	2008-present
American Academy of Forensic Sciences	2004-2008
Society of Electroanalytical Chemistry	2004-2008
Midwestern Association of Forensic Scientists	2007-2008
Society for Applied Spectroscopy	2007-2008

PROFESSIONAL DEVELOPMENT

Participant, The New ISO 13528:2015 Workshop on updated statistical methods for PT, Training Course, QuoData GmbH (2016).

Participant, Introduction to Chemometrics, Short Course, Washington Chromatography Discussion Group (2013).

Participant, Comprehensive Two-Dimensional Liquid Chromatography (LCxLC) Short Course, HPLC 2013 (2013).

Participant, Fundamentals of Uncertainty Analysis, National Institute of Standards and Technology Short Course (2012).

Participant, ISO 17043 Proficiency Testing Workshop, National Voluntary Laboratory Accreditation Program (NVLAP) (2011).

Participant, Introduction to Mass Spectrometry and Interpretation of Mass Spectra, Baltimore-Washington Mass Spectrometry Discussion Group Short Course (2010).

Participant, Single Laboratory Validation of Analytical Methods for Dietary Supplements, AOAC Training Course (2008).

Participant, Advanced HPLC Method Development, Washington Chromatography Discussion Group Short Course (2008).

Participant, Creating a Teaching Philosophy You Can Use, Workshop, Teaching Assistant Programs, Michigan State University (2007).

Participant, Talking about Teaching in the Interview, Workshop, Teaching Assistant Programs, Michigan State University (2007).

Participant, Understanding and Handling Classroom Incivility, Workshop, Teaching Assistant Programs, Michigan State University (2007).

Participant, Using Demonstrations to Promote Conceptual Understanding in Chemistry: Making Connections on the Macroscopic, Microscopic, and Symbolic Levels, Lilly Seminar Series, Office of Faculty and Organizational Development, Michigan State University (2006).

Participant, Making Classroom Lectures Interactive and Effective: Engaging Students in Course Content through Interactive Lecturing, Lilly Seminar Series, Office of Faculty and Organizational Development, Michigan State University (2006).

ACADEMIC AND PROFESSIONAL SERVICE

Co-Guest Editor, Journal of AOAC International, AOAC International (2016)
Special Section on Reference Materials with 6 original research articles

Co-Chair, Proficiency Testing Task Force, Stakeholder Panel on Infant Formula and Adult Nutritionals, AOAC International, Gaithersburg, MD (2015-present)
Provided expert guidance in establishing a proficiency testing program for infant formulas and adult nutritionals. Designed studies, including analyte and matrix selection, and established protocols for new program.

Member, AOAC INTERNATIONAL Editorial Board (2014-present)

Co-Chair, International Vitamin Conference (IVC), Washington, DC (2014)

Member, General Chapters Chemical Analysis Expert Committee, United States Pharmacopeia, Rockville, MD (2010-2015)
Review and approve changes to USP guidelines related to chemical analysis.
Member of Subcommittee on Dietary Supplements.
Member of Expert Panel on Elemental Impurities.

Stakeholder, Working Group Member, and Expert Review Panel Member, Stakeholder Panel on Infant Formula and Adult Nutritionals, AOAC International, Gaithersburg, MD (2010-present)
Provided expert guidance on method performance requirements for determination of vitamins in infant formulas.

Stakeholder, Working Group Member, and Expert Review Panel Member, Stakeholder Panel on Strategic Food Analytical Methods, AOAC International, Gaithersburg, MD (2014-present)
Provided expert guidance on method performance requirements for determination of analytes of interest in foods.

Stakeholder, Working Group Member, and Expert Review Panel Member, Stakeholder Panel on Dietary Supplements, AOAC International, Gaithersburg, MD (2014-present)
Provided expert guidance on method performance requirements for determination of analytes of interest in dietary supplements.

Co-Guest Editor, Analytical and Bioanalytical Chemistry, Springer (2012)
Special Issue on Functional Food and Dietary Supplements with 25 original research articles and critical reviews

Poster Committee, HPLC Conference, Boston, MA (2010)
Judged poster presentations to help identify a contest winner.

Presenter, Kids Adventures, Carderock Springs Elementary School, Bethesda, MD (2014)
Presented science demonstrations to elementary children.

Presenter, Kids Adventures, Rock Creek Forest Elementary School, Chevy Chase, MD (2009, 2013)
Presented science demonstrations to elementary children.
Developed a lab to demonstrate pH using red cabbage indicator and household chemicals.

Presenter, Kids Adventures, Candlewood Elementary School, Derwood, MD (2013)
Presented science demonstrations to elementary children.

Presenter, USA Science and Engineering Festival, Washington, DC (2012)

Presented science demonstrations to elementary children.

Presenter, Take your Daughters and Sons to Work Day**,** NIST, Gaithersburg, MD (April 2008-2010)
Developed a hands-on activity for 11 – 12 year olds.
Demonstrated chromatography principals using paper chromatography and separating food dye in grape soda.

Secretary, Washington Chromatography Discussion Group (2009-2015)

Board Member, Washington Chromatography Discussion Group (2008-2009)

Poster Committee, HPLC Conference, Baltimore, MD (2008)
Judged poster presentations to help identify a contest winner.

Co-chair and Member, ACS Women in Chemistry, Michigan State Local Section American Chemical Society (Member 2002-2007; Co-Chair 2004-2005)
American Chemical Society's National Chemistry Week. Performed demonstrations. Coordinated 30 demonstration teams in 2004.
Girls Math/Science Conference. Coordinated a hands-on session entitled "Solving Murder with Makeup" for sixth-grade girls. Sponsored by the Capital Area Science and Math Center.
Awards
Sustained Effort toward Excellence in Diversity, Office of Affirmative Action, Michigan State University, 2006.
Outstanding Overall Local Section Women Chemist Committee, American Chemical Society, 2003, 2004, 2005.
Outstanding Outreach to Girls or Young Women Finalist, American Chemical Society, 2003.

Co-chair and Member, Orientation Committee, Department of Chemistry, Michigan State University
Coordinated the orientation schedule for incoming graduate students. Organized and raised funds for a department-wide picnic. (Member 2003, 2004; Co-Chair 2005, 2006)

Graduate Student Representative, Educational Policies Committee, Department of Chemistry, Michigan State University
Modified graduate program course requirements and the written component for Ph.D. candidacy. Integrated a biological chemistry area into the department beginning Fall 2006. (2004-2007)

Co-editor, Teaching Assistant Manual, Department of Chemistry, Michigan State University
Prepared a document to assist incoming graduate students in their first experiences with teaching, including sections on learning styles, the types of students at MSU, tips on being an effective instructor, and a resource guide. (2004, 2006)

Co-author and Presenter, University Policies and Procedures on Teaching, Department of Chemistry, Michigan State University
Authored and delivered presentations designed to supplement the Teaching Assistant Manual, including skits and sections on learning styles, sexual harassment, academic dishonesty, and potential classroom situations. (2004-2006)

Coordinator and Volunteer, Scout Chemistry Merit Badge Day, Michigan State University
Coordinated a series of hands-on experiments and demonstrations in which 50 boy and girl scouts fulfill the requirements for the Chemistry Merit Badge. Administered a web-based sign up, communicated with scout leaders and parents, and organized volunteers. (Coordinator 2005-2006; Volunteer 2004)

State Event Supervisor and Volunteer, Chemistry Lab, Michigan Science Olympiad

Wrote and administered a laboratory practical for high school competition. Topics included thermodynamics, molecular structures, colligative properties, and redox reactions. Coordinated volunteers to set-up, proctor, and grade exams. (State Event Supervisor 2005, 2007; Volunteer 2006)

Graduate Student Representative, Advisory Committee to the Chair, Department of Chemistry, Michigan State University

Advised on departmental issues important to graduate students. Developed goals for other departmental committees. (2005-2007)

Graduate Student Representative, Anti-Discrimination Judicial Board, Michigan State University

Advised the President on issues related to discrimination in policy and procedure. (2005-2007)

Coordinator, "Things Every Scientist Should Know – Outside the Laboratory", Women in Chemistry, Michigan State University

Coordinated speakers on topics including intellectual properties, alternative careers in the sciences, conflict resolution, health and wellness, scientific writing, and financial planning. Received a Local Section Innovative Grant from the American Chemical Society to support the seminar series. (2005)

HONORS AND AWARDS

2015 William P. Slichter Award, NIST
2015 Expert Review Panel of the Year Member, AOAC International
2015 Best Poster Award, Scripps 12th Annual Natural Supplements: An Evidence Based Update
2013 Best Poster Award, HPLC 2013
2007 Educational Merit Fellowship, Department of Chemistry, Michigan State University
2007 Travel Fellowship, School of Criminal Justice, Michigan State University
2007 Travel Fellowship, American Chemical Society Michigan State University Local Section
2006 Educational Merit Fellowship, Department of Chemistry, Michigan State University
2006 Outstanding Graduate Student Woman, Faculty-Professional Women's Association, Michigan State University
2006 Excellence-in-Teaching Citation, College of Natural Science, Michigan State University
2006 Travel Fellowship, The Graduate School, Michigan State University
2005 Tracy A. Hammer Outstanding Graduate Student Award, College of Natural Science, Michigan State University
2005 Educational Merit Fellowship, Department of Chemistry, Michigan State University
2005 Travel Fellowship, Council of Graduate Students, Michigan State University
2002 Recruitment Fellowship, Department of Chemistry, Michigan State University

INVITED PUBLICATIONS

Melissa M. Phillips. "Choline: Properties and Determination." In: Caballero, B., Finglas, P., and Toldrá, F. (eds.) *The Encyclopedia of Food and Health* vol. 2, pp. 73-78. Oxford: Academic Press. (2016)

Catherine A. Rimmer, Melissa M. Phillips. "Solution to Certified Reference Material Recipe Challenge." *Anal. Bioanal. Chem.* 405 (2013) 6899-6900.

Catherine A. Rimmer, Melissa M. Phillips. "Certified Reference Material Recipe Challenge." *Anal. Bioanal. Chem.* 405 (2013) 4321-4322.

Melissa M. Phillips, Catherine A. Rimmer. "Functional Foods and Dietary Supplements." *Anal. Bioanal. Chem.* 405 (2013) 4323-4324.

Melissa M. Phillips. "Analytical Approaches to Determination of Total Choline in Foods and Dietary Supplements." *Anal. Bioanal. Chem.* 403 (2012) 2103-2112.

Hendrik Emons, Jane Weitzel, John Budin, Melissa Phillips, Catherine Rimmer, Donna Zink. "TDRM/TDLM Workshop on Reference Materials and Laboratory Accreditation at the AOAC Annual Meeting 2011." *Inside Laboratory Management*. (Nov/Dec 2011) 6-7.

Melissa M. Phillips. "André M. Striegel, Wallace W. Yau, Joseph J. Kirkland, and Donald D. Bly (Eds.): Modern size-exclusion liquid chromatography. Practice of gel permeation and gel filtration chromatography, 2nd ed." *Anal. Bioanal. Chem.* 399 (2011) 1571-2.

Catherine A. Rimmer, Melissa M. Phillips. "Analytical Tools for the Dietary Supplement and Food Laboratory." *Natural Products Insider* (Mar 7, 2011).

Paula Brown, Melissa Phillips, Catherine Rimmer, Laura Wood. "Quality Focus: GMPs: The Other Pieces of the Puzzle." *Nutraceuticals World*. (Jan/Feb 2011) 28-29.

Paula Brown, Catherine Rimmer, Melissa Phillips, Laura Wood. "Quality Focus: The GMP Puzzle: What's in Your Box?" *Nutraceuticals World*. (Nov 2010) 28-29.

PEER-REVIEWED SCIENTIFIC PUBLICATIONS

Melissa M. Phillips, Mary Bedner, Manuela Gradl, Carolyn Q. Burdette, Michael A. Nelson, James H. Yen, Lane C. Sander, Catherine A. Rimmer. "Liquid Chromatography with Absorbance Detection and with Isotope-Dilution Mass Spectrometry for Determination of Isoflavones in Soy Standard Reference Materials." (in preparation)

Janet Maxwell Roseland, Kristine Y. Patterson, Karen W. Andrews, Katherine M. Phillips, Melissa M. Phillips, Pamela R. Pehrsson, Guy L. Dufresne, Jette Jakobsen, Pavel A. Gusev, Sushma Savarala, Quynhanh V. Nguyen, Andrew J. Makowski, Chad R. Scheuerell, Guillaume P. Larouche, Stephen A. Wise, James M. Harnly, Juhi R. Williams, Joseph M. Betz, and Christine L. Taylor. "Interlaboratory Trial for Measurement of Vitamin D and 25-Hydroxyvitamin D [25(OH)D] in Foods and a Dietary Supplement Using Liquid Chromatography–Mass Spectrometry." *J. Agric. Food Chem.* 64 (2016) 3167-3175.

Lynn X. Zhang, Carolyn Q. Burdette, Melissa M. Phillips, Catherine A. Rimmer, R. Kenneth Marcus. "Determination of Isoflavone Content in SRM 3238 Using Liquid Chromatography-Particle Beam/Electron Ionization Mass Spectrometry." *J. AOAC Int.* 98 (2015) 1483-1490.

Melissa M. Phillips. "Liquid Chromatography with Isotope-Dilution Mass Spectrometry for Determination of Water-Soluble Vitamins in Foods." *Anal. Bioanal. Chem.* 407 (2015) 2965-2974.

Benjamin J. Place, Mallory J. Morris, Melissa M. Phillips, Lane C. Sander, Catherine A. Rimmer. "Evaluation of the Impact of Peak Description on the Quantitative Capabilities of Comprehensive Two-Dimensional Liquid Chromatography." *J. Chromatogr. A* 1368 (2014) 107-115.

Laura J. Wood, Katrice A. Lippa, Melissa M. Phillips, Catherine A. Rimmer, N. Alan Heckert, Stefan D. Leigh, Amanda J. Moors, Rebecca S. Pugh, and Lauren B. Rust. "Breakfast Cereal Sampling Study for Nutritional Elements." *Anal. Bioanal. Chem.* 405 (2013) 4569-4578.

Mark S. Lowenthal, Melissa M. Phillips, Catherine A. Rimmer, Paul A. Rudnick, Yamil Simón-Manso, Stephen E. Stein, Dmitrii Tchekhovskoi, Karen W. Phinney. "Developing Qualitative LC-MS Methods for Characterization of *Vaccinium* Berry Standard Reference Materials." *Anal. Bioanal. Chem.* 405 (2013) 4451-4465.

Lane C. Sander, Mary Bedner, David L. Duewer, Katrice A. Lippa, Melissa M. Phillips, Karen W. Phinney, Catherine A. Rimmer, Michelle M. Schantz, Katherine E. Sharpless, Susan Tai, Jeanice B. Thomas, Stephen A. Wise, Laura J. Wood. "The Development and Implementation of Quality Assurance Programs to Support Nutrient Measurements." *Anal. Bioanal. Chem*. 405 (2013) 4437-4441.

Melissa M. Phillips, Katherine E. Sharpless, Stephen A. Wise. "Standard Reference Materials for Foods: A Program Update." *Anal. Bioanal. Chem.* 405 (2013) 4325-4335.

Melissa M. Phillips, Lane C. Sander. "Microwave-Assisted Extraction and Quantitative LC/IDMS Measurement of Total Choline and Free Carnitine in Foods." *J. AOAC Int.* 95 (2012) 1479-1486.

Hendrik Emons, Jane Weitzel, John Budin, Melissa Phillips, Catherine Rimmer, Donna Zink. "TDRM/TDLM Workshop on Reference Materials and Laboratory Accreditation at the AOAC Annual Meeting 2011." *Accred. Qual. Assur.* 17 (2012) 101-105.

Melissa M. Phillips, Catherine A. Rimmer, Laura J. Wood, Katrice A. Lippa, Katherine E. Sharpless, David L. Duewer, Lane C. Sander, Joseph M. Betz. "NIST/NIH Dietary Supplement Laboratory Quality Assurance Program: The First Five Exercises." *J. AOAC Int.* 94 (2011) 803-814.

Ryan G. Brennan, Melissa M. Phillips, Liang Y.O. Yang, Thomas P. Moffat. "Characterization and Purification of Commercial SPS and MPS by Ion Chromatography and Mass Spectrometry." *J. Electrochem. Soc.* 158 (2011) D178-86.

Melissa M. Phillips, Ryan J. Case, Catherine A. Rimmer, Katherine E. Sharpless, Stephen A. Wise, Lane C. Sander. "Determination of Organic Acids in *Vaccinium* Berry Standard Reference Materials." *Anal. Bioanal. Chem.* 398 (2010) 425-434.

Melissa S. Meaney, Victoria L. McGuffin. "Investigation of Common Fluorophores for the Detection of Nitrated Explosives by Fluorescence Quenching." *Anal. Chim. Acta* 610 (2008) 57-67.

Melissa S. Meaney, Victoria L. McGuffin. "Luminescence-Based Methods for Sensing and Detection of Explosives." *Anal. Bioanal. Chem.* 391 (2008) 2557-2576.

NIST SPECIAL PUBLICATIONS

Melissa M. Phillips, Catherine A. Rimmer, Laura J. Wood. "Dietary Supplement Laboratory Quality Assurance Program: Exercise K Final Report." NIST Interagency Report 8032. Gaithersburg, MD, USA. DOI: 10.6028/NIST.IR.8032. http://dx.doi.org/10.6028/NIST.IR.8032 (November 2014).

Melissa M. Phillips, Catherine A. Rimmer, Laura J. Wood, Mary Bedner, Kaitlyn D. Chieh, Rick L. Paul. "Dietary Supplement Laboratory Quality Assurance Program: Exercise J Final Report." NIST Interagency Report 7997. Gaithersburg, MD, USA. DOI: 10.6028/NIST.IR.7997. http://dx.doi.org/10.6028/NIST.IR.7997 (April 2014).

Melissa M. Phillips, Catherine A. Rimmer, Laura J. Wood, Karen E. Murphy, Thomas W. Vetter. "Dietary Supplement Laboratory Quality Assurance Program: Exercise I Final Report." NIST Interagency Report 7955. Gaithersburg, MD, USA. DOI: 10.6028/NIST.IR.7955. http://dx.doi.org/10.6028/NIST.IR.7955 (August 2013).

Melissa M. Phillips, Catherine A. Rimmer, Laura J. Wood, Anthony F. Marlow, Michele M. Schantz, John R. Sieber. "Dietary Supplement Laboratory Quality Assurance Program: Exercise H Final Report." NIST Interagency Report 7903. Gaithersburg, MD, USA. DOI: 10.6028/NIST.IR.7903. http://dx.doi.org/10.6028/NIST.IR.7903 (Dec 2012).

PUBLISHED ABSTRACTS

Melissa M. Phillips. "NIST Tools for Quality Assurance in Botanical Dietary Supplement Measurements." *Planta Med.*, 77 (2011).

INVITED PRESENTATIONS

Melissa M. Phillips, Laura J. Wood, Katherine E. Sharpless, Stephen A. Wise. "Food Reference Materials for Nutritional Assessment." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M. Phillips. "The Role of Standard Reference Materials in Method Performance Verification Studies." 128th AOAC INTERNATIONAL Annual Meeting and Exposition, Boca Raton, FL, September 2014.

Melissa M. Phillips. "Metrology 101: No Umbrella Required." Penn State Erie, The Behrend College, Erie, PA, December 2013.

Melissa M. Phillips. "Eggs, Milk, Cereal, and Meat: SRMs for Breakfast." The Pittsburgh Conference, Philadelphia, PA, March 2013.

Melissa M. Phillips. "Challenges in the Certification of Dietary Supplement Standard Reference Materials." The Pittsburgh Conference, Orlando, FL, March 2012.

Melissa M. Phillips. "NIST Tools for Quality Assurance in Botanical Dietary Supplement Measurements." 10th Annual International Conference on the Science of Botanicals, Oxford, MS, April 2011.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "The Journey of a Standard Reference Material." College of the Holy Cross, Worcester, MA, June 2010.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Development of Cranberry Juice Cocktail and Other Related Reference Materials." 123rd AOAC Annual Meeting and Exposition, Philadelphia, PA, September 2009.

Melissa S. Meaney, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Characterization of NIST Dietary Supplement SRMs." Chromatography Forum of the Delaware Valley Spring Symposium, Fort Washington, PA, April 2009.

ORAL PRESENTATIONS

Melissa M. Phillips, Catherine A. Rimmer. "NIST Tools for the Analysis of Dietary Supplements and Foods." SupplySide East, Secaucus, NJ, May 2011.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, and Stephen A. Wise. "Determination of Water-Soluble Vitamins in NIST Food Matrix SRMs." The Pittsburgh Conference, Atlanta, GA, March 2011.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, and Stephen A. Wise. "Determination of Vitamins in NIST Food Matrix SRMs." The Pittsburgh Conference, Orlando, FL, March 2010.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Certification of Organic Acid and Flavonol Concentrations in *Vaccinium* Berry Standard Reference Materials (SRMs)." 238th American Chemical Society National Meeting and Exposition, Washington, DC, August 2009.

Melissa S. Meaney, Victoria L. McGuffin. "Fluorescence Quenching of Fluorescein for the Detection of Acids in Forensic Samples." The Pittsburgh Conference, Chicago, IL, March 2007.

Melissa S. Meaney, Victoria L. McGuffin. "Fluorescence Quenching of Fluorescein for the Detection of Carboxylic Acids." The Pittsburgh Conference, Orlando, FL, March 2006.

Melissa S. Meaney, Victoria L. McGuffin. "Investigation of Common Fluorophores for the Detection of Nitrated Explosives by Fluorescence Quenching." The Pittsburgh Conference, Orlando, FL, March 2005.

POSTER PRESENTATIONS

Melissa M Phillips, Catherine A Rimmer, Laura J Wood, Joseph M Betz. "NIST Tools for Dietary Supplements Testing: Ensuring Quality in Commercial Products." 13th Annual Natural Supplements: An Evidence-Based Update, San Diego, CA, January 2016.

Catherine A Rimmer, Melissa M Phillips, Michele M Schantz, Laura J Wood, Lee Yu, Joseph M Betz. "Marine Reference Materials for Dietary Supplement Analysis." 13th Annual Natural Supplements: An Evidence-Based Update, San Diego, CA, January 2016.

Melissa M Phillips, Catherine A Rimmer, Laura J Wood, Joseph M Betz. "Interlaboratory Studies for Dietary Supplements: Fundamentals for Understanding Supplement Composition." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M. Phillips, Benjamin J. Place, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Characterization of Polyphenols in Vaccinium Berry Dietary Supplement Standard Reference Materials." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Laura J. Wood, Melissa M. Phillips, Joseph F. Browning, Johanna E. Camara, Kaitlyn D. Chieh, Siva K. R. Chinthalapati, Grace E. Hahm, John Molloy, Rick L. Paul, Savelas A. Rabb, Michele M. Schantz, Katherine E. Sharpless, John R. Sieber, Lee L. Yu. "Characterization of a New Total Nutrient Standard Reference Material: Dry Cat Food." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M. Phillips, Laura J. Wood, Joseph F. Browning, Johanna E. Camara, Kaitlyn D. Chieh, W. Clay Davis, Grace E. Hahm, Jeanita S. Pritchett, Michele M. Schantz, Katherine E. Sharpless, John R. Sieber, Lorna T. Sniegoski, Michael J. Welch. "Characterization of a New Total Nutrient Standard Reference Material: Protein Drink Mix." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Brittany L. Catron, Kaitlyn D. Chieh, Peter B. Howell, Stephen E. Long, Karen E. Murphy, Michael A. Nelson, Rick L. Paul, Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise, Laura J. Wood. "Characterization of St. John's Wort Standard Reference Materials (SRMs)." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M. Phillips, Laura J. Wood, Catherine A. Rimmer, Mary Bedner, Jeanice B. Thomas, Katherine E. Sharpless, Lane C. Sander, Stephen A. Wise. "Soy Standard Reference Materials (SRMs) for Quality Assurance in Nutrition Measurements." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M. Phillips, Johanna E. Camara, Grace E. Hahm, Karen W. Phinney, Lane C. Sander, and Stephen A. Wise. "Using Isotope Dilution with LC/MS and LC/MS/MS to Measure Water-Soluble Vitamins in NIST Unfortified and Fortified Food-Matrix SRMs." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M Phillips, Catherine A Rimmer, Laura J Wood, Joseph M Betz. "Interlaboratory Studies for Dietary Supplements: Fundamentals for Understanding Supplement Composition." 129th AOAC INTERNATIONAL Annual Meeting and Exposition, Los Angeles, CA, September 2015.

Hannah Simon, Melissa M. Phillips, Catherine A. Rimmer, Caleb J. Porter. "Value Assignment of Curcuminoids in Turmeric Standard Reference Materials." 129th AOAC INTERNATIONAL Annual Meeting and Exposition, Los Angeles, CA, September 2015.

Melissa M. Phillips, Laura J. Wood, Joseph F. Browning, Johanna E. Camara, Kaitlyn D. Chieh, W. Clay Davis, Grace E. Hahm, Jeanita S. Pritchett, Michele M. Schantz, Katherine E. Sharpless, John R. Sieber, Lorna T. Sniegoski, Michael J. Welch. "Characterization of a New Total Nutrient Standard Reference Material: Protein Drink Mix." 129th AOAC INTERNATIONAL Annual Meeting and Exposition, Los Angeles, CA, September 2015.

Brittany L. Catron, Kaitlyn D. Chieh, Peter B. Howell, Stephen E. Long, Karen E. Murphy, Michael A. Nelson, Rick L. Paul, Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise, Laura J. Wood. "Characterization of St. John's Wort Standard Reference Materials (SRMs)." 129th AOAC INTERNATIONAL Annual Meeting and Exposition, Los Angeles, CA, September 2015.

Melissa M. Phillips, Laura J. Wood, Catherine A. Rimmer, Mary Bedner, Jeanice B. Thomas, Katherine E. Sharpless, Lane C. Sander, Stephen A. Wise. "Soy Standard Reference Materials (SRMs) for Quality Assurance in Nutrition Measurements." 129th AOAC INTERNATIONAL Annual Meeting and Exposition, Los Angeles, CA, September 2015.

Melissa M Phillips, Catherine A Rimmer, Laura J Wood, Joseph M Betz. "Interlaboratory Studies for Dietary Supplements: Fundamentals for Understanding Supplement Composition." 12th Annual Natural Supplements: An Evidence-Based Update, San Diego, CA, January 2015.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander. "LC-MS and LC-MS/MS for Determination of Water-Soluble Vitamins in Foods." 127th AOAC INTERNATIONAL Annual Meeting and Exposition, Chicago, IL, August 2013.

Melissa M. Phillips, Mallory J. Morris, Benjamin J. Place, Catherine A. Rimmer, Lane C. Sander. "Comparison of Commercial Software Approaches for Quantitation in Two-Dimensional Liquid Chromatography." HPLC2013, Amsterdam, the Netherlands, June 2013.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander. "LC-MS and LC-MS/MS for Determination of Water-Soluble Vitamins in Foods." HPLC2013, Amsterdam, the Netherlands, June 2013.

Melissa M. Phillips, Lane C. Sander, and Stephen A. Wise. "Using LC/MS/MS to Measure Water-Soluble Vitamins in NIST Unfortified Food-Matrix SRMs." 126th AOAC INTERNATIONAL Annual Meeting and Exposition, Las Vegas, NV, October 2012.

Catherine A. Rimmer, Melissa M. Phillips, Laura J. Wood. "Improving Measurement Capabilities: NIST Interlaboratory Studies for Food and Dietary Supplements." 126th AOAC INTERNATIONAL Annual Meeting and Exposition, Las Vegas, NV, October 2012.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander. "Microwave-Assisted Extraction and LC-MS Analysis of Total Choline and Free Carnitine in Foods." The Second International Vitamin Conference, Copenhagen, Denmark, May 2012.

Melissa Phillips, Mary Bedner, Johanna Camara, Danielle Cleveland, Candice Jongsma, Mark Lowenthal, Bryant Nelson, Karen Phinney, Karsten Putzbach, Catherine Rimmer, Lane Sander, Katherine Sharpless, Susan Tai, Jeanice Thomas, Stephen Wise. "Standard Reference Materials for the Determination of Vitamins in Food,

Supplement, and Clinical Samples." The Second International Vitamin Conference, Copenhagen, Denmark, May 2012.

Catherine A. Rimmer, Melissa M. Phillips, Laura J. Wood, Katherine E. Sharpless, Stephen A. Wise, Lane C. Sander. "NIST Dietary Supplement Laboratory Quality Assurance Program: A Tool for Improving Vitamin Measurements in Foods and Dietary Supplements." The Second International Vitamin Conference, Copenhagen, Denmark, May 2012.

Melissa M. Phillips, Lane C. Sander, Stephen A. Wise. "Microwave-Assisted Extraction and LC-MS Analysis of Total Choline in Foods." 125th AOAC INTERNATIONAL Annual Meeting and Exposition, New Orleans, LA, September 2011.

Catherine A. Rimmer, Mary Bedner, Manuela K. Gradl, Mariana Arce-Osuna, Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Klaus Albert. "Determination of Soy Isoflavones in Foods and Dietary Supplements." 125th AOAC INTERNATIONAL Annual Meeting and Exposition, New Orleans, LA, September 2011.

Catherine A. Rimmer, Melissa M. Phillips, Laura J. Wood, Katrice A. Lippa, Stephen A. Wise, Lane C. Sander. "NIST Dietary Supplement Laboratory Quality Assurance Program: The First Five Years." 125th AOAC INTERNATIONAL Annual Meeting and Exposition, New Orleans, LA, September 2011.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Determination of B-Vitamins, Choline, and Carnitine in NIST Food-Matrix SRMs." HPLC, Budapest, Hungary, June 2011.

Mary Bedner, Manuela K. Gradl, Mariana Arce-Osuna, Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, Klaus Albert. "Determination of Soy Isoflavones in Foods and Dietary Supplements." HPLC, Budapest, Hungary, June 2011.

Melissa M. Phillips, Ryan G. Brennan, Thomas P. Moffat. "Analytical Characterization of Commercial SPS and MPS by Ion Chromatography and Mass Spectrometry." The Pittsburgh Conference, Atlanta, GA, March 2011.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, and Stephen A. Wise. "Determination of Water-Soluble Vitamins in NIST Food-Matrix SRMs." 124th AOAC INTERNATIONAL Annual Meeting and Exposition, Orlando, FL, September 2010.

Lisa Steinhauser, Melissa M. Phillips, Catherine A. Rimmer, Klaus Albert, Lane C. Sander. "Method Development for the Determination of Yohimbine in Dietary Supplements." 124th AOAC INTERNATIONAL Annual Meeting and Exposition, Orlando, FL, September 2010.

Melissa M. Phillips, Catherine A. Rimmer, Kevin D. Krueger, Mark S. Lowenthal, Rachel A. Lieberman, Lane C. Sander. "Characterization of *Vaccinium* Berry Standard Reference Materials (SRMs)." HPLC, Boston, MA, June 2010.

Melissa M. Phillips, Catherine A. Rimmer, Karen W. Phinney, Jeanice B. Thomas, Bryant C. Nelson, Lane C. Sander. "Determination of Water-Soluble Vitamins in NIST Food-Matrix SRMs." The First International Vitamin Conference, Copenhagen, Denmark, May 2010.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Karen W. Phinney, Jeanice B. Thomas, Bryant C. Nelson, Karsten Putzbach, Katherine E. Sharpless, Stephen A. Wise. "Standard Reference Materials for the Determination of Vitamins in Foods and Dietary Supplements." The First International Vitamin Conference, Copenhagen, Denmark, May 2010.

Catherine A. Rimmer, Melissa M. Phillips, Laura J. Wood, Katrice A. Lippa, Lane C. Sander. "NIST Dietary Supplements Laboratory Quality Assurance Program: A Focus on Vitamin Exercises." The First International Vitamin Conference, Copenhagen, Denmark, May 2010.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Determination of Vitamins in NIST Food Matrix SRMs." NIST Sigma Xi Postdoctoral Poster Session, Gaithersburg, MD, February 2010.

Catherine Rimmer, Katrice Lippa, Melissa Phillips, David Duewer, Lane Sander, Katherine Sharpless, Stephen Wise, Laura Wood. "Dietary Supplement Laboratory Quality Assurance Program." 123rd AOAC INTERNATIONAL Annual Meeting and Exposition, Philadelphia, PA, September 2009.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Development of *Vaccinium* Berry Dietary Supplement Standard Reference Materials (SRMs)." 12th Biological and Environmental Reference Material (BERM) Symposium, Oxford, UK, July 2009.

Catherine A. Rimmer, Katrice A. Lippa, Laura J. Wood, Melissa M. Phillips, Katherine E. Sharpless, Stephen A. Wise, Lane C. Sander, David L. Duewer. "NIST Quality Assurance Program for Dietary Supplements." 12th Biological and Environmental Reference Material (BERM) Symposium, Oxford, UK, July 2009.

Melissa S. Meaney, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Characterization of Organic Acid and Flavonoid Profiles in *Vaccinium* Berry Dietary Supplement Standard Reference Materials (SRMs)." The Pittsburgh Conference, Chicago, IL, March 2009.

Melissa S. Meaney, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Characterization of Organic Acid and Flavonoid Profiles in *Vaccinium* Berry Dietary Supplement Standard Reference Materials (SRMs)." NIST Sigma Xi Postdoctoral Poster Session, Gaithersburg, MD, February 2009.

Melissa S. Meaney, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Development of *Vaccinium* Berry Dietary Supplement Standard Reference Materials (SRMs)." HPLC, Baltimore, MD, May 2008.

Melissa S. Meaney, Victoria L. McGuffin. "Fluorescence Quenching Detection of Nitrated Explosives." The Pittsburgh Conference, Chicago, IL, March 2004.

SRM ACTIVITIES

RM 8441a Wheat Hardness (TPL/TC)
Extended certification date based on USDA data.

RM 8445 Spray-Dried Whole Egg for Allergen Detection (TPL/TC)
Extended certification date based on FDA data.

RM 8642a FDA Saxitoxin Dihydrochloride Solution (TPL/TC)
Acquired material from FDA.

SRM 194a Ammonium Dihydrogen Phosphate
Measured ammonium and phosphate by IC-CD.

SRM 916b Bilirubin
Method developed for stabilization and measurement of bilirubin isomers XIIIα, IXα, and IIIα by LC-Abs.

SRM 1544 Fatty Acids and Cholesterol in a Frozen Diet Composite (TPL/TC)
To be discontinued when out of stock. To be replaced by SRM 1548b Typical Diet.

SRM 1546a Meat Homogenate (TPL/TC)
Measured water-soluble vitamins by ID-LC/MS/MS. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis. Prepared additional data for submission to SED. Updated and finalized Certificate of Analysis.

SRM 1548a Typical Diet (TPL/TC)
Planned and purchased material to prepare renewal SRM.

SRM 1549a Whole Milk Powder (TPL/TC)
Measured water-soluble vitamins, choline, and carnitine by ID-LC-MS.

SRM 1577c Bovine Liver
Prepared additional data for submission to SED.

SRM 1845a Whole Egg Powder (TPL/TC)
Measured water-soluble vitamins by ID-LC/MS/MS. Measured choline and carnitine by ID-LC-MS. Prepared data for submission to SED.

SRM 1849a Infant/Adult Nutritional Formula (TPL/TC)
Measured water-soluble vitamins, choline, and carnitine by ID-LC-MS. Prepared additional data for submission to SED. Drafted and finalized updated Certificate of Analysis.

SRM 1869a Infant/Adult Nutritional Formula (TPL/TC)
Acquired material and stratified samples. Coordinated technical measurements made by NIST staff and collaborating laboratories.

SRM 1974c Organics in Mussel Tissue (*Mytilus edulis*)
Prepared updated Certificate of Analysis.

SRM 2383a Baby Food Composite (TPL/TC)
Measured water-soluble vitamins by ID-LC-MS. Obtained additional carotenoid data from contracting laboratory. Prepared data for submission to SED. Drafted and finalized updated Certificate of Analysis.

SRM 2384 Baking Chocolate (TPL/TC)
Measured water-soluble vitamins by ID-LC-MS/MS. Coordinated stability for 5 additional analyte groups. Prepared data for submission to SED. Drafted and finalized updated Certificate of Analysis.

SRM 2385 Slurried Spinach (TPL/TC)

SRM 2386 Avocado Powder (TPL/TC)
Acquired material and stratified samples. Coordinated measurement of total nutrients through Grocery Manufacturer's Association. Coordinated technical measurements made by NIST staff.

SRM 2387 Peanut Butter (TPL/TC)
Measured water-soluble vitamins by ID-LC-MS/MS. Coordinated stability for 3 additional analyte groups. Prepared data for submission to SED. Drafted and finalized updated Certificate of Analysis.

SRM 3180 Iodide Anion Standard Solution
Measured iodide by IC-CD.

SRM 3233 Fortified Breakfast Cereal (TPL/TC)
Measured water-soluble vitamins by ID-LC-MS.

SRM 3234 Soy Flour (TPL/TC)
Measured water-soluble vitamins by ID-LC/MS/MS. Measured choline and carnitine by ID-LC-MS. Measured isoflavones by LC-UV. Prepared isoflavones data for submission to SED. Drafted and finalized updated Certificate of Analysis.

SRM 3235 Soy Milk (TPL/TC)
Measured isoflavones by LC-UV. Measured water-soluble vitamins by ID-LC/MS/MS. Coordinated measurement of total nutrients by Grocery Manufacturer's Association. Prepared data for submission to SED.

SRM 3236 Soy Protein Isolate (TPL/TC)
Measured isoflavones by LC-UV. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3237 Soy Protein Concentrate (TPL/TC)
Measured isoflavones by LC-UV. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3238 Soy-Containing Solid Oral Dosage Form (TPL/TC)
Measured isoflavones by LC-UV. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3239 Isoflavones Calibration Solution (TPL/TC)
Prepared solutions. Measured isoflavones by LC-UV. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3252 Protein Drink Mix (TPL/TC)
Measured water-soluble vitamins by ID-LC/MS/MS. Measured choline and carnitine by ID-LC-MS (via Grace Hahm, student intern). Coordinated measurement of total nutrients through Grocery Manufacturer's Association. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3253 Yerba Mate (TPL/TC)
Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3262 St. John's Wort Aerial Parts
Measured chlorogenic acid, flavonoids, and naphthodianthrones by LC with absorbance and fluorescence detection.

SRM 3264 St. John's Wort Methanol Extract
Measured chlorogenic acid, flavonoids, and naphthodianthrones by LC with absorbance and fluorescence detection.

SRM 3276 Carrot Extract in Oil (TPL/TC)

SRM 3277 Krill Oil
Coordinated measurement of fatty acids and astaxanthin through Grocery Manufacturer's Association.

SRM 3278 Tocopherols in Edible Oils (TPL/TC)
Extended certification range based on stability data.

SRM 3281 Cranberry (Fruit)
Measured organic acids by ID-LC-MS and ID-GC-MS. Method developed for measurement of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3282 Low-Calorie Cranberry Juice Cocktail
Measured organic acids by IC-CD and LC-UV, method developed for measurement of anthocyanidins and flavonols by LC-Abs. Conducted stability testing of organic acids by LC-MS.

SRM 3283 Cranberry Extract
Measured organic acids by IC-CD and ID-LC-MS, method developed for measurement of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3284 Cranberry-Containing Solid Oral Dosage Form
Measured organic acids by IC-CD and ID-LC-MS, method developed for measurement of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3285 Mixed Berry-Containing Solid Oral Dosage Form
Measured organic acids by IC-CD and ID-LC-MS, method developed for measurement of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3286 Organic Acids Calibration Solution (TPL/TC)
Prepared and measured organic acids by LC-UV. Drafted and finalized Certificate of Analysis. Conducted stability testing of organic acids by LC-MS.

SRM 3287 Blueberry (Fruit)
Measured organic acids by IC-CD and ID-LC-MS, method developed for measurement of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Measured water-soluble vitamins by ID-LC-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3290 Dry Cat Food (TPL/TC)
Measured water-soluble vitamins by ID-LC/MS/MS. Measured choline and carnitine by ID-LC-MS (via Grace Hahm, student intern). Coordinated measurement of total nutrients, gravimetric fat, and crude fiber through Grocery Manufacturer's Association. Collected final data and

prepared Report of Analysis summary for total nutrients. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3291 Bilberry Extract
Measured organic acids by ID-LC-MS, method developed for measurement of organic acids by IC-CD and of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3951 Vitamin B_{12} in Frozen Human Serum
Attempted to develop an ID-LC-MS/MS method for cyanocobalamin. Detection limits are not low enough for the SRM.

CATHERINE A. RIMMER

National Institute of Standards and Technology
100 Bureau Drive, Mail Stop 8392
Gaithersburg, MD 20899-8392

Phone: (301)975-3651
Fax: (301)977-0685
Email: catherine.rimmer@nist.gov

EDUCATION:

Ph.D. Analytical Chemistry, Florida State University, Tallahassee, FL, 2001
Dissertation title: "Toward more practical electrochromatography"
Advisor, John G. Dorsey

B.A., Chemistry/Anthropology, University of Vermont, Burlington, VT, 1993

EXPERIENCE:

RESEARCH EXPERIENCE**:**

Program Coordinator for Dietary Supplements *National Institute of Standards and Technology*, Chemical Sciences Division, 2013-

- Determine priorities for the development of new dietary supplement Standard Reference Materials
- Develop new dietary supplement standard reference data program
- Educate dietary supplement industry about the selection and use of Standard Reference Materials
- Work with industry to determine standards needs for measuring the potency and safety of dietary supplements

Research Chemist *National Institute of Standards and Technology*, Analytical Chemistry Division, September 2003-

- Coordinator for the NIST/NIH Dietary Supplement Laboratory Quality Assurance Program
- Developed methods for the extraction of complex matrix samples and performed trace organic analysis on botanical samples
- Examined extraction methods for the determination of vitamins and marker compounds in foods and dietary supplements
- Developed isotope dilution mass spectrometry methods for quantitation vitamins in dietary supplements and food matrices
- Performed certification measurements on a variety of dietary supplements and food samples
- Designed, synthesized, and characterized a series of stationary phases for liquid chromatography with special emphasis on fluorinated phases.
- Synthesized a novel liquid chromatographic phase for the determination of iodine in foods

***National Research Council Postdoctoral Fellowship**, National Institute of Standards and Technology*, Advisors Lane C. Sander and Stephen A. Wise, September 2001-2003

- Synthesized and characterized a series of stationary phases for a study of the effects of bonding chemistry and bonded phase length on shape selectivity and methylene selectivity in reversed phase liquid chromatography.
- Synthesized and examined novel immobilized polymer stationary phases for the separation of tocopherols (vitamin E) and carotenoid isomers.
- Measured trace organic compounds, specifically focusing on polycyclic aromatic hydrocarbons (PAH) in a variety of matrices by liquid chromatography with UV absorbance and fluorescence detection.

***Research Assistant**, Florida State University*, Advisor John G. Dorsey, 1996-2001

- Designed and tested instrumentation for the introduction of purely electroosmotically driven gradient separations in capillary electrochromatography.
- Developed an instrumental design for the use of "High Voltage" capillary electrochromatography/capillary electrophoresis. This system allows for faster electroosmotically driven separations, with decreased background noise.
- Studied the use of high viscosity solvents in chromatographic separations with electroosmotic flow. Electrochromatography is not limited by pressure, therefore, it is possible to use unconventional solvents to increase mobile phase strength and tune selectivity.

***Summer Intern**, Procter and Gamble, Miami Valley Laboratories*, Cincinnati, OH Advisor, Thomas Chester and G. Ed Burton Summer 1999

- Studied the use and feasibility of enhanced fluidity mobile phases in electroosmotically driven separations.

TEACHING EXPERIENCE:

***Adjunct Instructor**, Introduction to Analytical Chemistry, Florida State University* Summer 2001

***Teaching Assistant**, Introduction to Analytical Chemistry, Florida State University*, Fall 1997

***Teaching Assistant**, General Chemistry II Laboratory, Florida State University,* Fall 1996

Personal Tutor for Introduction to Analytical Chemistry (Quantitative Analysis), and Advanced Analytical Chemistry (Instrumental Methods)

WORK EXPERIENCE:

***Staff Analytical Chemist**, Wyeth Ayerst Laboratories*, Rouses Point, NY March 1993-June 1996.

- Primary duties involved writing and validating cleaning validation methods.
- Performed content uniformity, final product identification, and dissolution testing.
- Calibrated and maintained instrumentation.
- Trained new employees in use of instrumentation and methods.

***Park Ranger**, National Park Service, Cape Cod National Seashore,* Eastham, MA Summers 1989-1992.

- Planned and presented walks, talks, and evening campfire programs on the natural, geologic, and cultural history of Cape Cod for park visitors.

SERVICE:

- United States Pharmacopeia (USP)
  - Reference Standards Expert Committee Member (2010-ongoing)
  - Dietary Supplements Non-Botanicals Expert Committee Member (2008-2010)
  - Dietary Supplements Compendium Advisory Board (2009-2010)

- AOAC
  - Stakeholder panel on strategic food analytical methods, voting member
  - Stakeholder panel on Infant Formula and Adult Nutritionals
  - S-Adenosyl methionine Expert Review Panel
  - Cranberry Expert Review Panel
  - Vitamin D in Food Expert Review Panel
  - Turmeric Expert Review Panel

- International Conference Activities
  - Co-Chair of the 2014 Vitamin Conference
  - Scientific Committee 2015 BERM
  - Organizing Committee 2004 HPLC

- Product Quality Working Group for the National Advisory Council for Complementary and Alternative Medicine (NACCAM) (July 2007-July 2009)

- American Chemical Society Subdivision of Chromatography and Separations Chemistry
  - Chair Elect (2016-2018)
  - Secretary (2010-2016)
  - Executive Board Member (2008-2010)

- AOAC Technical Division on Reference Materials
  - Executive Board Member (2013-2017)
  - Membership Chair (2015-)

- Washington Chromatography Discussion Group
  - Executive board member (2012-2015)
  - Program Chair (2011-1012)
  - Executive board member (2006-2010)
  - President (2005-2006)

- Co-Program Chair/Vice President (2003-2005)

- Conference Chair Work
  - Co-Chair of the 2014 Vitamin Conference
  - Scientific Committee 2015 BERM
  - Organizing Committee 2004 HPLC

- Summer undergraduate research fellowship (SURF) mentor at NIST 2007 and 2009-2012

- Presented Great Grape Soda Race for Adventures in Science, Rockville Science Day, Girl Scouts: Get Psyched About Science, and Take our Daughters and Sons to Work Day, as requested (approximately 4 times/year)

- Coordinated Grape Soda Demonstration for the USA Science and Engineering Festival in DC, 2012 and in planning for 2014

- Graduate student representative, Florida State University, Department of Chemistry Safety Committee, 1998-1999

HONORS AND AWARDS:

- 2015 William P. Slichter Award
- 2015 AOAC Expert Review Panel of the Year Award
- 2015 MML Award for Mentorship
- National Research Council Postdoctoral Fellowship awarded at the National Institute of Standards and Technology 2001-present
- Teaching Assistant Appreciation Award, sponsored by Alpha Chi Sigma at Florida State University, Fall 1996 and Fall 1997
- Katherine Blood Hoffman Fellowship Fall 1996
- Member American Chemical Society since 1993

PUBLICATIONS:

Book chapter:

1. Katrice A. Lippa, Catherine A. Rimmer, Lane C. Sander, "Shape Selectivity in Reversed Phase Liquid Chromatography" Chapter for publication in Advances in Chromatography 2007.

Invited manuscripts:

1. Catherine A. Rimmer, Melissa M. Phillips "Solution to certified reference material recipe challenge" Anal. Bioanal. Chem, 405 (2013) 6899-6900.
2. Catherine A. Rimmer, Melissa WM. Phillips "Certified reference material recipe challenge" Anal. Bioanal. Chem, 405 (2013) 4321-4322.
3. Catherine A. Rimmer, Katherine E. Sharpless, Stephen A. Wise "Standard Reference Materials for dietary supplement analysis" Anal. Bioanal. Chem, 405(2013) 4337-4344.
4. Lane C. Sander, Mary Bedner, David L. Duewer, Katrice A. Lippa, Melissa M. Phillips, Karen W. Phinney, Catherine A. Rimmer, Michele M. Schantz, Katherine E. Sharpless, Susan S.C. Tai, Jeanice B. Thomas, Stephen A. Wise, Laura J. Wood, Joseph M. Betz, Paul M. Coates "The development and implementation of quality assurance programs to support nutritional measurements" Anal. Bioanal. Chem, 405(2013) 4437-4441.
5. Mark S. Lowenthal, Melissa M. Phillips, Catherine A. Rimmer, Paul A. Rudnick, Yamil Simon-Manso, Stephen E. Stein, Dimitri Tchekhovskoi, Karen W. Phinney "Developing qualitative LC-MS methods for the characterization of Vaccinium berry Standard Reference Materials" Anal. Bioanal. Chem, 405(2013) 4451-4465.
6. Laura J. Wood, Katrice A. Lippa, Melissa M. Phillips, Catherine A. Rimmer, N. Alan Heckert, Stefan D. Leigh, Amanda J. Moors, Rebecca S. Pugh, Lauren B. Rust "Breakfast cereal sampling study for nutritional elements" Anal. Bioanal. Chem, 405(2013) 4569-4578.
7. Catherine A. Rimmer "Book Review: Fortified foods with vitamins: analytical concepts to assure better and safer products" Anal. Bioanal. Chem, 402(2012) 2479-2480.
8. Hendrik Emons, Jane Weitzel, John Budin, Melissa Phillips, Catherine Rimmer, Donna Zink. "TDRM/TDLM Workshop on Reference Materials and Laboratory Accreditation at the AOAC Annual Meeting 2011." Inside Laboratory Management. (Nov/Dec 2011) 6-7.
9. Hendrik Emons, Jane Weitzel, John Budin, Melissa Phillips, Catherine Rimmer, Donna Zink. "TDRM/TDLM Workshop on Reference Materials and Laboratory Accreditation at the AOAC Annual Meeting 2011." Accred. Qual. Assur. 17 (2012) 101-105.
10. Catherine A. Rimmer "Book Review of Introduction to Modern Liquid Chromatography" Analytical and Bioanalytical Chemistry, 399 (2010) 1809-1810

11. Catherine A. Rimmer, Melissa M. Phillips, Laura A. Wood, Paula Brown "Quality Focus: The GMP Puzzle: What's in Your Box?" Nutraceuticals World, November (2010)
12. Melissa M. Phillips, Catherine A. Rimmer, Laura A. Wood, Paula Brown. "Quality Focus: GMPs; The Other Pieces of the Puzzle" Nutraceutical World January (2011)
13. Catherine A. Rimmer and Melissa M. Phillips, "Analytical Tools for the Dietary Supplement and Food Analysis Laboratory." Natural Products Insider, March 2011.
14. Catherine A. Rimmer, Katrice A. Lippa, Lane C. Sander "Shape Selectivity in Reversed Phase Liquid Chromatography" LC-GC 23(2008) 984.
15. Catherine A. Rimmer, Stephanie M. Piranio, John G. Dorsey "Gradient elution techniques for capillary electrochromatography" J. Chromatogr. A 877 (2000) 115-124.
16. Catherine A. Rimmer, Caroline Simmons, John G. Dorsey "The measurement and meaning of void volume in reversed-phase liquid chromatography" J. Chromatogr. A 965 (2002) 219-232.

Original research:

1. Zhang LX, Burdette CQ, Phillips MM, Rimmer CA, Marcus RK "Determination of Isoflavone Content in SRM 3238 Using Liquid Chromatography-Particle Beam/Electron Ionization Mass Spectrometry" Through WERB, for submission to JAOAC

2. Saldanah LG, Dwyer JT, Andrews KA, Betz JM, Harnly JM, Pehrsson PR, Rimmer CA, Savarala S "Process for Selecting Green Tea Botanical Dietary Supplements for Expansion of Analytically Verified Databases" J. Food Sci, 80 (2015) H883-H888.

3. Rimmer CA Liquid Chromatography Applications Invited Book review, Analytical and Bioanalytical Chemistry, 407 (2014)7-8

4. Rimmer CA Liquid Chromatography Fundamentals and Instrumentation Invited Book review, Analytical and Bioanalytical Chemistry, 407 (2014)5-6

5. Wood LJ, Phillips MM, Rimmer CA, Bedner M, Chieh K, Paul RL "Dietary Supplement Laboratory Quality Assurance Program:Exercise J Final Report" IR 7997

6. B.J. Place, M.J. Morris, M.M. Phillips, L.C. Sander, C.A. Rimmer, "Evaluation of the impact of peak description on the quantitative capabilities of comprehensive two-dimensional liquid chromatography", J. Chrom. A, 1368 (2014) 107-115
7. Phinney, Karen W. et al "Development of a Standard Reference Material for Metabolomics Research" Anal. Chem, 85, 24 (2013) 11732-11738.

8. Catherine A. Rimmer, Karsten Putzbach, Katherine E. Sharpless, Lane C. Sander "Preparation and Certification of SRM 3278 Tocopherols in Edible Oils", J. Ag. Food Chem, 60 (2012) 6794-6798.
9. Catherine A. Rimmer, Melissa M. Phillips, Laura A. Wood, Curtis Phinney, Katrice A. Lippa, David L. Duewer, Stephen A. Wise, and Joseph M. Betz "NIST Dietary Supplements Quality Assurance Program: Niacin, a Case Study", submitted to WERB September 28
10. Melissa M. Phillips, Catherine A. Rimmer, Laura J. Wood, Katrice A. Lippa, Katherine E. Sharpless, David L. Duewer, Lane C. Sander, Joseph M. Betz, "Dietary Supplement Laboratory Quality Assurance Program: The First Five Exercises", J. AOAC International, 94, 3 (2011) 803-814
11. Phillips MM, Case RJ, Rimmer CA, Sharpless KE, Wise SA, Sander LC "Determination of Organic Acids in *Vaccinium* Berry Standard Reference Materials" Analytical and Bioanalytical Chemistry, 398, 7-8 (2010) 2987-2995.
12. Thomas JB, Sharpless KE, Yen J, Rimmer CA "Determination of Fat-Soluble Vitamins and Carotenoids in Standard Reference Material 3280 Multivitamin/Multielement Tablets by Liquid Chromatography with Absorbance Detection" J. AOAC International, 94, 3 (2011) 815-822.
13. Wise AS, Poster DL, Leigh SD, Rimmer CA, Mossner S, Schubert P, Sander LC, Schantz MM, "Polycyclic Aromatic Hydrocarbons in a Coal Tar Standard Reference Material- SRM 1597a Revisited", Analytical and Bioanalytical Chemistry, 398, 2 (2010) 717-728.
14. Phinney KW, Rimmer CA, Thomas JB, Sander LC, Sharpless KE, Wise SA, "Isotope Dilution Liquid Chromatography-Mass Spectrometry Methods for Fat- and Water-Soluble Vitamins in Nutritional Formulations" Analytical Chemistry, 83, 1 (2011) 92-98.
15. Sander LC et al "Certification of Vitamins and Carotenoids in SRM 3280 Multivitamin/Multielement Tablets", Analytical Chemistry, 83, 1 (2011) 99-108.
16. Sharpless KE, Lindstrom RM, Nelson BC, Phinney KW, Rimmer CA, Sander LC, Schantz MM, Spatz RO, Thomas JB, Turk GC, Wise SA, Wood LJ, Yen JH "Preparation and Characterization of Standard Reference Material 1849 Infant/Adult Nutritional Formula", J. AOAC International, 93, 4 (2010) 1262-1274.
17. Cleveland D, Long SE, Sander LC, Davis WC, Murphy KE, Case RJ, Rimmer CA, Francini L, Patri AK "Chromatographic Methods for the Quantification of Free and Chelated Gadolinium Species in MRI Contrast Agent Formulations", Analytical and Bioanalytical Chemistry, 398, 1 (2010) 2987-2995.
18. Kuhnle M, Friebolin V, Albert, K, Rimmer CA, Lippa KA, Sander LC, "Architecture and Dynamics of C18 Bonded Interphases with Small Molecule Spacers", Anal. Chem. 81 (2009) 10136-10142.
19. Catherine A. Rimmer, Lane C. Sander "Shape Selectivity in Embedded Polar Group Stationary Phases for Liquid Chromatography", Analytical and Bioanalytical Chemistry, 394, 1 (2009) 285-291.

20. Michele M. Schantz, Mary Bedner, Stephen E. Long, John L. Molloy, Karen E. Murphy, Barbara Porter, Karsten Putzbach, Catherine A. Rimmer, Lane, C. Sander, Katherine E. Sharpless, Jeanice B. Thomas, Stephen A. Wise, Laura J. Wood, James H. Yen, Takashi Yarita, Agnes NguyenPho, Wendy R. Sorenson, Joseph M. Betz "Development of Saw Palmetto (Serenoa repens) Fruit and Extract Standard Reference Materials" Analytical and Bioanalytical Chemistry, 392, 3 (2008) 427-438.
21. Sander, L. C., Putzbach, K., Nelson, B. C., Rimmer, C. A., Bedner, M., Brown Thomas, J., Porter, B. J., Wood, L. J., Schantz, M. M., Sharpless, K. E., Wise, S. A., Yen, J. H., Siitonen, P. H., NguyenPho, A., Roman, M. C., and Betz, J. M., "Certification of Standard Reference Materials Containing Bitter Orange," Analytical and Bioanalytical Chemistry, 391, 6 (2008) 2023-2034.
22. Catherine A. Rimmer, et al. "Characterization of a Suite of Ginkgo-Containing Standard Reference Materials" Analytical and Bioanalytical Chemistry, 389, 1 (2007) 179-196.
23. Karsten Putzbach, Catherine A. Rimmer, Katherine E. Sharpless, Stephen A. Wise and Lane C. Sander "Determination of Bitter Orange Alkaloids in Dietary Supplement Standard Reference Materials by Liquid Chromatography with Atmospheric Pressure Ionization Mass Spectrometry", Analytical and Bioanalytical Chemistry, 389, 1 (2007) 197-205.
24. Katherine E. Sharpless, Jeanice Brown Thomas, David L. Duewer, Karsten Putzbach, Catherine A. Rimmer, Lane C. Sander, Michele M. Schantz, Stephen A. Wise, Takashi Yarita and James H. Yen, "Preparation and characterization of standard reference material 3276, carrot extract in oil" Analytical and Bioanalytical Chemistry, 389, 1 (2007) 207-217. Karsten Putzbach, Catherine A. Rimmer, Katherine E. Sharpless and Lane C. Sander "Determination of Bitter Orange alkaloids in dietary supplements standard reference materials by liquid chromatography with ultraviolet absorbance and fluorescence detection" J. Chromatogr. A. 1156 (2007) 304-307.
25. Catherine A. Rimmer, Lane C. Sander, Stephen A. Wise, "Selectivity of long chain stationary phases in reversed phase liquid chromatography" Analytical and Bioanalytical Chemistry, 382 (2005) 698-707.
26. Catherine A. Rimmer, Lane C. Sander, Stephen A. Wise, John G. Dorsey, "Synthesis and characterization of C_{13} to C_{18} stationary phases by monomeric, polymeric, and self-assembled monolayer approaches" J. Chromatogr. A. 1007(2003)11-20.
27. Catherine A. Rimmer, Paul McCall, John G. Dorsey "High Voltage Electrochromatography/Electrophoresis with Two Power Supplies" in preparation for submission to J. Chromatogr. A.
28. Ashley Lister, Catherine A. Rimmer, John G. Dorsey, "Gradient elution electrochromatography using a flow-injection analysis interface" J. Chromatogr. A 828 (1998) 105-112.

ORAL PRESENTATIONS:

Invited oral presentations:

1. Catherine A. Rimmer "Trueness and Traceability in the Analytical Laboratory" AOAC International Annual Meeting, Los Angles, CA September 2015
2. Hakan Emtoborg, Jane Weitzel, John Budin, Mitzi Rettinger, Catherine Rimmer, Donna Zink. "The use of proficiency testing programs in the analytical laboratory" AOAC International Annual Meeting, Los Angles, CA September 2015
3. Joseph Betz, Amit Chandra, Darryl Sullivan, Aniko Solyom, James Neal Kababick, Shauan Roman, Steven Dentali, Melissa Phillips, Catherine Rimmer, Rupa Das, "How to meet the requirements for dietary supplement GMPs" AOAC International Annual Meeting, Los Angles, CA September 2015
4. Catherine A. Rimmer, "Development of Reference Materials for Dietary Supplements", Natural Products and Dietary Supplements Technology Summit, Bethesda, MD
5. Catherine A. Rimmer, Melissa M. Phillips, Benjamin Place, Stephen A. Wise, Lane C. Sander "Liquid chromatography research at the National Institute of Standards and Technology" Pittcon, New Orleans, LA, March 2015.
6. Catherine Rimmer, "DNA Fingerprinting in Dietary Supplement Reference Materials" USP, DNA Barcoding Workshop, October 2014
7. Catherine A. Rimmer, "Dietary Supplement SRMS and RMs for Authenticity" AOAC International Annual Meeting, Boca Raton, FL September 2014.
8. Catherine A. Rimmer, Laura J. Wood, Melissa M. Phillips, "Dietary supplement quality assurance program: lessons learned" AOAC Annual Meeting, Chicago, IL, August 2013.
9. Hendrik Emons, Jane Weitzel, John Budin, Melissa Phillips, Mitzi Rettinger, Catherine Rimmer, Donna Zink. "The use of certified reference materials in dispute resolution" AOAC Annual Meeting, Chicago, IL, August 2013.
10. Catherine A. Rimmer "Development and Use of Standard Reference Materials" FERA/JIFSAN Meeting, College Park, MD, June 2013.
11. Catherine A. Rimmer "Design and synthesis of stationary phases for liquid chromatography" Macromolecular Separations by Design Workshop, Gaithersburg, MD, October 2012.
12. Hendrik Emons, Jane Weitzel, John Budin, Michele Schantz, Catherine Rimmer, Donna Zink. "TDRM/TDLM workshop on reference material: enabling accuracy/trueness control in analytical method validation and verification" AOAC Annual Meeting, Las Vegas, NV, September 2012.

13. Catherine A. Rimmer "The use of NIST tools for dietary supplement analysis", Annual Covance Science Symposium, Madison, WI, August 2012.
14. Hendrik Emons, Jane Weitzel, John Budin, Melissa Phillips, Catherine Rimmer, Donna Zink. "TDRM/TDLM Workshop on Reference Materials and Laboratory Accreditation at the AOAC Annual Meeting, New Orleans, LA, 2011.
15. Catherine A. Rimmer "NIST-NIH Dietary Supplements Laboratory Quality Assurance Program" Supplyside East, Secaucus NJ, May 2011
16. Catherine A. Rimmer "NIST Tools for Food and Dietary Supplement Analysis" Pittcon, Atlanta GA, March 2011
17. Catherine A. Rimmer "The Use of Reference Materials" NIH-ODS Botanical Centers Annual Meeting, Rockville MD, November 2011.
18. Catherine A. Rimmer "National Institute of Standards and Technology, SRMs for Analysis of Food and Dietary Supplements", Pittcon, March 2010.
19. Catherine A. Rimmer, "Methods Validation, Quality and Compliance: Analytical Tools for a Quality Assurance Unit" Supply Side West, Educational Session, November 2009.
20. Catherine A. Rimmer, "NIST Tools for Dietary Supplement and Functional Food Analysis: Standard Reference Materials, Analytical Method Development, and Quality Assurance Programs" International Society for Nutraceuticals and Functional Foods, November 2009.
21. Catherine A. Rimmer, Katherine E. Sharpless, Lane C. Sander, Stephen A. Wise, Joseph M. Betz, Agnes A. NguyenPho "Status of NIST SRMs for Dietary Supplements" AOAC International, September 2009, Philadelphia, PA.
22. Catherine A. Rimmer, "Soy Isoflavone Standard Reference Materials" NIH-ODS Conference on Soy Isoflavones, July 28, 2009, Bethesda, MD.
23. Catherine A. Rimmer, Katrice A. Lippa, Laura J. Wood, Katherine E. Sharpless, Stephen A. Wise, Lane C. Sander "NIST Tools for Dietary Supplement Analysis" National Health Products Research Society of Canada Meeting, February 19, 2009.
24. Catherine A. Rimmer, Katrice A. Lippa, Lane C. Sander, "Shape selective stationary phases: design, function, and synthesis" MASSEP, October 21, 2008, Boston, MA.
25. Catherine A. Rimmer et al. "Analysis of Vitamins in Reference Materials by LC/MS" AOAC International 2008, September 24, Dallas, TX.
26. Catherine A. Rimmer et al. "Dietary Supplement Proficiency Testing: NIST Pilot Program" AOAC International 2008, September 23, Dallas, TX.
27. Catherine A. Rimmer "Analytical Challenges in the certification of botanical dietary supplement Standard Reference Materials" 7th Annual Oxford International Conference on the Science of Botanicals, April 12-16, 2008, Oxford, MS.

28. Catherine A. Rimmer, Meghan E. Kern, Katrice A. Lippa, Lee J. Richter, Lane C. Sander, Lucile C. Teague, Rebecca Zangmeister, "Understanding chromatographic surfaces: an interdisciplinary approach", Pittcon 2008, March 2-6, New Orleans, LA.
29. Catherine A. Rimmer, Katrice A. Lippa, Lane C. Sander, "Shape selective stationary phases: design, function, and synthesis" Chromatography Forum of the Delaware Valley, January 15, 2008.
30. Catherine A. Rimmer, Katrice A. Lippa, Lane C. Sander, "Structure and function of chromatographic surfaces" Florida State University Department of Chemistry and Biochemistry, October 12, 2006, Tallahassee, FL.
31. Catherine A. Rimmer, Katrice A. Lippa, Lane C. Sander, "Structure and function of chromatographic surfaces" 231rst American Chemical Society Meeting, March 26- March 30, 2006, Atlanta, GA.

Contributed oral presentations:

1. Catherine Rimmer, Melissa Phillips, and Laura J. Wood "NIST Dietary Supplement Laboratory Quality Assurance Program: The First Five Years" Pittcon, Orlando, FL, March 2012
2. Catherine Rimmer, Melissa Phillips, Kevin Krueger, Jonathon Truong, Lane Sander, Stephen Wise, Katherine E. Sharpless, "Procyanidin Fingerprints in Food and Dietary Supplement Standard Reference Materials", February 28- March 5, 2010 Pittcon, New Orleans, LA.
3. Catherine A. Rimmer, Karen W. Phinney, Jeanice Brown-Thomas, Bryant Nelson, Katherine E. Sharpless, Stephen A. Wise, L.C. Sander "Determination of vitamins in Standard Reference Materials by liquid chromatography with isotope dilution mass spectrometry" March 7-12, 2009, Chicago, IL.
4. Catherine A. Rimmer, David L. Duewer, Katherine Sharpless, Laura J. Wood, "Dietary supplement laboratory proficiency testing-NIST pilot program" Pittcon 2008, March 2-6, New Orleans, LA.
5. Catherine A. Rimmer, Katrice A. Lippa, Lane C. Sander "Structure, function, and design of surfaces for liquid chromatography" HPLC 2007, June 17-21, Ghent, Belgium.
6. Catherine A. Rimmer, Samuel B. Howerton, Lane C. Sander "Preparation and certification of *Ginkgo biloba* Standard Reference Materials", HPLC 2005, June 26- June 30, 2005, Stockholm, Sweden.
7. Catherine A. Rimmer, Lane C. Sander, Stephen A. Wise, "The optimization of poly (ethylene co-acrylic acid) stationary phases for the separation of carotenoids", Pittcon, 2003, March 9-14, 2003, Orlando.
8. Catherine A. Rimmer, John G. Dorsey "Advances in gradient elution electrochromatography" paper 947, Pittcon 1999, March 7-12, 1999, Orlando, Florida
9. Catherine A. Rimmer, Ashley S. Lister, John G. Dorsey "Gradient capillary electrochromatography using a flow-injection interface"Pittcon 1998, March 1-5, 1998, New Orleans, LA.

JANE WEITZEL

15 Park Royal Bay
Winnipeg, MB R3P 1P2

Home: 204.488.2168 **mljweitzel@msn.com** **Cell: 204.298.3014**

SUMMARY OF QUALIFICATIONS

Over 35 years experience in analytical chemistry in highly regulated, fast paced companies with the last 5 years at the director/associate director level. Expertise includes managing labs compliant with ISO/IEC 17025, cGMP, and ALACC; use of measurement uncertainty; and improving lab system efficiency. Analytical decision maker with excellent people skills. Internationally recognized expert in laboratory management systems and lab accreditation.

- Appointed to USP Expert Committee on Statistics for 2015 to 2020 cycle
- Appointed to USP Expert Committee on Reference Standards for 2010 to 2015 cycle.
- Appointed to Chinese NIFDC Reference Standards Committee 2013 - 2016
- Member of USP Expert Panel on Method Validation and Verification.
- Past Chair of "Analytical Laboratory Accreditation Criteria Committee" of AOAC International. This committee publishes "*AOAC INTERNATIONAL Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals*", the criteria that are used to assess laboratories for ISO 17025 accreditation.
- Lead Auditor for Standards Council of Canada and A2LA for accreditation to ISO 17025 and ISO 17043.
- Member of AOAC Statistics Committee.

PROFESSIONAL EXPERIENCE

Trainer and Consultant

Provided training and presentations to both the United States Pharmacopiea (USP) and FDA on many aspects of Quality systems, specifically the use of Measurement Uncertainty to demonstrate compliance with specifications. This resulted in my being invited by the FDA to speak about the use of Measurement Uncertainty at the FDA's Second International Analytical Methods conference in February 2011.

- Wrote and maintained International Standards for lab accreditation.
- Created and revised several international standards for accrediting laboratories. As a result labs around the world are using these standards in many industries.
  - Assisted in creating the Standards Council of Canada PALACN 1579 guide *"Requirements for the Accreditation of Mineral Analysis Testing Laboratories"*. This guide has been used for over 15 years now to accredit labs in countries such as Russia, Peru, Mexico, US, and Canada.
- Responsible for Quality Systems to support lab operations and manufacturing operations.
  - Experienced in implementing, maintaining, and improving compliance with cGMP regulations of many regulatory bodies including US FDA, Health Canada, UK MHRA and others in drug and biologics manufacturing facilities.
  - Managed and mentored people effectively, enabling them to work at their potential and to develop self-directed teams, resulting in efficient work structures.
  - Learned new technologies quickly and worked with R & D scientists in order to apply Quality Systems in a wide variety of technical and scientific businesses such as transdermal manufacturing, solid dosage manufacturing, plasma collection, plasma fractionation, contract manufacturing, and the mining and environmental industries.
- Changed Quality Systems in response to regulatory actions such as Warning Letters and Consent Decrees.
  - Led a project in response to an FDA consent decree to validate over 200 methods to today's standards while maintaining normal lab operations and ensuring compliance with regulatory requirements. This resulted in all methods being validated to current standards, meeting a key requirement of the consent Decree.

- Redesigned the Quality Systems of a Biologics company as a result of an FDA Warning Letter. This project resulted in a compliant Quality System and ensured no further regulatory action.

- Achieved registration to ISO 9001 at a pharmaceutical company in one year. This gave the company a competitive advantage and demonstrated the Quality Systems met the current standard.

WORK HISTORY

JANE WEITZEL CONSUTANT, Winnipeg, Manitoba **2000 – Present**

Consultant
Consulted and trained on lab Quality Systems, both cGMP and ISO 17025, with specialization on Method Validation and the estimation and use of Measurement Uncertainty. Clients represent many industries including mining, pharmaceutical, environmental, food testing, etc. In all cases, the labs achieved ISO 17025 accreditation on the first audit enabling them to attract new business and meet requirements of both their customers and regulatory bodies.

- Assessor A2LA
- Auditor for Standards Council of Canada

QUALITY ASSURANCE PERSON FOR MEDICAL MARIHUANA COMPANY **2014 - Present**

Responsible for all Quality Assurance Person duties regarding growing and selling medical marihuana in Canada according to the Marihuana for Medical Purposes Regulations (MMPR).

VALEANT PHARMACEUTICALS INTERNATIONAL, Steinbach, Manitoba **2010 – 2011**

Director, Laboratory Services
Responsible for all activities of lab with over 70 staff to support commercial drug manufacturing, including method development, validation and routine QC testing, equipment qualification, calibration and maintenance. Also responsible for the stability program and the Annual Product Review. Managed the lab budget of over $5M.

- Implemented use of Measurement Uncertainty which identified opportunity to reduce costs by $50K per month and reduce testing by 25%.
- Reorganized lab documentation system and introduced use of lab worksheets with real time data review which is expected to reduce test turnaround time by 30%.

WATSON LABORATORIES **2005 – 2010**

Associate Director, Laboratory Operations, Corona, California 2007 – 2010
Responsible for remediation activities in response to Consent Decree. Handled all method development, validation, and transfer as well as all document control for the Lab. Oversaw Instrumentation Purchase, Qualification and Maintenance and annual budget of over $4M.

Quality Assurance Manager, Salt Lake City, Utah 2005 – 2007
Responsible for Quality Assurance in the commercial and development transdermal manufacture plants and in the analytical labs

- Oversaw the lot release program and redesigned the investigation process to eliminate delays in lot releases.
- Improved the efficiency and effectiveness of the QA systems, by implementing a process audit program and streamlining the Batch Record Release process.
- Reorganized the Quality Assurance department along function to improve GMP compliance and efficiency.
- Mentored and developed staff resulting in people being promoted internally to supervisory positions.

CANGENE CORPORATION, Winnipeg, Manitoba **1997 – 2005**

Quality Assurance Manager 2000 – 2005
Responsible for cGMP and ISO 9001 Quality Systems in the plasma collection facilities around North America, and the plasma fractionation Manufacturing facility, including the aseptic filling line, contract manufacturing.

- Revised the Corrective / Preventive Action system which added notifications to people of their responsibilities and resulted in actions being closed on time.
- Hosted, managed, coordinated and participated in regulatory inspections for many regulatory bodies including FDA, Health Canada, the Medicines and Healthcare Products Regulatory Agency (UK). This resulted in many successful audits and licensing of new products.

Quality Assurance Supervisor 1998 – 2000

Performed all tasks in the Quality Assurance department, such as approving change controls, validations, performing internal audits and releasing product. Supervised 4 staff.

- Implemented an improved external audit program that improved standards of the audits and allowed many suppliers to be qualified.

CANGENE CORPORATION (Continued)

Good Manufacturing Practices Compliance Specialist 1997 – 1998

Performed all tasks in the Quality Assurance department, such as approving change controls, validations, performing internal audits and releasing product.

- Learned the cGMP requirements quickly so that backlogs in approving change controls and validations were eliminated.

BIOVAIL CORPORATION, Steinbach, Manitoba **1997**

Validation Chemist, Lab Analyst

Analysed routine Quality Control lab samples and validated new lab methods.

- Validated methods quickly, supporting the quick launch of a new product.
- Tested samples with very little rework needed resulting in timely release of product.

MANITOBA MINES LAB, Winnipeg, Manitoba **1976 – 1997**

Chemist

Analyzed mineral samples, developed and validated new methods as needed and qualified new ICP instrument, including developing and validating test methods.

Publications

Books

Application of ISO/IEC 17025 Technical Requirements in Industrial Laboratories: Method Validation, 2013,
M.L. Jane Weitzel and Dr. Wesley M. Johnson, Friesenpress
http://www.friesenpress.com/bookstore/title/119734000004601536/M.L.-Jane-Weitzel-and-Wesley-M.-Johnson-Application-of-ISO/IEC-17025-Technical-Requirements-in-Industrial-Laboratories

Method Validation in Pharmaceutical Analysis: A Guide to Best Practice, *Chapter 3 Establishment of Measurement Requirements – Analytical Target Profile and Decision Rules*, ed Dr. Joachim Ermer, Dr. Phil Nethercote, 2015, Wiley-VCH

Papers

Using Target Measurement Uncertainty to Determine Fitness for Purpose, Accreditation and Quality Assurance: Journal for Quality, Comparability and Reliability in Chemical Measurement, 2012, (DOI) 10.1007/s00769-012-0899-x, available on-line at
http://www.springerlink.com/content/mx80h69p23218646/?MUD=MP

The Estimation and Use of Measurement Uncertainty for a Drug Substance Test Procedure Validated According to USP <1225>, Accreditation and Quality Assurance: Journal for Quality, Comparability and Reliability in Chemical Measurement, 2012, Volume 17, Number 2, Pages 139-146
http://www.springerlink.com/content/1w56j163804w55h7/

TDRM/TDLM workshop on reference materials and laboratory accreditation at the AOAC annual meeting 2011, Hendrik Emons, Jane Weitzel, John Budin, Melissa Phillips and Catherine Rimmer, et al. Accreditation and Quality Assurance: Journal for Quality, Comparability and Reliability in Chemical Measurement, 2012, Volume 17, Number 1, Pages 101-105
http://www.springerlink.com/content/j47474w33w187333/

The Use of the Analytical Target Profile in the Lifecycle of an Analytical Procedure: with an example for an HPLC Procedure | IVT, Jane Weitzel, Robert A. Forbes, Ronald D. Snee, Journal of Validation Technology, Vol. 20, Issue 4, Jan 2015

Multiple articles on analytical Quality by Design and the Lifecycle of Analytical Procedures for a column in The Journal of Validation Technology JVT) and the Journal of GXP Compliance from 2013 to 2015

EDUCATION

BSc (First Class Honors), Chemistry, University of Manitoba
ASQ Certified Quality Engineer, 2005
ASQ Certificate in Quality Assurance Management, 2001 – 2006
Quality Assurance Management Certificate, 1991, University of Manitoba
Conferences and training programs on cGMP, Quality and Management skills
Several courses on auditing to ISO 9001, ISO 17025 and cGMP

JON W. WONG

Curriculum vitae

Work Address: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740, Tel: 240-402-2172; Email: jon.wong@fda.hhs.gov

1. Education

1995 **Ph.D.**, Agricultural and Environmental Chemistry, University of California, Davis.

1990 **M.S.**, Chemical Engineering, Purdue University, W. Lafayette, IN.

1988 **B.S.**, Chemistry, University of California, Davis.
B.S., Chemical Engineering, University of California, Davis.

2. Professional Experience

December 2002 - present **Research Chemist**, November 2010 - present
Chemist, December 2002 - November 2010

U. S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Regulatory Science, 5100 Paint Branch Parkway, College Park, MD 20740

Develop, validate and implement multiresidue, efficient and cost-effective procedures for the analysis of pesticides, mycotoxins, veterinary drugs, and other chemical residues and contaminants and industrial chemicals in fresh produce, dairy products, agricultural commodities, and dried botanical dietary supplements using advanced technologies (gas chromatography, liquid chromatography, mass spectrometry) and presenting at scientific meetings and forums, publishing in peer-reviewed publications, mentoring to others, providing scientific guidance and technical support, and serving as a technical expert in the aforementioned chemistry areas.

March 1997 – December 2002 **Chemist**

Bureau of Alcohol, Tobacco and Firearms, National Laboratory Center, 1401 Research Blvd, Rockville, MD 20850

Main responsibilities involved the regulation, analysis, and research of beverage alcohol and related alcohol-based products at the Alcohol and Tobacco Laboratory of the Bureau of Alcohol, Tobacco and Firearms including developing methods to screen, quantitate and identify pesticides and organic compounds in alcohol beverages; completed laboratory analysis and reports for market approval and market basket survey products with highly efficient turn-around times and consumer complaint and enforcement projects; presented and published research; and served as a mentor and technical expert to others.

3. Additional Training

2015 Pesticide and Veterinary Drug Residues: Method Validation and Routine Quality Control, *52nd North American Chemical Residue Workshop*, St Pete Beach FL, July 18-19, **2015**.

2014 High Resolution MS for Qualitative and Quantitative Analysis: An Introduction. *62nd ASMS Conference and Short Course*, Baltimore MD, June 14-15, **2015**.

2012 ISO 17025 Certification Training. *FDA CFSAN Staff College*, College Park, MD, December 5-6, **2012**.

2010 Quality Assurance for Analytical Laboratories, *AOAC*, Orlando, FL, September 25-26, **2010**.

2009 Office Methods of Analysis Program: Quantitative Collaborative Study of Chemical Methods, *AOAC*, Philadelphia, PA.

2009 SCIEX 4000 QTrap Training, *Applied Biosystems*, Framingham, MA

2008 Basic Food and Drug Law Course, *U.S. Food and Drug Administration*, College Park, MD

2007 1200L GC-Tandem Mass Spectrometry On-site Training, *Varian Corp*., on-site training, College Park, MD

2006 Premier Tandem Mass Spectrometer Training Course, *Micromass Corp*., Beverly, MA

2005 SCIEX 2000 Training (Applied Systems SCIEX 2000 Triple Quadrupole Mass Spectrometer), IR-4 Trace Analytical Laboratory, Department of Environmental Toxicology, *University of California, Davis*

2002 1100 Series LC/MSD Techniques and Software Operation Course, Agilent Technologies, Wilmington DE

2001 GC-MSD Troubleshooting and Maintenance Course, Agilent Technologies, Atlanta GA

2001 Agilent 6890 GC Retention Time Locking Training Course, Agilent Technologies, XIII California Pesticide Residue Workshop, Sacramento, CA

1999 Instructor Training, Bureau of Alcohol, Tobacco and Firearms, Langevin Learning Services, Greenbelt, MD

1998 Court Training, Bureau of Alcohol, Tobacco and Firearms, Atlanta GA

1998 HP 6890/ALS GC Chemstation Operation Training (Course H5926A), Hewlett-Packard Co., Atlanta, GA

4. Awards

2015 **Award of Appreciation**, FLAG Works, Inc., sponsor of the North American Chemical Residue Workshop (NACRW) for Co-Chairing the Technical Program of the 2015 NACRW, St Pete Beach FL, July 18-23, **2015**.

2012 **FDA Leveraging and Collaboration Award** for superior contribution to collaborate in the development and delivery of the IFSTL's Methods of Pesticide Residue Analysis training courses in March and September **2012**.

2012 **Plenary Speaker**, Taiwan AOAC 2012 Annual Meeting, Taipei, Taiwan (Republic of China

2012 **Certificate of Appreciation**, Taiwan Food and Drug Administration

2009 **AOAC International**, **Community Volunteer of the Year** "for the dedication and excellence on the part of the volunteer who significantly contributes to AOAC INTERNATIONAL's analytical and technical communities, with noted accomplishments relating to their area of expertise."

2009 **Quality step increase** for Outstanding Performance in FY 2008, US FDA.

2008 **Group Recognition Award** for Melamine**,** FDA/CFSAN

2003-15 **Cash or Credit Hour Bonus** based on Work Performance Appraisal Satisfactory or Better (Exceptional Performance Evaluation for **2014**, **2010**, **2009, 2008**) US FDA

2002 **Overall rating of "Outstanding"** for Employee Performance Appraisal for 2001-02, ATF.

2000 **Special Act Award**, Bureau of Alcohol, Tobacco and Firearms

1998 **Overall rating of "Outstanding"** for Employee Performance Appraisal for 1997-98, ATF.

1995-97 **National Institute of Health (NIH) Postdoctoral Fellowship,** Department of Internal Medicine, University of California School of Medicine, 1995-1997.

1993-94 **Jastro Shields Fellowship**, University of California, Davis.

1992-93 **Donald G. Crosby Fellowship in Agricultural and Environmental Chemistry**, University of California, Davis.

1991-92 **Jastro Shields Fellowship**, University of California, Davis.

1991-92 **Thomas Archer Fellowship in Analytical Chemistry**, Department of Environmental Toxicology, University of California, Davis.

1990-91 **Ecotoxicology Trainee Fellowship**, University of California Toxic Substances Research and Teaching Program.

5. Membership in Professional or Honorary Societies

Current membership:
American Association for the Advancement of Science (AAS)
American Chemical Society (ACS)
Association of Official Analytical Chemists (AOAC)

Past membership (no longer active):
American Society for Mass Spectrometry
American Society for Enology and Viticulture (ASEV)
International Society for Horticultural Science (ISHS)
American Institute of Chemical Engineers (AIChE)
Institute of Food Technologists (IFT)
International Society for Free Radical Research
Oxygen Society
Institute for Food Technologists (IFT)

6. Offices, Committee Assignments or Special Assignments Held in Professional Organizations or Honorary Societies:

2015-present **U.S. representative,** electronic Working Group (eWG) on "Proposed Draft Guidance on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues", *Codex Committee on Pesticide Residues*

2015 **Co-Chair, Technical Program Committee**, *52nd North American Chemical Residue Workshop*, St Pete Beach, FL, July 18-23, **2015**.

2015 **Member**, AOAC SPIFAN Expert Review Panel for Pesticide Contaminants-sodium fluoroacetate, *AOAC International Mid-Year Meeting*, Gaithersburg, MD, March 16-18, **2015**.

2015-present **Editorial Advisory Board Member**, *Journal of Agricultural and Food Chemistry*

2014 **Session Chair**, *51st North American Chemical Residue Workshop*, St Pete Beach, FL, July 20-23, **2014**.

2014-2015 **Member**, Intelligence for Emerging Technologies – Recommendations for the Scientific Equipment Acquisition Committee, *Canadian Food Inspection Agency*

2013-current **Co-Chair**, New Blood Session: Developing Methods for the Detection of Chemical Analytes and Contaminants, 127th, 128th, and 129th AOAC Annual Meeting and Exposition, **2013** – **2015**.

2013-current **Organizing Committee Member**, *50th, 51st, and 52nd North America Chemical Contaminants Workshop*, St Pete Beach, FL.

2012-current **Technical Expert on Pesticides**, Pesticide Task Group for Dietary Supplements, NSF/ANSI 173, *NSF International*.

2010-current **Technical Programming Council Member**, *AOAC International*

2009 **Organizing Committee Member** and **Session Chair**, *46th Florida Pesticide Residue Workshop,* St Pete Beach, FL, July 19-22, **2009**.

2008-2012 Organizing Committee Member, *45th, 46th, 47th, 48th, and 49th Florida Pesticide Residue Workshop*, St Pete Beach, FL.

2008-2015 **Subgroup Chair** in Pesticides, Chemical Contaminants & Residues in Food Community, *AOAC International*

2007 **Roster Participant**, AOAC Task Force on Pesticide Detection Methods for Soft Drinks (PSD), AOAC International, 121st Annual Meeting Anaheim, CA, September 19, 2007.

2006 **FDA Roster Participant**, AOAC Task Force on Pesticide Detection Methods for Soft Drinks (PSD), New Delhi, India, November 28 – December 2, 2006.

2006 **FDA Roster Participant**, AOAC Task Force on Pesticide Detection Methods for Soft Drinks (PSD), AOAC International, 120th Annual Meeting, Minneapolis, MN, September 21-22, 2006.

2006-2008 **General Referee** on Pesticides and Other Contaminants for the Methods Committee on Residues and Related Topics, AOAC International

2003-current **Co-editor**, *American Journal of Enology and Viticulture*

7. Outside Professional Advisory and Consulting Activities

Invited reviewer for the following journals:

Analytica Chimica Acta
Analytical Chemistry
Analytical and Bioanalytical Chemistry
Food and Chemical Toxicology
Journal of Agricultural and Food Chemistry

Journal of Chemical Education
Journal of Chromatography A
Journal of the Association of Official Analytical Chemists International
Journal of Chromatographic Science
Pest Management Science
Rapid Communications in Mass Spectrometry

8. FDA Special Assignments and Advisory Activities

2014-current **Member**, Veterinary Drugs and Animal Feeds Technical Advisory Group

2013-current **Member,** Exact Mass Measurement Working Group

2013-current **Member**, Electronic Laboratory Notebook Working Group

2010 **Chair, Pesticide Steering Committee**, Office of Regulatory Affairs/Center for Food Safety and Applied Nutrition

2008-current **Member, Pesticide Steering Committee**, Office of Regulatory Affairs/Center for Food Safety and Applied Nutrition

9. Other Significant Information

Post-doctoral or Visiting Scientists Supervised or Collaborated With:

1. Dr. Kelli Simon, ORISE Fellow, 2014-present.

2. Dr. James Wittenberg. ORISE Fellow, 2014-present.

3. Zhengwei Jia, Visiting Scientist, Shanghai Institute for Food and Drug Control, Shanghai, People's Republic of China, November 2012-May 2013. Present affiliation: Senior Application Chemist, Waters Corp., Shanghai, People's Republic of China.

4. Jiwei Liu, Visiting Scientist, Shanghai Institute for Food and Drug Control, Shanghai, People's Republic of China, September 2011-March 2012. Present affiliation: Senior Scientist, Shanghai Institute for Food and Drug Control, Shanghai, People's Republic of China.

5. Dr. Chia-Ding Liao, ORISE Fellow, May 2011-May 2012. Present affiliation: Branch Chief, Division of Research and Analysis, Taiwan Food and Drug Administration, Taipei, Taiwan, Republic of China. Present affiliation:

6. Dr. Feng Shi, ORISE Fellow, January 2010-November 2010. Present affiliation: Research Manager, Givaudan, Cincinnati, OH.

Undergraduate Students Supervised:

1. Hoon Yong Park, Student Intern, Joint Institute for Food Safety and Applied Nutrition, University of Maryland, College Park, June 2013 – May 2015.
   Present affiliation: Chemist, Becton, Dickinson and Company (BD), Glencoe, MD

2. Nathaniel S. Lee, Student Intern, Joint Institute for Food Safety and Applied Nutrition, University of Maryland, College Park, June 2010 – May 2013.
   Present affiliation: Application Developer, J. P. Morgan, Newark, DE

3. Alex L. DiBenedetto, Student Intern, Joint Institute for Food Safety and Applied Nutrition, University of Maryland, College Park, August 2009 – May 2010.
   Present affiliation: Senior Manufacturing Associate, Genzyme, Boston MA

4. Katherine Tech, Student Intern, Joint Institute for Food Safety and Applied Nutrition, University of Maryland, College Park, May 2008 – August 2009.
   Present affiliation: Ph.D. student, University of North Carolina/North Carolina State University Graduate Program in Biomedical Engineering

5. Sara Alizai, Student Intern, Joint Institute for Food Safety and Applied Nutrition, University of Maryland, College Park, November 2007 – March 2008. Present affiliation: Pharmacst, Walgreens

6. Piyush Sheladia, Student Intern, Joint Institute for Food Safety and Applied Nutrition, University of Maryland, College Park, September 2006 – July 2007. Present affiliation: Manager, Clinical Project & CRA Management, Accelovance, Inc., Rockville, MD

10. Publications

Peer-reviewed journals

61. Rering, C.; **Wong, J. W.***; Williams, K.; Hengel, M. J.* Design and applications of QuEChERS for teaching pesticide analysis to undergraduates in an environmental chemistry laboratory course. Manuscript in preparation, *J. Chem. Educ.* **2016**. ***corresponding author, co-first author**

60. Simon, K*.; **Wong, J.W.;***, K. Zhang*; D. G. Hayward; Yang, P.*; Schreiber, A.; Su-Hsiang T.; Liao, C.-D.; Lissemore, L.*; Banerjee, K.*; Oulkar, D. Validation Study of 204 Pesticides in Fruits and Vegetables by QuEChERS and LC-MS/MS. Manuscript in preparation, *J. Agric. Food Chem.* **2016**. ***corresponding authors**

59. Jia, Z.; **Wong, J.W.***; Yang, P.; Zhang, K.; Hayward, D. G.; Park, H. Y.; Chang, J. S.; Wang, J. Multiresidue Pesticide Analysis of Teas using Ultrahigh Performance Liquid Chromatography coupled with Quadrupole-Orbital trap Mass Spectrometry. Manuscript in preparation, *J. Agric. Food Chem.* **2016**. ***corresponding author, co-first author**.

58. Zhang, K.; Schaab, M. R.; Tor, E. R.; Aston, L.; Song, W.; Eitzer, B.; Majumdar, S; Lapainis, T.; Mai, H.; Trent, K.; El-Demerdash, A.; Vega, V.; Cai, Y.; **Wong, J. W.**;

Krynitsky, A. J.; Begley, T. H. A Collaborative Study: Determination of Mycotoxins in Corn, Peanut Butter and Wheat Flour using Stable Isotope Dilution Assay (SIDA) and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS). J. *Agric. Food Chem.* **2016**, submitted.

57. Zhang, K.; Wong, J.W.; Krynitsky, A. J.; Trucksess, M. W. Perspective on advancing FDA regulatory monitoring for mycotoxins in foods using liquid chromatography and mass spectrometry (invited review). *J. AOAC Int.* to be submitted, **2016**.

56. **Wong, J.W.**; Wang, J.; Kowalski. The 52nd North American Chemical Workshop. *J. Agric. Food Chem.* **2016**, submitted.

55. Chen, Y.*; Lopez, S.; Hayward, D.G*.; Park, H. Y.; Kim, S. S.; **Wong, J. W.***; Wan, J.; Reddy, R. M.; Quinn, D. J.; Steiniger, D. Determination of multiresidue pesticides in botanical dietary supplements using gas chromatography-triple quadrupole mass spectrometry (GC-MS/MS). Manuscript in preparation, *J. Agric. Food Chem.* **2016**. **DOI:** 10.1021/acs.jafc.6b00746, * **corresponding authors**

54. Wang, J.; Leung, D.; Chow, W.; Chang, J. S.; **Wong, J. W.** The development and validation of a multi-class method for analysis of veterinary drug residues in milk using ultra-high performance liquid chromatography electrospray ionization quadrupole orbitrap mass spectrometry. *J. Agric. Food Chem.* **2015**, *63*(41), 9175-9187. **DOI:** 10.1021/acs.jafc.5b04096.

53. Hayward, D.G.; **Wong, J. W*.**; Park. H. Y. Determinations for pesticides on black, green, Oolong and white teas by gas chromatography triple quadrupole mass spectrometry. Manuscript accepted. *J. Agric. Food Chem.* **2015**, *63* (37), 8116-8124. **DOI:** 10.1021/acs.jafc.5b02860. ***corresponding authors.**

52. Yang, P.; Chang, J.S.; **Wong, J. W.***; Zhang, K.; Krynitsky, A. J.; Brominiski, M.; Wang, J. Effect of sample dilution on matrix effects in pesticide analysis of several matrices by liquid chromatrography-high resolution mass spectrometry. *J. Agric. Food Chem.* **2015**. *63* (21), 5169-4177. DOI: 10.1021/jf505168v. ***corresponding authors.**

51. Liao, C.D.; **Wong, J. W.***; Zhang, K.; Yang, P.; Wittenberg, J.B.; Trucksess, M. W.; Hayward, D. G.; Lee, N.S., Chang, J. S. Multi-mycotoxin analysis of finished grain and nut products using ultrahigh-performance liquid chromatography and positive electrospray ionization-quadrupole orbital ion trap high resolution mass spectrometry. *J. Agric. Food Chem.* **2015**, *63* (37), 8314-8332. DOI: 10.1021/jf505049a. ***corresponding authors.**

50. Wang, J.; Chow, W.; Chang, J.; **Wong, J. W.** Ultrahigh-performance liquid chromatography electrospray ionization Q-Orbitrap mass spectrometry for the analysis of 451 pesticide residues in fruits and vegetables: method development and validation. *J. Agric. Food Chem.* **2014**, *62*(42), 10375-10391. DOI: 10.1021/jf503778c.

49. Zhang, K.; **Wong, J. W.**; Krynitsky, A. J.; Trucksess, M. W. Determining mycotoxins in baby foods and animal feeds using stable isotope dilution and liquid chromatography tandem

mass spectrometry. *J. Agric. Food Chem.* **2014**, 62(36), 8935-8943. DOI: 10.1021/jf503943r.

48. Zhang, K.; **Wong, J. W.;** Jia, Z.; Vaclavikova, M.; Trucksess, M. W.; Begley, T.H. Screening multi-mycotoxins in food-grade gums by stable isotope dilution and liquid chromatography tandem mass spectrometry. *J. AOAC Int.,* **2013**, 97(3), 889-895.

47. Zhang, K.; **Wong, J. W.;** Mai, H.; Trucksess, M. W. Dopant-assisted atmospheric pressure photoionization of patulin in apple juice and apple-based food with liquid chromatography-tandem mass spectrometry. *J. Agric. Food Chem.* **2014**, 62(18), 4112-4118. DOI: 10.1021/jf5006726.

46. Zhang, K.; **Wong, J**.; Hayward, D.; Vaclavikova, M.; Liao, C.-D.; Trucksess, M. Determination of mycotoxins in milk based products and infant formula using stable isotope dilution assay and liquid chromatography tandem mass spectrometry. *J. Agric. Food Chem*. **2013**, 61 (26), 6265-6273. DOI: 10.1021/jf4018838

45. Kwegyir-Afful, E. E.; DeJager, L. S.; Handy, S. M.; **Wong, J.**; Begley, T. H.; Luccioli, S. An investigational report into the incidence and causes of pine mouth syndrome events in US consumers. *Food Chem. Toxic.,* **2013**, 60, 181-187. DOI: 10.1016/j.fct.2013.07.038.

44. Liao, C.-D.*; **Wong, J. W**.*; Zhang, K.; Hayward, D. G.; Lee, N. S.; Trucksess, M. W. Multi-Mycotoxin Analysis of Finished Grain and Nut Products Using High-Performance Liquid Chromatography-Triple Quadrupole Mass Spectrometry. *J. Agric. Food Chem.* **2013**, *61(20),* 4771-4782. DOI: 10.1021/jf4000677. ***corresponding authors.**

43. Hayward, D. G.*; **Wong, J. W.***; Shi, F.; Zhang, K.; Lee, N. S.; DiBenedetto, A. L.; Hengel, M. J. Multi-residue Pesticide Analysis of Botanical Dietary Supplements using Salt-out Acetonitrile Extraction, Solid-phase extraction cleanup column and Gas Chromatography-Triple Quadrupole Mass Spectrometry. *Anal. Chem.* **2013**, *89(5),* 4686-4693. DOI: 10.1021/ac400481w. ***corresponding authors**.

42. Croley, T. R.; White, K. D.; **Wong, J**.; Callahan, J. H.; Musser, S. M.; Antler, M.; Lashin, V.; McGibbon, G. A. Combining targeted and nontargeted data analysis for liquid chromatography/high-resolution mass spectrometric analysis. *J. Sep. Sci.,* **2013**, *36(5)*, 971-979. DOI: 10.1002/jssc.201200348.

41. Kaewsuya, P.; Brewer, W. E.; **Wong, J. W**.; Morgan, S. L. Automated QuEChERS tips for GC/MS analysis of fruits and vegetables. *J. Agric. Food Chem.,* **2013**, *61 (10),* 2299-2314. DOI: 10.1021/jf304648h.

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Process for Selecting Members of the Official Methods Board (OMB)

The process begins with the OMB Search Committee.

Composition

The Search Committee shall consist of three (3) members: two members of the current OMB and the Immediate Past Chair of the OMB who shall serve as chair of the Search Committee.

Purpose

The objective of the Search Committee is to identify and recommend a slate of nominees as potential candidates for membership on the OMB. They shall seek candidates from such sources as the Association Membership, the Communities, and Stakeholders Groups. The OMB will select a nominee from this slate.

Process

Criteria for Member of the OMB

- Must provide a current Curriculum Vitae
- Must be a member of AOAC INTERATIONAL in good standing
  - Must have a letter of support from the sponsoring organization [employer/supervisor]
  - Must have an executed AOAC Volunteer Acceptance Form
  - Must provide two letters of recommendation from someone other than an employee, employer or supervisor.
- Should be willing and capable of acting as a Liaison with the Communities, Technical Divisions, Research Institute, and other major Stakeholders.
- Should possess the minimum of a Bachelor's degree in chemistry, biology, mathematics or a related scientific field
- Should demonstrate technically competent written and oral communication and networking skills
- Should demonstrate leadership capabilities through documentation of project management, supervisory experience, or leadership positions within AOAC
- Should have experience in the AOAC collaborative study process
- Should be familiar with the AOAC Program Manual and the Official Methods of Analysis appendices
- Should have successfully completed OMB training in the method validation process, demonstrate ability to perform adequate review of AOAC collaborative studies, and agree to appropriate retraining at least every three years.

Appointment of the Candidate

The nominee shall be contacted by the Chair of the OMB to confirm his/her willingness and ability to serve. Once confirmation has been received, the nominee shall be presented to the Board of Directors for their approval and subsequent appointment by the President of the Association.

Composition of The Official Methods Board

The OMB shall be composed of the Chair, Vice Chair, the Chair of the Committee on Safety, the Chair of the Committee on Statistics, and up to 9 more members not to exceed a total of 13 members at any given time. The 9 appointed members are to represent a balance of government, industry, and academia as appropriate to the needs of the Association. No more than one-half of the members of the OMB may be from a single agency and no more than one-half of the members may be from industry.

PROCESS FOR SELECTING THE VICE CHAIR OF THE OFFICIAL METHODS BOARD (OMB)

The process begins with the OMB.

Criteria for the Vice Chair of the OMB

- Must have served for at least one year as a Member of the OMB
- Must fulfill all the criteria for a Member of the OMB

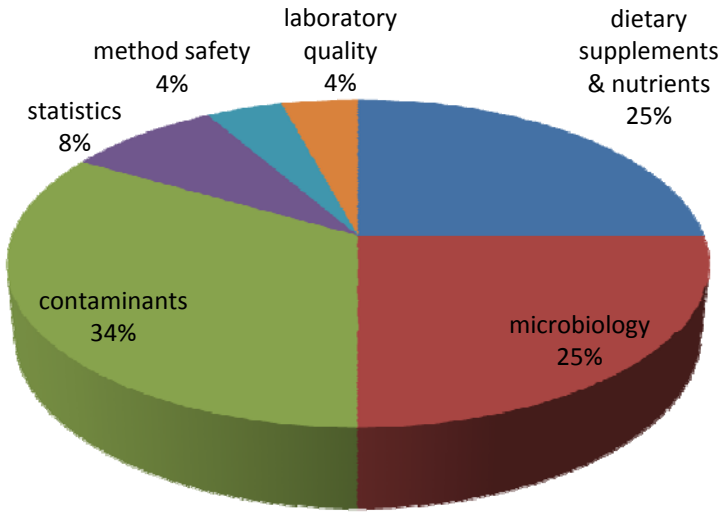
The members of the OMB serve as the search committee for a Vice Chair. They identify and recommend a slate of nominees as potential candidates for Vice Chair. The nominees shall be contacted by the Chair of the OMB to confirm his/her willingness and ability to serve. Once confirmation has been received, the nominee(s) will be presented to the OMB for a vote. An email ballot shall be sent out to the members of the OMB with the slate of nominees. The current Vice Chair collects and tallies the ballots.

The selection of the Vice Chair will be decided by at least a majority vote of the OMB. If there is a tie, the Chair will cast the determinative vote. If no one receives a majority vote, another email ballot will be sent out with the top two nominees who received the highest number of votes.

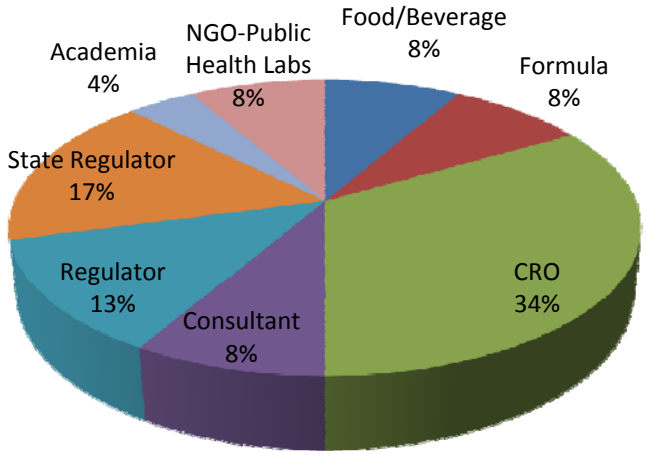
Composition of Official Methods Board

- Maximum of 13 members
  - includes OMB chair, OMB vice chair, chair of the Committee on Safety, and chair of the Committee on Statistics representative of the various stakeholder panel communities and AOAC technical groups

Current OMB Composition by Method Interests

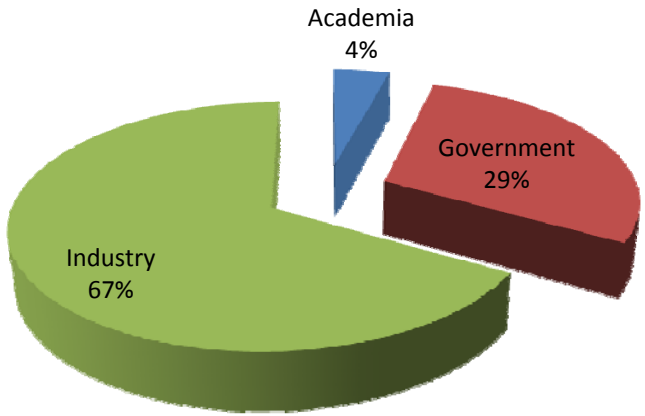


Current OMB Composition by Affiliation Type

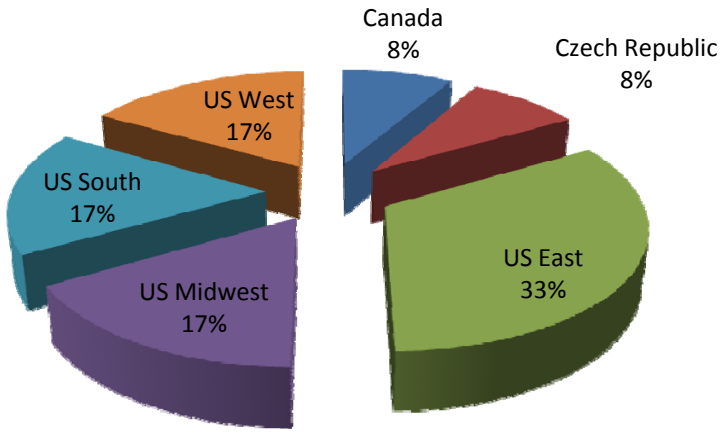


Composition of Official Methods Board

Broad Perspective

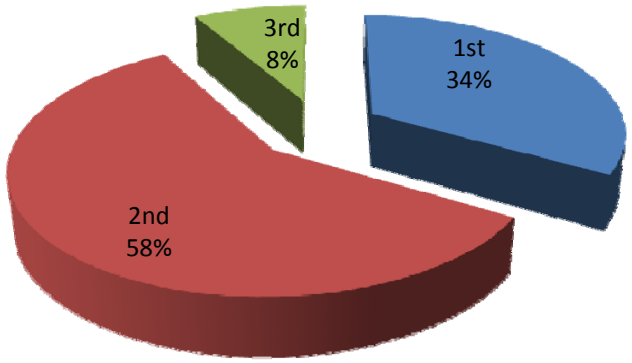


Regions

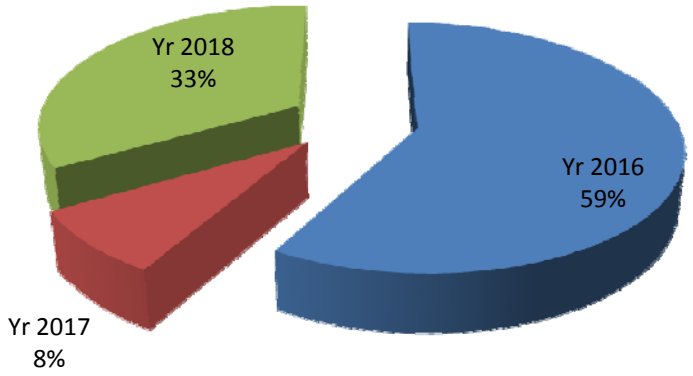


Composition of Official Methods Board

Terms Served by Current OMB



End of Term for Current OMB



AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 22, 2016

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: IIe-f. Update on Terms of Reference for Committees on Safety and Statistics

Both chairs of the Committee on Safety and the Committee on Statistics initiated the review of their committee Terms of Reference. This effort is still continuing. However, these committees operate under the guidance of the Official Methods Board. As it has been some time since the committees' Terms of Reference has been reviewed and in light of the changes in the last few years of AOAC, it would be good for OMB to consider the role of these committees and active volunteers.

RECOMMENDATION: For OMB to provide guidance to the committees on their function in an evolved.

ATTACHMENTS: Terms of Reference for each committee with comments

AOAC INTERNATIONAL

TERMS OF REFERENCE

I. NAME:

COMMITTEE ON SAFETY

II. MISSION:

To promote an awareness of safety and health matters within the AOAC membership and to give guidance in that area with particular emphasis on the integration of safety into the methods development process.

III. RESPONSIBILITIES:

To review all methods in process, as Methods Committee Safety Advisors, in order to integrate safety in methods.

To serve as a resource for AOAC membership with regard to safety matters.

submit information on laboratory safety to The Referee.

All Committee members, other than those holding *ex officio* appointments, serve at the pleasure of the President. All Committee members are expected to actively participate in the work of the Committee; including, but not limited to, promptly responding to communications, attending and actively participating in meetings, reviewing meeting background materials and agendas prior to meetings, and accepting and following through on assignments. Persons who do not actively participate will be removed from the committee by the President at the request of the chair.

IV. COMPOSITION AND ORGANIZATION:

There shall be a minimum of 5 and a maximum of 12 members, including the chair and past chair. A member shall be appointed for a three-year term, with no maximum limitation. The chair is appointed for one three-year term and may serve one additional year on the Committee as immediate past chair.

All members of the Committee are appointed by the President Elect and assume office immediately following the Annual Meeting.

The Committee shall be composed of members representing a balance of government, industry, and academia as appropriate to the scope of the

Committee. No more than one-half of the members may be from a single agency. Less than one-half of the members must be from industry.

Subcommittees, task forces, and other appropriate subgroups shall be appointed as the needs arise.

V. STAFF LIAISON:

The Executive Director shall assign a member of the staff to serve as staff liaison.

VI. REVIEW SCHEDULE:

Every three years.

VII. DATE ESTABLISHED:

1965

VIII. DATES REVISED:

8/91; 3/99; 9/99

Method Safety & Risk Assessment Guide

- Methods submitted to AOAC *Official Methods*[SM] Program are subject to undergo a risk assessment.
  - Appropriate safety instructions (in general or specific terms) must be included in the method if there is a likelihood of exposure to actual or potential hazards when using the method.

- Method authors should complete the safety checklist to assess and expose potential safety hazards. Expert review panels will review methods for safety and all potential or actual hazards must be addressed as a requirement for Final Action *Official Method*[SM] status. A safety advisor can serve a resource to address any outstanding concerns.

- The method submitter or Expert Review Panel should make every attempt to be proactive in providing the suitable wording and documentation to address the potential or actual safety hazard.

  - Safety advisors reviewing a method that lacks safety precautions and a suitable wording concerning safety should be suggested for inclusion in the text.
    - May suggest appropriate wording or require additional information.
    - Must clearly state objections if not recommending the method to move forward in the review process until the safety concerns are satisfactorily addressed.

- For methods that contain numerous hazards, the text may be best improved with a comprehensive safety statement, prominently displayed early in the method, e.g. in the materials and methods section of the text A text hyperlink such as http://www.ilpi.com/msds/ may be advantageous, as it provides the user with up-to-date pertinent safety information.

- http://www.cdc.gov/biosafety/publications/bmbl5/index.htm/ is the "Biosafety in Microbiological and Biomedical Laboratories" 2009 Manual. For microbiology methods, it describes the hazardous nature of many pathogens, together with their biosafety level requirements.

- Methods that contain a small number of specific safety hazards may best be improved with a caution in the text immediately following the first mention of the hazard.

  - For example (a modified version of some of the text below may be appropriate):
    - Use effective ventilation equipment when fumes or aerosols are generated.
    - Keep skin exposure to ultraviolet radiation to a minimum.
    - Conduct reactions behind a safety barrier. Wear face shield and gloves.
    - Wear skin, eye, and respiratory protection when handling.
    - Corrosive substance.
    - Biosafety containment level (1, 2 or 3) required with pathogen.
    - Microbiologically contaminated liquid or solid wastes should be sterilized.
    - See Appendix B of the OMA
    - See MSDS information for safety precautions.
    - See "Biosafety in Microbiological and Biomedical Laboratories" Manual (2009)

- Following revision, the method should alert the user to hazards / potential hazards in a general or specific way, whichever is considered most appropriate and effective.

Online Technical Resources

Method Development, Optimization & Validation

- OMA - Appendix F - Guidelines for Standard Method Performance Requirements
- Homogeneity
- Guide for Writing Methods in AOAC Format
- Statistics Protocol Review Form
- OMA - Appendix D: Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis
- OMA - Appendix G: Procedures and Guidelines for the Use of AOAC Voluntary Consensus Standards to Evaluate Characteristics of a Method of Analysis
- OMA - Appendix I: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Biological Threat Agent Methods and/or Procedures
- OMA - Appendix J: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces
- OMA - Appendix K: Guidelines for Dietary Supplements and Botanicals
- OMA - Appendix L: AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation
- OMA - Appendix M - Validation Procedures for Quantitative Food Allergen ELISA Methods: Community Guidance and Best Practices
- Safety Checklist

Method Review

- Examples of Statistical Analysis
- Statistics Manuscript Review Form
- OMA - Appendix A: Standard Solutions and Reference Materials
- OMA - Appendix D: Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis
- OMA - Appendix H: Probability of Detection (POD) as a Statistical Model for the Validation of Qualitative Methods

Miscellaneous

- Definition of Terms and Explanatory Notes
- OMA - Appendix B: Laboratory Safety
- OMA - Appendix E: Laboratory Quality Assurance
- OMA - Appendix C: Reference Tables

All resources are accessible at
http://www.aoac.org/vmeth/guidelines.htm

For questions, please contact:
P 301-924-7077 x157 E dmckenzie@aoac.org

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Safety Checklist Questions

- ✓ Are any materials used or compounds formed that are explosive or flammable?
- ✓ Are there any side reactions that could occur that might produce flammable or explosive products or conditions?
- ✓ Are there any hazards created from electric or mechanical equipment?
- ✓ Are pressure differentials created that could result in an explosion or implosion?
- ✓ Are any substances used or formed which are:
  - o radioactive?
  - o carcinogenic?
  - o mutagenic?
  - o tetratogenic?
  - o abortogenic:?
  - o otherwise a significant health hazard?
- ✓ Would there be increased hazards if the reaction temperature were increased even modestly?
- ✓ Are special procedures required if a spill of the reaction mixture occurs?
- ✓ Is there a risk in producing a dangerous aerosol?
- ✓ Are special procedures required for the disposal of reagents or reaction products?
- ✓ Are there any organisms and/or their products used/present that are:
  - o Pathogenic?
  - o allergenic?
  - o carcinogenic?
  - o mutagenic?
  - o tetratogenic?
  - o otherwise a significant health hazard?
- ✓ Are there any potential hazards in handling or storage of reagents, test samples, or standards?
- ✓ Are there any other hazards that should be addressed regarding the method?
- ✓ Does your method use chlorinated solvents?
- ✓ If "yes" to question13, have non-chlorinated solvents equivalent to chlorinated solvents been investigated?
- ✓ Include appropriate precautionary statements in method write-up.
- ✓ Provide specific information on hazard (MSDS or other supporting documentation)

Online Safety Resources

Useful source information concerning safety hazards is available in:

- Official Methods of Analysis of AOAC INTERNATIONAL Appendix B: http://www.eoma.aoac.org
- US Department of Labor / Occupational Health and Safety Administration (OSHA): http://www.osha.gov/web/dep/chemicaldata/default.asp
- American Chemical Society / Chemical Abstracts Service: http://www.cas.org/
- MSDS Solutions Centre MSDS online : http://www.ilpi.com/msds/ http://www.ilpi.com/msds/#Manufacturers http://www.msds.com/
- Biosafety information: http://www.cdc.gov/biosafety/publications/bmbl5/index.htm/
- Public Health Agency of Canada MSDS for pathogens: http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php
- IATA transportation information for hazardous materials http://www.iata.org/whatwedo/cargo/dangerous_goods/Pages/index.aspx

Examples of Caution Statements

For example (a modified version of the text given below may be appropriate):

Caution - This procedure uses substances that are neurotoxic, corrosive and hazardous. Care should be taken to avoid ingestion or contact with the skin. Laboratory personnel should follow normal laboratory safety precautions and have ready access to the material safety data sheets (MSDS, http://www.ilpi.com/msds/) for all hazardous substances used in the test procedure, should work in a well ventilated environment and be provided with appropriate safety protection including clothing, protective gloves and appropriate eye protection (http://www.eoma.aoac.org).

Caution - This procedure uses / detects pathogenic microorganisms and / or their metabolic products. Care should be taken to avoid ingestion, inhalation of potentially infectious aerosols, or contact with the skin. Laboratory personnel should follow normal laboratory safety precautions and have ready access to the appropriate material safety data sheets (MSDS, http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php) should use the appropriate biosafety containment (http://www.cdc.gov/biosafety/publications/bmbl5/index.htm/) and be provided with appropriate safety protection including clothing, protective gloves and appropriate eye protection http://www.eoma.aoac.org.

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AOAC INTERNATIONAL
TERMS OF REFERENCE

Committee on Statistics

The AOAC Committee on Statistics develops and recommends harmonized statistical guidelines for the AOAC *Official Methods* Program and encourages greater use of standardized statistical techniques. The committee ~~advised~~ advises the Official Methods Board and Methods Committees on statistical matters concerning collaborative study design and criteria for approval.

There shall be a minimum of 5 and a maximum of 12 members, including the chair and past chair.

Members of the Committee on Statistics should be consulted and included at any point in the method validation and collaboration process as requested by any AOAC groups.

Members of the Committee on Statistics can be voting members of the Methods Committee provided they are not statistics members for that method.

Duties and Responsibilities of Committee on Statistics Members:

a. Statistically evaluate interlaboratory study design, results, and respond to questions and concerns in a timely manner.
b. Serve as advisor to Methods Committees by giving comments and advice to Methods Committee on statistical matters, in particular, the precision and accuracy parameters of interlaboratory studies.
c. Participate as non-voting participants on committee conference calls.
d. Provide statistical review of protocols and collaborative studies submitted to the Methods Committee.
e. Propose updates to Appendix D in the OMA and Appendix X in the Program Manual as needed.
f. Work with Study Directors and potential Study Directors in designing interlaboratory studies, preparing reporting work sheets, and using correct statistical procedures.
g. Committee on Statistics chair serves as a member of the Official Methods Board.

Criteria for Serving as a Committee on Statistics Member:

a. Should be a member of AOAC INTERNATIONAL.
b. Must have a letter of support from the sponsoring organization.
c. Must have an executed AOAC Volunteer Acceptance Form.
d. Documented formal training in statistics.

Comment [DM1]: AOAC has transitioned and this function is no longer primary

Comment [DM2]: No more method committees

Comment [DM3]: This needs to be modified to facililtate better management of committee activities

Comment [DM4]: Not relevant any more and ERP member has served as both a committee member and statistical advisor

Comment [DM5]: Limited to RI method studies only

Comment [DM6]: No more method committees; ERPs approve methods now

Comment [DM7]: No more method committees. See previous comment.

Comment [DM8]: Scope can be broaden to include working groups and SMPRs beyond the scope of method validation

Comment [DM9]: Not relevant any more

Comment [DM10]: Needs to be revised

Comment [DM11]: Needs to be revised

Comment [DM12]: Method authors. Study director is no longer an AOAC volunteer term

e. Must be familiar with OMA Appendix D, Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis and Appendix X, Method Committee Guidelines for Validation of Qualitative and Quantitative Food Microbiological Official Methods of Analysis.

f. Must have successfully completed training from the AOAC Committee on Statistics to ensure the member is able to perform adequate statistical reviews of AOAC pre-collaborative/collaborative studies with appropriate refresher training.

Comment [DM13]: Probably should be reconsidered. Familiarity with these documents are fine; however, there are revisions and new documents that should be included.

Comment [DM14]: Training may need to be revised based on agreed upon duties

Process for Appointing a Member of the Committee on Statistics

Comment [DM15]: Language can be simplified

If members are needed on the Committee on Statistics, the general membership is solicited. Interested parities are asked to submit letters of interest addressing the criteria, resumes/CVs, and a letter of support from their sponsoring organization when applicable, to the AOAC staff. These letters are forwarded to the chair of the Committee on Statistics.

The Committee on Statistics chair recommends members to the OMB chair. Upon agreement by the OMB, the OMB chair requests that the President send a letter of appointment to the Committee on Statistics candidate selected. Copies of the letter will be sent to Committee on Statistics chair and the candidate's supervisor. The appointment is generally for a three-year term unless otherwise recommended by the Committee on Statistics chair.

The President sends a thank you letter and a Certificate of Appreciation to the Committee member, with copies sent to the Committee chair and OMB chair at the conclusion of a Committee appointment. Letters are also sent if a Committee member resigns his/her appointment because of retirement, changes in employment responsibilities, removal, or if he/she becomes unable to carry out the duties of a Committee member.

Process for Removing a Member of the Committee on Statistics

Comment [DM16]: Language can be simplified.

If a member of the Committee is not performing the duties appropriately; the Committee chair will recommend replacement of the member to the OMB chair. The OMB chair will bring the matter before the OMB for discussion and a vote. It will take at least two-thirds of the OMB to remove a Committee member. Upon a determination by the OMB to remove a Committee member, the OMB chair will notify the President.

Upon removal, a thank you letter from the President is sent to the Committee member, with copies sent to the Committee chair and the Official Methods Board Chair.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 22, 2016

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: IIg. Update on OMB Working Group on Terms of Reference

The working group consisting of Shauna Roman and Erin Crowley along with Delia Boyd and Deborah McKenzie met on Wednesday, May 11, 2016. In reviewing the OMB's Terms of Reference (ToR), the group agreed that there were some minor editorial changes that could be made; however, the changes are not significant enough to warrant review and approval by the AOAC INTERNATIONAL Board of Directors at this time.

After all the OMB working groups meet and revise their documentation, this working group will reconvene and assess again if any addition revisions should be made to the OMB ToR and bring it forward to the entire OMB.

The Scientific Association Dedicated to Analytical Excellence®

AOAC INTERNATIONAL

TERMS OF REFERENCE

I. NAME:

OFFICIAL METHODS BOARD (OMB)

II. MISSION:

To serve the Association in a scientific and advisory capacity on standards and methods with ethical, timely, open and independent scientific oversight for the implementation of standards development and conformity assessment policies and procedures of AOAC INTERNATIONAL.

III. RESPONSIBILITIES:

To provide ethical, timely, open and independent scientific oversight for the policies and procedures of AOAC INTERNATIONAL.

To approve "Final Action" status for First Action Methods (new and revised) following a proactive review;

To repeal methods, if necessary, in accordance with established policies and procedures;

To participate in addressing appeals and requests for action or guidance, and in resolving disputes;

To endorse and monitor all voluntary consensus panels for appropriate representation and balance of stakeholders' perspectives;

To endorse and monitor all volunteer subject matter experts for volunteer conformity assessment activities;

To adopt and monitor scientific and technical guidance and references;

To acknowledge outstanding scientific and technical volunteer activity and achievement within AOAC;

To actively participate in AOAC standards development activities and maintain and communicate explicit knowledge of AOAC standards development and conformity assessment;

IV. COMPOSITION AND ORGANIZATION:

The Official Methods Board shall consist of up to 13 voting members including a Chair, a Vice-chair, the Chair of the Committee on Safety and the Chair of the Committee on Statistics. The Committee on Safety and the Committee on Statistics may contain co-chairs. The co-chairs for these committees represent one vote on the OMB. Members of the OMB may serve in multiple volunteer roles for the benefit of the Association. The Chair of the Official Methods Board shall have previously served as a member of the Official Methods Board. The Chair, Vice-chair, and members of the Official Methods Board including the chairs of standing committees shall be appointed for a term of three years. A member of the OMB may be reappointed upon the recommendation of the Chair of the Official Methods Board with a maximum term of service of six (6) years. Exceptions may be made at the discretion of the President. The Chair of the Official Methods Board is eligible to serve an additional post chair term of up to three (3) years as an *ex-officio* member. Members of the Official Methods Board must be members of AOAC.

All members of the Official Methods Board are recommended by the Chair and appointed by the President. All Official Methods Board members serve at the pleasure of the President.

The Official Methods Board represents the membership of AOAC INTERNATIONAL. It shall be composed of members representing a balance of scientific expertise, government, industry, and academia as appropriate to the scope of the Board. Every effort should be made to include international representation on the Board.

Additional working groups, task forces, and other appropriate subgroups shall be appointed as needs arise by the Chair of the Official Methods Board.

V. STAFF LIAISON:

The Executive Director shall assign a member of the staff to serve as staff liaison.

VI. REVIEW SCHEDULE:

Every three years.

VII. DATE ESTABLISHED:

Renamed in 1981

VIII. DATES REVIEWED

01/08,

IX. DATES REVISED:

9/89; 5/90; 1/91; 8/06;
02/07; 07/07; 2/08; 4/13; 8/13

AOAC INTERNATIONAL
The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **June 22, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **IIIa. ERP for SPDS Aloin, Cinnamon and Tea**

AOAC issued a call for methods for Aloin and Tea. AOAC also extended the call for methods for Cinnamon. As a result, five methods have been received. In the meantime, AOAC issued a call for experts in anticipation of forming an expert review panel to review methods for these ingredients.

Please find attached the list of candidates along with their CVs and information on the proposed ERP. Brian Schaneberg of Starbucks is proposed to be the chair of this ERP. The meeting is tentatively scheduled for August 2, 2016.

RECOMMENDATION: For OMB to vet ERP for SPDS Aloin, Cinnamon, and Tea.

ATTACHMENTS: ERP Candidate Package

Stakeholder Panel on Dietary Supplements

Expert Review Panel for SPDS Ingredients:

Aloin, Cinnamon, Tea and Vitamin D

PROPOSED CANDIDATES

Expected to Convene:
August, 2016
AOAC INTERNATIONAL HEADQUARTERS
Rockville, Maryland

AOAC INTERNATIONAL
2275 Research Blvd, Suite 300
Rockville, Maryland 20850
Phone: (301) 924-7077

Stakeholder Panel on Dietary Supplements
Expert Review Panel for Set 3 Ingredients

TABLE OF CONTENTS

I. LIST OF METHODS 3

II. PROPOSED EXPERT REVIEW PANEL ROSTER AND PERSPECTIVES 4

III. SUMMARIES OF EXPERTISE and CVs 5

AOAC INTERNATIONAL: Expert Review Panel for SPDS Ingredients: Aloin, Cinnamon, Tea and *Vitamin D*

LIST OF METHODS:

- ALN-01: Determination of Aloin A and Aloin B in Aloe vera Raw Materials and Finished Products by High-Performance Liquid Chromatography: Single-Laboratory Validation
  - Author(s): Paula N. Brown, Ronan Yu, Chiow Hui Kuan, Jamie Finley, Elizabeth M. Mudge, Seven Dentali
  - Submitted by: Elizabeth Mudge, BCIT

- CIN-01: Identification of Selected Cinnamomum spp. Bark in Dietary Supplement Raw Materials and/or Finished Products, Gas Chromatography with Flame Ionization Detection After Hydrodistillation
  - Author(s): Myron Sasser, Gary Jackoway, Craig Kunitsky
  - Submitted by: Craig Kunitsky, MIDI, Inc.

- TEA-01: Analysis of Theanine in Tea (Camellia sinensis) Dietary Ingredients and Supplements by High-Performance Liquid Chromatography with Post-Column Derivatization: Single Laboratory Validation
  - Author(s): Maria Ofitserova, Sareeta Nerkar
  - Submitted by: Maria Ofitserova, Pickering Laboratories

- TEA-02: Determination of Catechins and Caffeine in Camilla sinensis Raw Materials, Extracts, and Dietary Supplements by HPLC-UV: Single-Laboratory Validation
  - Author(s): Mark C. Roman, Jana Hildreth, Silvia Bannister
  - Submitted by: Jana Hildreth, Synutra Pure

Note: As of 5/25/2016, no Vitamin D methods have been submitted.

Proposed ERP Rosters

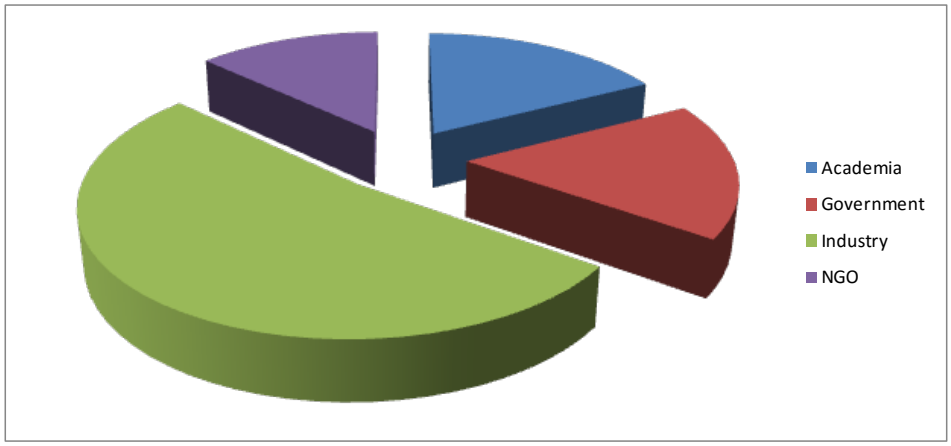
Chair: Brian Schaneberg, Starbucks			
Aloin	Cinnamon	Tea	Vitamin D
1. Nour Eddine Es-Safi, Mohammed V University, Rabat	1. Premal Bhatt, USP	1. Nour Eddine Es-Safi, Mohammed V University, Rabat	Nour Eddine Es-Safi, Mohammed V University, Rabat
2. Quanyin Gao, Herbalife	2. Nour Eddine Es-Safi, Mohammed V University, Rabat	2. Tetsuhisa Goto, Shinshu Univ. (Retired)	April Hall, GNC
3. Holly Johnson, Alkemist Labs	3. Milda Embuscado, McCormick	3. Martha Jennens, Covance	Martha Jennens, Covance
4. Philip Koerner, Phenomenex	4. John Finley, LSU (Retired)	4. Holly Johnson, Alkemist	Philip Koerner, Phenomenex
5. Jasen Lavoie, Pharmachem Labs	5. Martha Jennens, Covance	5. Philip Koerner, Phenomenex	Palma Ann Marone, Virginia Commonwealth University
6. Palma Ann Marone, Virginia Commonwealth University	6. Cuiying (Macy) Ma, USP	6. Palma Ann Marone, Virginia Commonwealth University	Melissa Phillips, NIST
7. Charles Metcalfe, Custom Analytics	7. Tom Phillips, SCS MDA	7. Melissa Phillips, NIST	Tom Phillips, SCS MDA
8. Tom Phillips, SCS MDA	8. Darryl Sullivan, Covance	8. Tom Phillips, SCS MDA	Justin Ringling, Pfizer
9. Klaus Reif, PhytoLab GmbH & Co.	9. Yanjun Zhang, Herbalife	9. Klaus Reif, PhytoLab GmbH & Co.	Darryl Sullivan, Covance
10. Jianming Tao, Spextrix Analytical Services	10. Joseph Zhou, Sunshineville Health Products	10. Aniko Solyom, GAAS Analytical	Dan-Hui Dorothy Yang, Agilent
11. Marina Torres, LABORATORIO TECNOLOGICO DEL URUGUAY[1]		11. Darryl Sullivan, Covance	Jinchaun Yang, Waters
12. Aniko Solyom, GAAS Analytical		12. Dan-Hui Dorothy Yang, Agilent	Seong-Jae Yoo, USP
13. Darryl Sullivan, Covance		13. Jinchaun Yang, Waters	Yang Zhou, Eurofins
14. Yanjun Zhang, Herbalife		14. Kurt Young, GNC	
		15. Yanjin Zhang, Herbalife	

[1] Unable to attend August ERP meeting

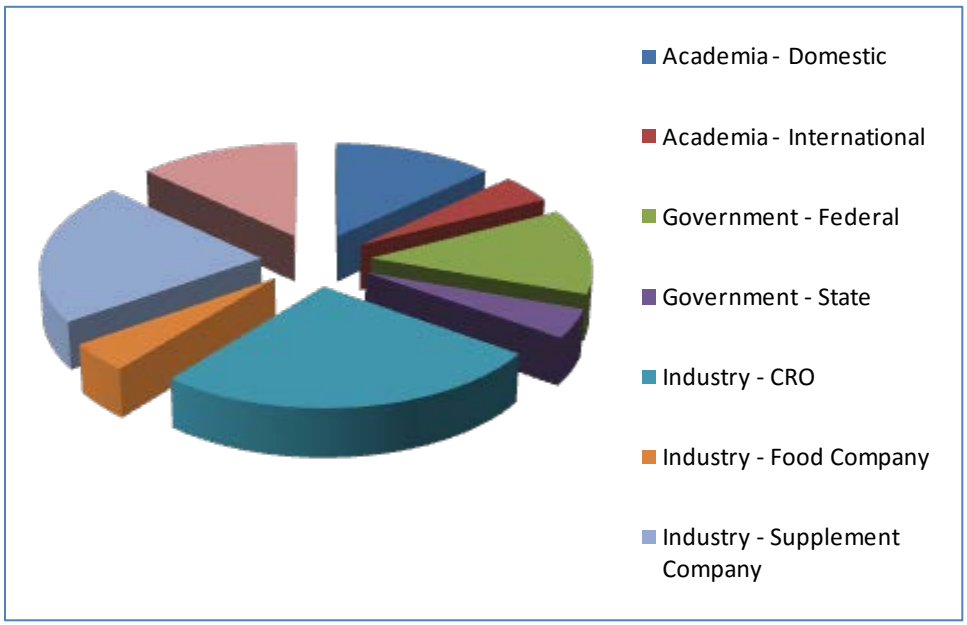
All Applicants

First	Last	State	Country	Organization
Premal	Bhatt	Maryland	USA	USP
Milda	Embuscado	Maryland	USA	McCormick
Nour Eddine	ES-SAFI	n/a	Morocco	Mohammed V University in Rabat
john	Finley	Louisiana	USA	LSU (Retired)
Quanyin	Gao	California	USA	Herbalife
Tetsuhisa	Goto	n/a	Japan	Retiered, Shinshu Univ.
Martha	Jennens	Wisconsin	USA	Covance
Holly	Johnson	California	USA	Alkemist Labs
Philip	Koerner	California	USA	Phenomenex
Jasen	Lavoie	Utah	USA	Pharmachem Labs
Cuiying (Macy)	Ma	Maryland	USA	USP
Palma Ann	Marone	Virginia	USA	Virginia Commonwealth University
Charles	Metcalfe	South Carolina	USA	Custom Analytics
Melissa	Phillips	Maryland	USA	NIST
Tom	Phillips	Maryland	USA	SCS MDA
Klaus	Reif	n/a	Germany	PhytoLab GmbH & Co. KG
Aniko	Solyom	Arizona	USA	GAAS Analytical
darryl	Sullivan	Wisconsin	USA	covance
Jianming	Tao	Connecticut	USA	Spectrix Analytical Services, LLC
Marina	Torres		Uruguay	LABORATORIO TECNOLOGICO DEL URUGUAY
Dan-Hui (Dorothy)	Yang	California	USA	Agilent Technologies, Inc.
Jinchuan	Yang	Massachusetts	USA	Waters
Kurt	Young	South Carolina	USA	GNC/Nutra Manufacturing
Yanjun	Zhang	California	USA	Herbalife
Yang	Zhou	Iowa	USA	Eurofins Scientific Inc.
Joseph	Zhou	California	USA	Sunshineville Health Products, Inc

Major Perspectives



Specific Perspectives



AOAC Expert Review Panel for AOAC Stakeholder Panel on Dietary Supplements (SPDS) Set 3 Ingredients
Summaries of Expertise

BHATT, PREMAL

Area of Expertise: Varied

Premal is an Associate Scientific Liaison for the Food Program Unit at US Pharmacopeial Convention (USP) since 2011. Previously, he worked as a Scientist II for USP's R&D Laboratory from 2005 to 2011.

As a Scientific Liaison-Foods, Premal is engaged in developing standards for identity, purity, and authenticity of food components. One of the areas of Premal's interest is developing such standards for various spices.

Premal has a background in analytical chemistry with more than 25 years of experience in various laboratory settings, such as pharmaceutical, chemical, and waste management. Premal holds two Master of Science degrees in Plant Pathology; one from Kansas State University and one from Gujarat Agricultural University, Anand, India. Premal has authored ten research papers in peer-reviewed journals.

FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/320740221947628159/P. Bhatt.Resume.pdf

EMBUSCADO, MILDA

Area of Expertise: Cinnamon

Dr. Milda Embuscado, currently a Senior Principal Scientist at the Materials and Process Technology, Applied Research at McCormick & Co., Inc., Hunt Valley, Maryland, obtained her Ph. D. from Purdue University, West Lafayette, IN and worked as a Research Scientist at the Whistler Center for Carbohydrate Research, a world renowned carbohydrate research institute. Her areas of research include ingredient characterization and functionality, new product innovation, process improvement and flavor/bioactive microencapsulation including optimization of formulations and processes through the employment of design of experiment and response surface methodology to optimize ingredient functionality in food systems such as food emulsion and flavor/bioactive encapsulated products. Her research also includes bioactives and antioxidants from spices and herbs and the effects of processing and cooking on these bioactive components; and the effects of spice/herb extracts on altering digestion of starches. She has given invited presentations to the Institute of Food Technologist (IFT)and has edited and authored books on Functionalizing carbohydrates for food applications: Texturizing and bioactive/flavor delivery systems and on Edible films and coatings for food applications, a best seller book in its category. She also authored several refereed scientific articles on carbohydrates and food bioactives. She was the chairman of the IFT Nutraceuticals and Functional Foods Division (2012-13) and the CarbohydrateDivision (2006-07). She was elected a full member to the following honor societies: Sigma Xi (The Scientific Research Society), Phi Tau Sigma (The Honor Society of Food Science and Technology) and Gamma Sigma Delta (The Honor Society of Agriculture). She is a professional member of the IFT and a Certified Food Scientist (April 1, 2013) awarded by the International Food Science Certification Commission and a member of the inaugural class.

FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/320829664381101461/Milda Embuscado-CV.docx

ES SAFI, NOUR EDDINE

Area of Expertise: Technologies for Analyzing Ingredients

In connection with the question about my expertise appropriate to the ERP under formation, I am hereby stating that my expertise is with the technologies and the methods used for the detection, the qualitative and the quantitative analysis of the ingredients.

FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/327153304632666744/CV_EsSafi-11-15.pdf

FINLEY, JOHN

Area of Expertise: Antioxidant Methods

Historically I have organized two international symposia on antioxidant methods. I also have spoken several times at ACS and IFT concerning antioxidant methods. Perhaps most important on the Folin-C issue, I led the development of

the SPDS Folin-C Working Group and request for methods proposal for AOAC.
FULL CV: http://www.jotform.com/uploads/christopherdent/51735966869173/318047971181188068/Finley Biosketch 2014 .doc

GAO, QUANYIN
More than 20 years experience in laboratory operation and management for pharmaceuticals, dietary supplement, and food product testing. Lab system establishment for cGMP compliance for 21CFR part 111, 114, 110, and 211. Botanical identification program committee member of Herbalife. Authored a book chapter for method development and validation.
FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/336208805828909632/CVGao.doc

GOTO, TETSUHISA
Area of Expertise: Tea
I developed and published a green tea catechine analysis method on J. Cromatogr. 749, (1-2), 295-299(1996). Also I served head of Tea Chemistry Lab in a National Institute in Japan 4.5 years(1990-94). Since that I always interested in tea chemistry.
FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/327175882612530962/Short CV(2015.09.17).doc

JENNENS, MARTHA
Area of Expertise: Dietary Supplements and Testing
During my time at Covance I have had the opportunity to work in a group that does a large amount of testing on dietary supplements. This has provided me with hands on experience in testing various analytes, including, catechins, vitamins and polyphenols among many others. I was also tasked with improving our existing methodology as well as run client provided methods. This has given me a greater depth of understanding for analytes and testing methods as well as challenges that arise during the testing process.
FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/337592238101869472/MCJ.2.doc

JOHNSON, HOLLY
My lab does potency testing of botanicals, extracts, ingredients, and finished supplements every day. We run the USP method for Aloin in aloe. I hold a B.S. in Botany and took a Ph.D. in Pharmacognosy with Norman Farnsworth in one of the first NIH Centers for Botanical Dietary Supplements. I have done analytical method development and validations for many years specializing in methods for quantification of low concentration analytes in complex matrices such as botanicals and finished product supplements. I have 18 years experience in natural products chemistry and spent many happy years conducting research on medicinal plants and giving courses at the University of Hawaii. I also worked for Waters Corporation conducting technical training and consulting for pharmaceutical and supplements companies and am a Research Associate with the National Tropical Botanical Garden. As Laboratory Director at Alkemist Labs I oversee scientific operations and quality to ensure delivery of the highest quality testing services while providing transparency and confidence to our clients in the natural products industry. We use standard and compendial methods routinely; I am happy to contribute to establishing much needed standard methods for dietary supplements.
FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/335887238091524847/HEJohnson_CV_Jan16.pdf

KOERNER, PHILIP
I am an analytical chemist with over 27 years of experience in HPLC, GC and SPE. I have a BS degree in chemistry from the University of California, Irvine, and MS and PhD degrees in analytical chemistry from the University of Illinois, Urbana-Champaign. I am currently employed by Phenomenex, the leading global provider of HPLC products where I hold the position of Senior Technical Manager. I have extensive experience in the application of liquid chromatography and sample preparation in the fields of food safety, food quality, clinical toxicology, pharmaceuticals and environmental.

I have had the distinct privilege of serving on the AOAC Expert Review Panel for the Set 2 SPDS ingredients (anthocyanins, chondroitin and PDE5 inhibitors). I believe that my strong background in separation science allowed me to make a positive contribution to the method review process since most of the submitted methods were chromatography based. In addition, my practical experience in chromatography allowed me to critically evaluate methods that are intended for use in a working analytical laboratory, rather than in an academic setting.

I have reviewed the SMPRs for the Set 3 SPDS ingredients (aloin, tea and vitamin D) and again observe that the

majority of the methods submitted will likely be based upon some form of liquid chromatography and/or solid phase extraction. In addition, I have had direct experience with the chromatographic behavior of the specific molecular species (or closely related species) cited in the Group 3 SMPRs. Therefore, I believe that I will be able to make a positive contribution to the scientific evaluation for these method submissions as well.
FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/329319887371181577/Phil Koerner Resume_2016.DOC

LAVOIE, JASEN
Area of Expertise: Aloe Vera
I have been working in the supplement industry for over 23 years, and aloe vera industry for over 16 years. My training is in chemistry, and have applied to R&D, Quality, and Regulatory positions.
Currently, I am in charge of technical aspects of aloe vera production. I oversee R&D, Quality, and Regulatory aspects of the operation.
FULL CV: https://www.jotform.us/uploads/christopherdent/51735966869173/338719929851198010/jasen%20c.v..docx

MA, CUIYING (Macy)

FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/320838002947923719/Ma_Cuiying-10-16-2015.doc

MARONE, PALMA ANN
Area of Expertise: Aloin and Tea
Dr. Marone is a European board-certified toxicologist and Fellow of the American College of Nutrition responsible for direct technical oversight, program/project development and lead.
FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/334474663241549777/PAMarone 2016.pdf

METCALFE, CHARLES
Area of Expertise: Aloin
I am on the IASC (International Aloe Science Council) board and also on their Technical Committee (have been for the last 10 years). We have been assaying aloin for over 10 years for various aloe raw materials and finished products.
FULL CV: http://www.jotform.com/uploads/christopherdent/51735966869173/319343104296175371/CEM Resume.doc

PHILLIPS, MELISSA
Area of Expertise: Various methodologies
I have several years experience in analysis of polyphenols and vitamins in foods and dietary supplements, as well as preparation and characterization of reference materials. In addition, I have experience in evaluation of methods through the ERP process, with thoughtful and critical comparison of methods to the SMPR**.**
FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/334119816491152840/Phillips CV.docx

PHILLIPS, TOM
Area of Expertise: Various Methodologies
I have experience with analyzing tea, vitamin D and cinnamon, both as pure products and in combination with other ingredients. I am well versed in the techniques used to analyze the above, i.e., LC-PDA, LC-MS/MS, GC-FID, GC-MS, GC-MS/MS. I have quite a bit of experience in the ERP process, as well.
FULL CV: http://www.jotform.com/uploads/christopherdent/51735966869173/320642535762514400/resumechemist.doc

REIF, KLAUS
25 years experience in the Analysis of Herbal Products with chromatographic techniques. PhytoLab has established Routine procedures for these types of samples.
FULL CV:

SOLYOM, ANIKO
I have more than 30 years of comprehensive experience in analytical method development and validation, using a wide variety of analytical techniques. My expertise is in development and validation of analytical methods with particular emphasis on HPLC, LC-MS applications and bioactivity guided preparative separation of complex mixtures and analysis of biological samples and dietary supplements. In addition to HPLC technique I have significant

experience with atomic absorption spectroscopy (AA), inductively coupled plasma emission spectroscopy (ICP), photoacoustic spectroscopy (PA), UV-Vis spectroscopy, elemental analysis, mass spectrometry (MS), gas chromatography (GC), GC-MS, LC-MS, NMR and wet techniques.
Before founding GAAS Corporation/GAAS Analytical, I served as director of the Analytical Core at an NIH funded Botanical Center (Arizona Center for Phytomedicine Research). The Facility focused on quantitation and identification of natural products and dietary supplements, particularly anti-inflammatory compounds from turmeric, ginger and boswellia. I developed methods to analyze these compounds from the plant materials, extracts, commercially available dietary supplements and from different biological matrices. I also developed and validated new assay methods according to cGLP regulations, to quantify novel cancer drugs in plasma and urine using QQQ LC/MS technique; identifying metabolites of new cancer drugs in plasma and urine using TOF LC/MS technique and calculating pharmacokinetic parameters.
I am an active member of AOAC International; I joined the organization in 2002. Currently I am member of AOAC's Stakeholder Panel on Dietary Supplements and member of various working groups. I have participated in multiple AOAC organized collaborative studies (glucosamine, ginkgo, saw palmetto) in order to validate analytical methods to be used by the dietary supplement industry. I was Horwitz advisor of AOAC until the restructuring the Official Methods of Analysis (OMA) process in January 2008, when the role of method advisors and Horwitz advisors was retired. For 5 years I have been serving as member of the Presidential Task Force on Dietary Supplements of AOAC, and also served as member of Expert Review Panels of AOAC. I was selected in June 2015 to serve a 5 year term as the member of USP's Non-botanical Dietary Supplements Expert Committee.
FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/328025585213558829/Curriculum_vitae_Aniko Solyom_Jan.2016.pdf

SULLIVAN, DARRYL

Darryl Sullivan is a Fellow of AOAC and has been an active member since 1980. He has served terms as secretary, president-elect, president, past president, and director of the Board of Directors, and previously served a three-year term as chair of the Official Methods Board, and is currently serving as Chair of the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals. In 2012 Darryl lead a very successful AOAC engagement with government and industry thought leaders in India and China on behalf of SPIFAN. He is also active with the Stakeholder Panel for Strategic Food Analytical Methods and the Stakeholder Panel for Agent Detection Assays. Sullivan also served a three-year term as a director on the AOAC Research Institute Board of Directors. He was a founding member and chair of the Presidential Task Force on Dietary Supplements and a member of the Task Force on Bacillus anthracis, as well as the AOAC Task Force on Nutrition Labeling and the AOAC Task Force on Sulfites. Prior to chairing the OMB, he served as a member and chair of the Methods Committee on Commodity Foods and Commodity Products. Sullivan was a founding member of the AOAC Technical Division on Reference Materials and served three terms on the Division's Executive Board. A staunch supporter of the Association, Sullivan was active in the e-CAM and Scholar I projects at AOAC, has exhibited at the annual meetings for many years, has presented hundreds of papers and posters at AOAC meetings and regularly publishes his research in the journal of the AOAC. He has also presented a significant number of papers on behalf of AOAC at other scientific meetings in many different parts of the world.
FULL CV: http://www.jotform.com/uploads/christopherdent/51735966869173/322906973781589371/Sullivan, Darryl CV.pdf

TAO, JIANMING

Expertise in: analytical HPLC and LCMS analysis… GCMS analysis… ICPMS analysis… microbiological examinations… cell / tissue culture… DNA / RNA isolation… immunoprecipitation… northern and western blot… expression vector construction… oligonucleotide primer design… DNA sequencing… DNA transformation and transfection… PCR and quantitative RT-PCR… in vitro cytotoxicity and genotoxicity studies under compliance of GLP…SOP writing…Routinely analyze aloe anthraquinones in aloe vera products from customers using HPLC and UPLC-MS.
FULL CV:
https://www.jotform.com/uploads/christopherdent/51735966869173/335266406442476546/TAO_Jianming_MAR2016.doc

TORRES, MARINA

I have been working in chromatography analysis for more than 20 years using LC and GC with many detectors, including MSMS detectors. I work developing and validating chromatography methods. My expertise is mostly in nutrients, additives and pesticide residues in food. I work in environmental, non food and dietary supplements samples too. I am interested in this ERP because I am working now in Aloin in dietary supplements.
FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/330433484631758258/curriculum ingles febrero 2016 enviado para ERP SPDS.rtf

YANG, DAN-HUI (Dorothy)

I have been working on food safety and environment testing for the past 5 years, mainly taking the advantage of Mass Spec technology advancements. For every application, we need to demonstrate the analytical performance -- precision, accuracy, sensitivity etc. Before that, I worked for Agilent clinical program, where we developed reagents and assay protocol, conduct multi-site validation and clinical trial. I would love to apply my analytical experience and serve in expert review panel. I am currently a reviewer for American Chemical Society publications on demand basis.
FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/335280804082920215/CV4dhy_AOAC-2016.doc

YANG, JINCHUAN

Jinchuan Yang has 14 years of experience in the analysis of food nutrients, food contaminants, environmental contaminants, and industrial chemicals, such as vitamins, lipids, pesticide residues, polymers, and polymer additives. The techniques that Jinchuan has extensive knowledge include UPLC, UPC2 (or SFC), SEC (or GPC), MS (single quadruple, triple quadruple, time of flight, MALDI), viscometer, laser light scattering detector(small angle and multi-angle), evaporate light scattering detector, and other common LC optical detectors.
FULL CV: https://www.jotform.com/uploads/christopherdent/51735966869173/334662843252771941/JYang Resume 2016.docx

YOUNG, KURT

Area of Expertise: Method development and analysis

For greater than 15 years at a major supplement manufacturing facility I have:
Overseen method development, quality specification confirmation and identity testing with Ashwaganda (Withania somnifera) extract and powdered herb incoming raw materials and finished products. Interacted with major suppliers of standardized extracts and powdered herb material to determine best methodology to support product development and quality control testing.
FULL CV: http://www.jotform.com/uploads/christopherdent/51735966869173/320148913132890861/KYoung_CV.docx

ZHANG, YANJUN

Area of Expertise: methodologies and dietary supplements

Yanjun Zhang, has been trained in a Pharmacy School 30 years ago (1985) and has been working in the field of botanical natural product analysis since then, including natural products isolation, structure determination, quantitative and qualitative analysis of natural products, new drug development from Herbal medicine, etc. I have been using and guiding to use numerous analytical instruments and techniques, such as HPLC, LC-MS, GC, GC MS, NMR, NIR, and HPTLC etc. The natural products I've been studied include flavonoids, alkaloids, terpenoids, lignans, saponions, essential oils, sugars, organic acids, fatty acids, and polysacchrides etc. Currently I guide establish the Qualitative and Quantitative analytical method in Herbalife Quality group for internal use. With all the expertise mentioned above, I believe I can make great contribution to the review panel, and most important I want to contribute my expertise on the biological botanical natural products analysis to the AOAC Expert Review Panel for Dietary Supplement Ingredients.

FULL CV: http://www.jotform.com/uploads/christopherdent/51735966869173/320666720739751921/YANJUN ZHANG CV 2014.pdf

ZHOU, JOSEPH

Area of Expertise: dietary supplements and method development

I am currently the technical director of Sunshineville Health Products, Inc, a dietary supplement manufacturer in state of West Virginia. I have been working in the US dietary supplement industry since 1995, and was a technical director of NOW Foods and Nature's Sunshine Products, respectively, in charge of dietary supplement analytical methods development, GMP and quality control. I have been actively participating in the AOAC dietary supplement official method program since 2000. I was the AOAC study director and SLV coordinator of the glucosamine method, and one of the SLV coordinators for the chondroitin method, as well as an ERP member for many AOAC methods. I received a special recognition: AOAC 2005 study director of the year.

I am willing to continue to make my contribution to the AOAC official method program for dietary supplements, and believe I have the technical capability to be an ERP member for many dietary supplement analytical methods.

FULL CV: http://www.jotform.com/uploads/christopherdent/51735966869173/320648427679132288/Joseph Zhou CV.pdf

ZHOU, YANG

Area of Expertise: nutritional analysis and method development

I have total 15 years research experience in nutrition analysis and current lead the method development for vitamins, enzymes, and authenticity etc. at Eurofins Nutrition Analysis Center. I developed Vitamin D LC-MSMS method for Eurofins (ENAC) and oversees its performance on all matrices samples we tested. I am a participant of SPIFAN Vitamin D MLT in 2014.

PREMAL BHATT

18465 Crownsgate Circle
Germantown, MD 20874
☎ (205) 586-7079
premalbhatt@outlook.com

Scientific Liaison

Accomplished, skilled professional offers extensive, progressive experience with leading food, pharmaceutical, chemical, and environmental organizations for a position in scientific relationship management, project coordination, and quality assurance.

Skill Set

- Experienced in working with protocols for: Food Chemical Codex (FCC), USP, ICH, EPA, ASTM, and QA/QC.
- Represent organizations at scientific symposium, conferences, and forums.
- Valued scientist and collaborator recognized for strong command of scientific concepts, impeccable work ethic, and high degree of integrity.
- Excellent technical background complemented by recent experience.
- Up-to-date on emerging technologies and recent scientific developments.
- Solid team player and supervisor; routinely assist in troubleshooting departmental experiments, training staff, and overseeing departmental productivity.
- Exceptional relationship-building skills and sound interpersonal abilities.

Experience

The US Pharmacopeia (USP), Rockville, MD. 2005-present
Associate Scientific Liaison – Foods (2011-present)

Promoted competitively to provide comprehensive support within Science-Foods department to establish documentary standards for foods safety and quality.

- Develop new as well as review and revise existing monographs, general tests, and assays.
- Maintain lines of communication among multiple departments during implementation of validation studies, method development, and creation of reference standards.
- Adeptly establish, foster, and maintain partnerships with internal and external constituents, including lab associates, documentation standards staff, suppliers/vendors, trade associations, and advisory panels to support attainment of collective goals and objectives.
- Conduct literature searches, evaluate relevant documents, and draft materials for review by staff and Expert Committee.
- Respond in timely manner to internal and external inquiries related to FCC.

Scientist II (2009-2011)
Senior Chemist II (2005-2009)

Leveraged technical expertise to determine optimal approaches to specific analytical requests and problems related to a broad variety of materials. Prepared, coordinated, and executed project test plans adapted to each situation; evaluated results to ensure the validity of adaptations and robust outcomes.

- Proactively improved processes; tapped into scientific knowledge and provided sound recommendations to advance methods, procedures, and data acquisition. Elevated staff competencies; trained chemists in standard operating procedures (SOPs), analytical methods, safety, chemical hygiene, and laboratory techniques.
- Utilized excellent communication skills to create clear, concise laboratory reports consisting of sample identification, data validation, and results.
- Oversaw the appropriate disposal of chemicals and hazardous substances as laboratory waste officer; managed a $50K budget to support compliance activities.
- *Received Lightning Recognition award for excellent performance.*

Enzon Pharmaceutical Inc., Piscataway, NJ
Research Associate III (2003-2005)

Supported pharmaceutical development through the accurate and timely completion of drug photostability investigations, studies to support drug stability-indicating assay development, and evaluation of raw materials and injectable, I.V., and lyophilized formulations. Knowledgeable in ICH protocols for active pharmaceutical ingredient (API) and drug products.

- Engaged in methods development and validation; devised, evaluated, and transferred formulation assays to support a variety of formulation characterizations. Employed Biuret and BCA assays to carry out methods development and validation; contributed to validation programs for product lines.
- Conducted drug release assays and tested product samples for stability, performed quality control testing to determine safety and alignment with specifications.

Bhate Environmental Associates, Inc., Birmingham, AL
Senior Chemist (2001-2003)

- Contributed technical expertise to government and private agency projects.
- Applied Air Force Center for Engineering and the Environment (AFCEE) protocols in the development and implementation of an Environmental Restoration Program Information Management System (ERPIMS).
- Knowledgeable in Test Methods for:
  - Evaluating Solid Waste
  - Physical/Chemical Methods (SW-846)
  - Resource Conservation and Recovery Act (RCRA)
  - Comprehensive Environmental Response, Compensation Liability Act (CERCLA)
  - Toxic Substances Control Act (TSCA) regulations

Hukill Chemical Corporation, Cleveland, OH
Lab Manager (1997-2001)

Ensured smooth laboratory operations through proactive management of staff, processes, and equipment.

- Established a valuable quality control (QC) and quality assurance (QA) program in concert with SOPs to provide consistency and efficiency in process execution.
- Directed sample analysis in accordance with SW-846, Environmental Protection Agency (EPA), and American Society for Testing and materials (ASTM) protocols.
- Applied resourceful procurement skills to obtain equipment highly suitable to company needs at 20% lower cost than similar equipment available in the market.

North East Chemical Corporation, Cleveland, OH
Chemist (1995-1996)

Performed qualitative and quantitative analysis on a variety of wastes; implemented QA and QC programs and SOPs for analysis of organic and inorganic materials. Managed the performance of laboratory technicians.

Systech Environmental Corporation, Xenia, OH
Chemist (1990-1995)

Conducted waste analysis, trained employees, and provided corporate technical support.

- Increased laboratory efficiency through the establishment of toxicity characteristic leaching procedure (TCLP) testing, resulting in improved service offering.
- Achieved a 70% reduction in sample preparation time and increased safety through the adoption of microwave-assisted sample preparation techniques in lieu of hot plate digestion.

First Environmental Lab, Inc., Danville, NJ
Lab Technician (1990)

Prepared and analyzed samples for TCLP and GC analysis using SW-846, EPA and ASTM protocols.

Education & Affiliations

MS in Plant Pathology, KANSAS STATE UNIVERSITY, Manhattan, KS
MS in Plant Pathology & BS in Agriculture, GUJARAT AGRICULTURAL UNIVERSITY, India

Institute of Food Technologists (IFT), DC Section, Chair, (2015-present), Student Activities and Education
American Chemical Society (ACS), Cleveland Section, Chairman (1996-2001), Career Services
Association of Analytical Communities (AOAC), Member

Technical Competencies

- FTIR
- HPLC
- ICP
- ICP-MS
- GC-MS
- ICH Stability Studies
- GMP/GLP
- Analytical Validation
- Gas Chromatography
- Protein Quantitation Assays
- Flame Atomic Absorption
- Graphite Furnace Atomic Absorption
- Methods Development & Validation
- Microwave Assisted Sample preparation
- UV/VIS, Fluorescence, ELS Spectroscopy
- Energy Dispersive X–Ray Fluorescence

MILDA E. EMBUSCADO, PHD, CFS

Milda_Embuscado@mccormick.com
Ph: 410-527-6009
McCormick & Co., Inc.
204 Wight Avenue, Hunt Valley, MD 21031

MATERIALS & PROCESS TECHNOLOGY

More than 20 years of progressive ingredient/raw materialchemical and functionality characterization, new product innovation, process improvement, and flavor microencapsulation optimization experience, statistical designing, implementing, and buildingconsumer product value for industrial and retail customers. Expertise in employment of design of experiment and response surface methodology (RSM) to optimize ingredient functionality in food systems especially in food emulsion and flavor encapsulated products. Expertise in polysaccharide isolation, modification and characterization (including analytical chemistry of carbohydrates), bioactives of spices and herbs and the effects of processing on their bioactive components including analytical methods applied on spices and herbs.

Combine knowledge of powder properties, innovation and creativity to minimize product failure at the customers' plants during process application and storage. Device several innovative testing methods to characterize powder properties, flowability and caking tendencies of dry products and seasoning blends. Genuine relationship-builder with colleagues, internal customers and vendors.

KEY COMPETENCIES

Ingredient technology/food material science including analytical chemistry–Cost Reduction–Process Improvement - Design of Experiments, RSM&Product Design & Development – Design of novel testing methods - Project Management–Team Leadership&Motivation

PROFESSIONAL EXPERIENCE

MCCORMICK & COMPANY, INC.– Hunt Valley, MD 2000 to Present
Global manufacturer seasoning, spices, condiments and flavors.

Senior Principal Scientist
Principal Scientist
Senior Scientist
Senior Food Scientist

Excelled in global innovation research and developmentinmaterial science and ingredient technology, overseeingthe ingredient technology needs of product development and flavor design groups.Drove formulation and launch of new and improved products in partnership with product developers.Excellent technical problem solvingskill. In depth experience in product testing to determine product differences & product stability.Teamed with purchasing and supply chain teams in qualification of new suppliers and raw materials, and collaborated with global colleagues on product enhancements and process improvement.

CERESTAR, USA INC.– Hammond, IN 1997to 2000
Global manufacturer and marketer of starches, maltodextrins & cyclodextrins, sweeteners and polyols

Senior Carbohydrate Specialist
Carbohydrate Specialist
Project Leader

Multifaceted roles leading research and development team in creation and launch of new and improvement of existing products for industrial customers. Adept in various instrumental & analytical techniques and processing equipment used in food chemistry and food processing (HPLC, GC, rheology/viscometry, emulsifying and textural properties, wet chemistry).Improved flavor and chemical reactivity of starches by removal of proteins through physicochemical and enzymatic techniques.Conducted troubleshootingon product issues by working closely with food application specialists and manufacturing staff. Training of sales and manufacturing staff in starch chemistry and technology. Responsible foremulsifying starches, polyols and gluten product lines (manufacturing, food application and technical support). Active participant of research projects on flavor encapsulation including encapsulation of flavors using beta-cyclodextrin and beta-cyclodextrin-carbohydrate matrices

WHISTLER CENTER FOR CARBOHYDRATE RESEARCH, PURDUE UNIVERSITY – West Lafayette, IN 1991 to 1997
World leader in Carbohydrate Research

Research Scientist
Post Doc

Lead several projects on carbohydrate and polysaccharide chemistry – isolation and physicochemical characterization (carrageenan, pectin, arabinoxylans from wheat flour, tomato paste, modified starches, onion, ice-nucleating agents from *Lobelia*plants). Evaluation of commercial and experimental seaweeds. Synthesis of starch derivatives (emulsifying starches, xylitol). Training of graduate students in the operation and uses of analytical equipment; co-directed their research projects.

EDUCATION

PhD (areas of specialization - carbohydrate and food chemistry, food process engineering)
Purdue University–West Lafayette, IN
MSin Food Chemistry–University of the Philippines–Quezon City, Philippines
BS in Food Technology – University of Philippines–Quezon City, Philippines

SELECTED PUBLICATIONS AND PRESENTATIONS

Embuscado, ME (in press) Rosemary (*Rosmarinusofficinalis*). *In*Dawn C.P. Ambrose, AnnamalaiManickavasagan and RavindraNaik (Editors) Botany, Chemistry and Processing of Leafy Medicinal Herbs.CABI Publishing.

Embuscado, ME (2015) Herbs and spices as antioxidants for food preservation. *In*FereidoonShahidi (Ed) Handbook of Antioxidants for Food Preservation.Woodhead Publishing. Pp 251-284.

Embuscado, ME (2015) *Spices and herbs: Natural sources of antioxidants – a mini review.* Journal of Functional Foods, April 2015.

Embuscado, ME (editor & author, 2014)Carbohydrates as Texturizing and Delivery Systems. Lancaster, PA: DesTECH Publications Inc.

Perera, C, Embuscado ME (2014). Texture design for breaded and battered foods.*In* Food Texture Design and Optimization.IFT Press/Wiley Blackwell. pp 128-158.

Embuscado, ME. 2013. *Herbs and spices as antioxidants for food preservation*. Lecturer at the Antioxidants: Fundamentals, Food Application and Health Effects. Institute of Food Technologists, Chicago, IL, July 11-13, 2014.

Embuscado, ME (2011) Hydrocolloids in flavor stabilization.*In* Thomas R. Laaman, ed. Hydrocolloids in Food Processing. Blackwell Publishing, LTD. pp 215-242.

Embuscado, ME & Huber KC (eds). 2009. Edible Films and Coatings for Food Applications.NY: Springer. 403 pp.

Embuscado, ME. 2009. Carbohydrate-based flavor and bioactive delivery systems. **An invited presentation** at the Symposium on Carbohydrates, Institute of Food Technologists, Anaheim, CA, June 8, 2009.

Embuscado, ME. 2006. Edible films – A historical perspective. **An invited presentation** at the Symposium on Carbohydrates, Institute of Food Technologists, Orlando, FL, June 6, 2006.

Embuscado, ME. 2006. Polyols. *In* W Spillane, eds. Optimising sweet taste in foods. Cambridge, England: CRC Press. pp.153-174.

Embuscado ME, Patil SK. 2001. Erythritol. *In* L O'Brien Nabors, R Gelardi, eds. Alternative Sweeteners.3rd edition. New York: Marcell Dekker, Inc.

Embuscado, ME. 2000. *Erythritol, a unique low calorie alternative sweetener.* **An invited presentation** at the Symposium on Carbohydrates, Institute of Food Technologists, Dallas, Texas, June 13, 2000.

Embuscado ME, Friedman RB. 1998. *Carbohydrates as packaging materials*. **An invited presentation** at the Symposium on Carbohydrates: The Renewable Resources, International Carbohydrate Symposium, San Diego, California, August 10.

Embuscado ME, Sikorski B, Lowe E, Wang S, Wang Y. 1999. *Hydrolysis of proteins in cornstarches using commercial proteolytic enzymes*. Presented at the 1999 Annual Meeting of the American Association of Cereal Chemists in Seattle, Washington, October 31 – November 3, 1999.

Qi ZH, Xu A and Embuscado ME. 1999. *Methods and techniques for encapsulation of flavors using beta-cyclodextrin*. Presented at the 1999 Annual Meeting of the American Association of Cereal Chemists in Seattle, Washington, October 31 – November 3, 1999.

Xu A, Qi ZH, Embuscado ME and Gottneid D. 1999. *Comparative study of orange oil encapsulation using different carriers*. Presented at the 1999 Annual Meeting of the American Association of Cereal Chemists in Seattle, Washington, October 31 – November 3, 1999.

Embuscado ME, BeMiller JN, Knox, EB. 1996. *A survey and partial characterization of ice-nucleating fluids secreted by giant-rosette (Lobelia and Dendrosenecio) plants of the mountains of eastern Africa*. Carbohydrate Polymers, **31**, 1-9.

Embuscado ME, BeMiller JN, Marks JS. 1995. *Isolation and partial characterization of bacterial cellulose*. Food Hydrocolloids, **10**, 75-82.

Embuscado ME, Marks JS, BeMiller JN. 1994. *Bacterial cellulose I. Factors affecting the batch cellulose production by a strain of A. xylinum.* Food Hydrocolloids, **8**, 407-418.

Embuscado ME, Marks JS, BeMiller JN. 1994. *Bacterial cellulose II. Optimization of cellulose production by A. xylinum using Response Surface Methodology.* Food Hydrocolloids, **8**, 419-430.

Yadav MP, BeMiller JN, Embuscado ME. 1994. *Compositional analysis of polysaccharides via solvolysis with liquid hydrogen fluoride*. Carbohydrate Polymers, **25**, 315-318.

HONOR SOCIETIES &PROFESSIONAL ASSOCIATIONS

Elected full member in Honor Societies - Sigma Xi, Phi Tau Sigma, Gamma Sigma Delta
Professional member - Institute of Food Technologists
Chairman, IFT Carbohydrate Division (2006-07)
Chairman, IFT Nutraceuticals & Functional Foods Division (2012-13)
Member, IFT Carbohydrate Leadership Team (2011-12)
Member, IFT Product Development & Ingredient Innovations Subpanel
Member - AACC International
Member – ACS
Chairman, IFT Nutraceuticals& Functional Foods Division (2015-16)
Member, IFT Division Champion Team (2015-18)
Chairman, Cinnamon Working Group, AOAC

Curriculum Vitae

Nour-Eddine ES-SAFI

Date of birth: 04/20/1962

Place of birth: Morocco.

ADDRESS

Team of Organic Chemistry and Physical and Chemical Studies.
Mohammed V - University in Rabat
Ecole Normale Supérieure
B.P 5118 Takaddoum, Rabat, Morocco.
Ph. : +212 5 37 75 80 96.
Mobile: +212 6 72 64 30 86.
Fax.: +212 5 37 75 90 63.
E-mail: nouressafi@yahoo.fr

ACADEMIC EDUCATION

1997 : Ph.D in Organic Chemistry. Mohammed V University in Rabat, Morocco. Thesis entitled "**Phenolic compounds of red vine (*Vitis vinifera* L.) cultivated in Morocco: Structure, reactivity and pharmacological properties**".

1990 : Master of Science in Organic Chemistry. Ecole Normale Supérieure, Rabat, Morocco. Thesis entitled "**Contribution to the study of essential oils and tanins of Eucalyptus trees cultivated in Morocco**"

1986 : Certificate for teaching chemistry in training centers frames. Ecole Normale Supérieure Rabat, Morocco.

1984 : Graduate of the Ecole Normale Supérieure, Option Physique – Chimie, Rabat, Morocco.

EMPLOYMENT

July 2014- Present: Deputy Director of the Ecole Normale Supérieure. Mohammed V University in Rabat – Morocco.

Jan 2001-Present: Professor at Mohammed V University in Rabat. Ecole Normale Supérieure, Rabat – Morocco (Chemisty department).

Jan 1997- 2001: Associate Professor at the same department.

1986-1997 : Assistant Professor at the same department.

1984-1986 : Assistant at the same department.

PROFESSIONAL EXPERIENCE

Research Competence:

- Expertise in synthesis of natural bioactive molecules.
- Dexterous in isolation and characterization of natural bioactive molecules.
- Endured in minor natural products purification.
- Familiar with HPLC and related chromatographic techniques.
- Adept in analyzing spectral data like ^{1}H, ^{13}C, 2D NMR (COSY, NOESY, HMBC and HMQC), IR and MS (ESI-MS, Tandem MS-MS, Maldi-Tof MS).
- Design and synthesis of biologically active compounds.
- Development of synthetic methodologies for natural/modified compounds synthesis.
- Isolation and characterization of naturally occurring bio-active compounds, hemisynthesis of isolated natural products for the confirmation of their chemical structures, transformations of natural products into their novel derivatives.
- Isolation of novel compounds (polyphenols, iridoids, phenylethanoids) from Moroccan plants.
- Development of regio- and stereoselective methodologies for modified polyphenols synthesis.
- Development of thioacidolysis method for structural elucidation of bridged flavanols.
- Capable of both collaborative and independent research.
- Possession of good communication and management skills.

Research Conducted or Supervised

- *Natural Products:*
  - Essential oils, polyphenols, iridoids
  - Eucalyptus trees: Extraction, quantitative and qualitative analysis of essential oils (leaves) and condensed tannins (bark).
  - Vine leaves polyphenols (proanthocyanidins, flavonols, anthocyanidins): Extraction, quantitative analysis, isolation and identification by spectroscopic tools (mass and 1D and 2D NMR spectroscopy).
  - Phytochemical investigations of various Moroccan medicinal plants used in traditional pharmacopeae.

- *Analytical methods:*
  - Chromatography: HPLC/DAD, HPLC/ESI-MS. Application to the study of the condensation of flavanols and anthocyanins in model solution systems.
  - Spectroscopy: ESI/MS, MS/MS, ICD MS, 1D (^{1}H, ^{13}C) and 2D (COSY, HSQC, HMBC, NOESY, ROESY) NMR techniques. Application to the structural elucidation of natural and synthesized compounds.

- *Composition of foods:*
  - Grape proanthocyanidins: Extraction from different parts (seeds, stems and skins), quantitative and qualitative analysis by HPLC and cleavage methods (thiolacidoysis).
  - Grape anthocyanins: Extraction, quantitative and qualitative analysis.
  - Food polyphenols and their role in human health
  - Polyphenols and their role in food technology

- *Flavor and aroma:*
  - Essential oils: extraction, analysis by GC/MS techniques, antibacterial and antifungal properties.

- *Chemical changes during processing:*
  - Chemical transformations which contribute to the organoleptic properties alterations (de-astringency, browning, darkening, etc …) of foods during processing, maturation, storage and aging.
  - Evolution of phenolic compounds during processing, maturation, storage and aging of foods in model solution systems.
  - Evolution of phenolic compounds in model solution systems. Detection, isolation and identification of the new formed compounds and confirmation of their presence in in foods.
  - Role of the new formed compounds in food organoleptic properties and huaman health.

- *Pharmacological activity:*
  - Antibacterial and antifungal activity of natural and synthesized compounds.
  - Mollusciscidal activity of proanthocyanidols and flavonols isolated from grapes and vine leaves.
  - Antioxydant and free radical scavenging properties of natural and synthesized compounds.
  - Strucure-activity relationships.

Teaching Experience

- Organic Chemistry: Stereochemistry, reactions, mechanisms and structures.
- Natural Products.
- Spectral Analysis: IR, MS, NMR.
- Chromatography: PC, GPC, HPLC.
- Polyphenols chemistry.

Scientific stays in foreign laboratories:

- Unité de Phytopharmacie et Médiateurs Chimiques. Team: Chemistry of Natural Products. National Institute for Agricultural Research, Versailles, France.
- UMR Sciences for Enology. Polyphenols team. National Institute for Agricultural Research, Montpellier, France.

- Laboratory of Polyphenols. National Institute for Agricultural Research, Narbonne, France.
- Materia Medica and Pharmacognosy Laboratory, School of Pharmacy, Montpellier, France..

LANGUAGES

- English, French and Arabic (Native Language): Writing, Speaking and Reading.

MICROCOMPUTER USE

- Operating systems : WINDOWS
- MS OFFICE
- Others: Chemdraw, Chemsketch, … etc.

OTHERS

- **Deputy Director** of Ecole Normale Supérieure, Rabat, Morocco. Since July 2014.
- **Head of the Chemistry department** at Ecole Normale Supérieure, Rabat, Morocco. 2011-2014.
- **Professor** at Ecole Normale Supérieure, Mohammed V University of Rabat. Since 2001.
- **Responsible of the research team** "Organic Chemistry and Physical and Chemical Studies".
- **Responsible of the Research Master** "Valorization of the natural resources plant".
- **Responsible of the professional bachelor's degree** "university course teaching in physics and chemistry".
- **Expert Review Panel** for the AOAC Stakeholder Panel on Strategic Food Analytical Methods (Flavanols, St. John's Wort, Chondroitin, Kratom, Ashwagandha, Folin C, …)
- **Member** of various scientific associations.
- **Post-doc** at the French National Agricultural Research Institute. Montpellier & Versailles INRA centers.
- **Supervisor** of PhD students.
- **Editor in Chief** of *Green and Sustainable Chemistry* journal
- **Regional Editor** of the *American Journal of Food Technology.*
- Guess Editor *of Current Bioactive Compounds* journal *special issue* on

"Current Hyphenated Methods in Polyphenol Analysis".

- **Editorial Board Member** of various scientific journals
  - *Journal of Food Composition and Analysis*
  - *Organic Chemistry Insight*
  - *Recent Patents on Food, Nutrition and Agriculture*
  - *The Open Agriculture Journal*
  - *The Open Natural Products Journal*
  - *The Open Organic Chemistry Journal*
  - *International Journal of Medicinal and Aromatic Plants*
- **Reviewer** for many scientific journals
  - *American Journal of Food Technology*
  - *Arabian Journal of Chemistry*
  - *Asian Journal of Agricultural Research*
  - *Biotechnology*
  - *British Journal of Pharmacology*
  - *Current Bioactive Compounds*
  - *Food Chemistry*
  - *International Journal of Agricultural Research*
  - *International Journal of Dairy Science*
  - *International Journal of Food Sciences and Technology*
  - *International Journal of Pharmacology*
  - *Journal Marocain de Chimie Hétérocyclique*
  - *Journal of Agricultural and Food Chemistry*
  - *Journal of Chromatography A*
  - *Journal of Food Biochemistry*
  - *Journal of Food Composition and Analysis*
  - *Journal of Molecular Structure*
  - *Journal of Mass Spectrometry*
  - *Journal of Natural Products*
  - *Journal of Pharmaceutical and Biomedical Analysis*
  - *Journal of Physical Chemistry*
  - *Journal of Separation Science*
  - *Journal of the Science of Food and Agriculture*
  - *Journal of Zhejiang University-SCIENCE B*

- *LWT-Food Science and Technology*
- *Molecules*
- *Natural Products Research*
- *Pakistan Journal of Biological Sciences*
- *Phytochemical analysis*
- *Phytochemistry*
- *Rapid Communications in Mass Spectrometry*
- *Recent Patents on Food, Nutrition & Agriculture*
- *Tetrahedron Letters*
- *The Open Agriculture Journal*
- *The Open Natural Products Journal*
- *The Open Organic Chemistry Journal*
- *The Open Spectroscopy Journal*

LIST OF PUBLICATIONS

1 Elbir, M.; **Es-Safi, N.**; Amhoud, A.; Mbarki, M. (**2015**). Characterization of phenolic compounds in olive stones of three Moroccan varieties. *Maderas, Ciencia y tecnología, 17,* 479-492.

2 Benayad, Z. ; Gomez-Cordoves, C. ; **Es-Safi, N.** (**2014**). Characterization of flavonoid glycosides from fenugreek (*Trigonella foenum-graecum*) crude seeds by HPLC-DAD-ESI/MS analysis. *International Journal of Molecular Sciences, 15,* 20668-20685.

3 Benayad, Z. ; Gomez-Cordoves, C. ; Martinez-Villaluenga, C.; Frias, J. ; **Es-Safi, N.** (**2014**). Phenolic composition, antioxidant and anti-inflammatory activities of extracts from Moroccan Opuntia ficus–indica flowers obtained by different extraction methods. *Industrial Crops and Products*, *62*, *412-420*

4 Benayad, Z. ; Gomez-Cordoves, C. ; **Es-Safi, N.** (**2014**). Identification and quantification of flavonoid glycosides from fenugreek (*Trigonella foenum-graecum*) germinated seeds by LC–DAD–ESI/MS analysis. *Journal of Food Composition and Analysis*, 35, 21-29.

5 **Es-Safi, N**. (**2012**). Plant Polyphenols: Extraction, Structural Characterization, Hemisynthesi and Antioxidant Properties. Phytochemicals as Nutraceuticals - Global Approaches to Their Role in Nutrition and Health, Dr Venketeshwer Rao (Ed.), Intech Open Access Publisher, ISBN 979-953-307-611-8, 181-206**.** Available from: http://www.intechopen.com/books/phytochemicals-as-nutraceuticals-global-approaches-to-their-role-in-nutrition-and-health/polyphenols-as-potent-antioxidants-with-a-major-role-in-food-organoleptic-properties-and-human-healt

6 **Es-Safi, N**. Mass Spectroscopic Methods for the Characterization of Flavonoid Compounds. *Current Bioactive Compounds* **2012,** 8, 240-265**.**

7 **Es-Safi, N.** (**2014**). Review of the Book ''Green Materials for Sustainable Water Remediation and Treatment'' Edited by Anuradha Mishra and James H Clark**.** *Green and Sustainable Chemistry*.

8 **Es-Safi, N**. (**2012**). Mass Spectroscopic Methods for the Characterization of Flavonoid Compounds. *Current Bioactive Compounds*, 8, 240-265**.**

9 **Es-Safi, N**. **(2012).** Editorial Hot Topic: Current Hyphenated Methods in Polyphenol Analysis. *Current Bioactive Compounds*, 8, 189**.**

10 **Es-Safi, N.**; Essassi, E. M.; Massoui, M.; Banoub, J. Mass Spectrometry as a Powerful Analytical Technique for the Structural Characterization of Synthesized and Natural Products. In: *Detection of Biological Agents for the Prevention of Bioterrorism*, NATO Science for Peace and Security Series A: Chemistry and Biology, ISBN 978-90-481-9814-6. Springer Science+Business Media B.V., **2011**, p. 319

11 Tene Ghomsi, J.; Hamou Ahabchane, N.; **Es-Safi, N.**; Essassi, E.M. 4-Phenyl-1,5-benzodiazepin-2-one Compound as a Precursor of Various New heterocyclic Systems with Potent pharmacological Properties. *Frontiers in Science and Engineering An International Journal Edited by Hassan II Academy of Science and Technology*, 1-2**,** 17 pages, **2011**.

12 Boutayeb, M.; El Imadi, S.; Benchidmi, M.; Essassi, E.M.; **Es-Safi, N.**; El Ammari, L. Synthesis of New Pyrazolo[1.5.4-*de*]quinoxalines. *Synthetic Communications* **2010**, 40, 2130-2137.

13 Rida, M.; El Meslouhi, H.; **Es-Safi**, **N.**; Essassi, E.M.; Banoub, J. Structural fragmentation study of new synthetic benzodiazepine derivatives using electrospray ionization tandem mass spectroscopy. *Rapid Communications in Mass Spectrometry* **2008**, *22*, 2253-2268.

14 Rida, M.; El Meslouhi, H.; Hammou Ahabchane, N.; Garrigues, G.; **Es-Safi**, **N.**; Essassi, E.M. A Convenient Method for the Synthesis of 1,5-benzodiazepin-2-one. *The Open Organic Chemistry Journal* **2008**, 2, 83-87.

15 **Es-Safi, N.**; Meudec, E.; Bouchu, C.; Fulcrand, H.; Ducrot, P.H.; Gaëtan, H.; Cheynier, V. New compounds obtained by evolution and oxidation of malvidin 3-*O*-glucoside in ethanolic medium. *Journal of Agricultural and Food Chemistry* **2008**, *56*, 4584-4591.

16 **Es-Safi, N.;** Le Guernevé, C.; Ducrot, P. H. Application of NMR and MS Spectroscopy to the Structural Elucidation of Modified Flavan-3-ols and their Coupling Reaction Products**.** *Specroscopy Letters,* **2008**, *41*, 41-56.

17 Guidouche, S.; **Es-Safi, N.;** Ducrot, P. H. Mechanistic study on the enzymatic oxidation of flavonols. *Tetrahedron Letters* **2008**, *49*, 619-623.

18 **Es-Safi, N.;** Beauhaire, J.; Ducrot, P. H. (**2007**). Antioxidative activity of modified flavanols derivatives. *American Journal of Food Technology*, *2*, 618-629*.*

19 Guidouche, S.; **Es-Safi, N.;** Ducrot, P. H. (**2007**). *Trametes versicolor* laccase mediated oxidation of flavonoids. Influence of the hydroxylation pattern of ring B of flavonols. *American Journal of Food Technology*, *2*, 630-640.

20 **Es-Safi, N.;** Guidouche, S.; Ducrot, P. H. (**2007**). Flavonoids: Hemisynthesis, reactivity and antioxidative properties. *Molecules*, *12*, 2228-2258

21 **Es-Safi, N.;** Kerhoas, L.; Ducrot, P. H. (**2007**). Fragmentation study of iridoid glucosides through positive and negative ESI/MS, CID/MS and tandem MS/MS. *Rapid Communications in Mass Spectrometry*, *21*, 1165-1175.

22 **Es-Safi, N.;** Kerhoas, L.; Ducrot, P. H. (**2007**). NMR Analysis and Fragmentation Study of Globularin through Positive and Negative ESI/MS, CID/MS and Tandem MS/MS**.** *Specroscopy Letters*, *40*, 695-714.

23 Tene Ghomsi, J.; Hammou Ahabchane, N.; **Es-Safi**, **N.**; Essassi, E.M. (**2007**). Synthesis and Spectroscopic Stuctural Elucidation of New Quinoxaline Derivatives. *Spectroscopy Letters*, *40*, 741, 751.

24 **Es-Safi, N.;** Kollmann, A.; Khlifi, S.; Ducrot, P. H. (**2007**). Antioxidative effect of compounds isolated from *Globularia alypum* L**.** Structure–activity relationship. *LWT-Food Science and Technology*, *40*, 1246-1252.

25 **Es-Safi, N.;** Khlifi, S.; Kollmann, A.; Ducrot, P. H. (**2006**). Antioxidative activity of polyphenoolic compounds isolated from *Globularia alypum* L. Structure-activity relationship. *Polyphenol Communications*, 493-494

26 Ghidouche, S.; **Es-Safi, N.;** Ducrot, P. H. (**2006**). Importance of the substitution pattern of ring B of flavonols on their transformation by *Trametes versicolor* laccase. *Polyphenol Communications*, 161-162.

27 **Es-Safi, N.;** Guyot, S.; Ducrot, P.H. (**2006**). NMR, ESI/MS and MALDI-TOF/MS analysis of pear juice polymeric proanthocyanidins with potent free radical scavenging activity. *Journal of Agricultural and Food Chemistry*, *54*, 6969-6977.

28 **Es-Safi, N.;** Beauhaire, J.; Boyer, F.D.; Ducrot, P. H. (**2006**). Substituent effects on flavanol couplings. *Polyphenol Communications*, 57-58**.**

29 **Es-Safi, N.;** Khlifi, S.; Kollmann, A.; Kerhoas, L.; El Abbouyi, A.; Ducrot, P.H. (**2006**). Iridoid glucosides from the aerial parts of *Globularia alypum* L. (Globulariaceae). *Chemical and Pharmaceutical Bulletin*, *54*, 85-88.

30 **Es-Safi, N.;** Ducrot, P.H. (**2006**). Oxidation of flavan-3-ols: Gram-Scale synthesis of taxifolin. *Letters in Organic Chemistry*, *3*, 231-234.

31 Khlifi, S.; El Hachimi Y., Khalil A., **Es-Safi, N.;** El Abbouyi, A. (**2006**). Antioxidant properties of *Salvia verbenaca* L. hydro-methanolic extract. *Indian Journal of Pharmacology*, *38*, 276-280.

32 **Es-Safi, N.;** Le Guernevé, C.; Kerhoas, L.; Ducrot, P.H. (**2006**). Influence of an 8-trifluoroacetyl group on flavanol couplings. *Tetrahedron*, *62*, 2705-2714.

33 **Es-Safi, N.;** Kerhoas, L.; Einhorn, J.; Ducrot, P.H. (**2005**). Application of ESI/MS, CID/MS and tandem MS/MS to the fragmentation study of eriodictyol 7-*O*-glucosyl-(1→2)-glucoside and luteolin 7-*O*-glucosyl-(1→2)-glucoside. *International Journal of Mass Spectrometry*, *247*, 93-100

34 **Es-Safi, N.;** Kerhoas, L.; Ducrot, P. H. (**2005**). Application of positive and negative ESI-MS, CID/MS and tandem MS/MS to a study of fragmentation of 6-hydroxyluteolin 7-*O*-glucoside and 7-*O*-glucosyl-(1→3)-glucoside. *Rapid Communications in Mass Spectrometry*, *19*, 2734-2742.

35 **Es-Safi, N.;** Khlifi, S.; Kerhoas, L.; Kollmann, A.; El Abbouyi, A.; Ducrot, P. H. (**2005**). Antioxidant constituents of the aerial parts of *Globularia alypum* growing in Morocco. *Journal of Natural Products*, *68*, 1293-1296.

36 Khlifi, S.; El Hachimi Y., Khalil A., **Es-Safi, N.;** El Abbouyi, A. (**2005**). Antioxidant properties of *Globularia alypum* L. hydro-methanolic extract. *Indian Journal of Pharmacology*, *37*, 227-231.

37 Boyer, F.D.; **Es-Safi, N.;** Beauhaire, J.; Le Guernevé, C.; Ducrot, P. H. (**2005**). Synthesis of modified proanthocyanidins: easy and general introduction of an hydroxy group at C-6 of catechin; efficient synthesis of elephantorrhizol. *Bioorganic & Medicinal Chemistry Letters*, *15*, 563-566.

38 Beauhaire, J.; **Es-Safi, N.;** Boyer, F.D.; Kerhoas, L.; Le Guernevé, C.; Ducrot, P. H. (**2005**). Synthesis of modified proanthocyanidins: introduction of acyl substituents at C-8 of catechin. Selective synthesis of a C-4 → O →C-3 ether-linked procyanidin-like dimer. *Bioorganic & Medicinal Chemistry Letters*, *15*, 559-562.

39 **Es-Safi, N.;** Cheynier, V**.** (**2004**). Flavanols and anthocyanins as potent compounds in the formation of new pigments during storage and aging of red wine. In *Red Wine Color - Exploring the Mysteries.* Waterhouse AL, Kennedy JA (Eds), *ACS Symposium*, Series 886, Washington, DC, USA, 143-159.

40 **Es-Safi, N.** (**2004**). Colour of a xanthylium pigment in aqueous solutions at different pH values. *Food Chemistry*, *88*, 367-372.

41 **Es-Safi, N.;** Kerhoas, L.; Boyer, F. D.; Le Guernevé, C.; Ducrot, P. H. (**2004**). Selective synthesis and structure of a C4-O-C3 ether-linked procyanidin-like dimer. *Polyphenols Communications*, 578-579.

42 Beauhaire, J.; Boyer, F. D.; **Es-Safi, N.;** Le Guernevé, C.; Ducrot, P. H. (**2004**). New methodologies for the synthesis of proanthocyanidins. *Polyphenols Communications*, 73-74.

43 Boyer, F. D.; **Es-Safi, N.;** Beauhaire, J.; Le Guernevé, C.; Ducrot, P. H. (**2004**). Hydroxylation on ring of the catechin, studies on the stability of resulting flavanol derivatives. *Polyphenols Communications*, 577-578.

44 **Es-Safi, N.;** Cheynier, V.; Moutounet, M. (**2003**). Implication of phenolic reactions in food organoleptic properties. *Journal of Food Composition and Analysis*, *16*, 535-553.

45 **Es-Safi, N.;** Cheynier, V.; Moutounet, M. (**2003**). Effect of copper on oxidation of (+)-catechin in a model solution system. *International Journal of Food Science & Technology*, *38*, 153-163.

46 **Es-Safi, N.;** Cheynier, V.; Moutounet, M. (**2002**). Interactions between cyanidin 3-O-glucoside and furfural derivatives and their impact on food color changes. *Journal of Agricultural and Food Chemistry*, *50*, 5586-5595.

47 **Es-Safi, N.;** Cheynier, V.; Moutounet, M. (**2002**). Role of aldehydic derivatives in the condensation of phenolic compounds with emphasis on the sensorial properties of fruit-derived foods. *Journal of Agricultural and Food Chemistry*, *50*, 5571-5585.

48 **Es-Safi, N.;** Le Guernevé, C.; Cheynier, V.; Moutounet, M. (**2002**). 2D NMR analysis for unambiguous structural elucidation of phenolic compounds formed through reaction between (+)-catechin and glyoxylic acid. *Magnetic Resonance in Chemistry*, *40*, 693-704.

49 **Es-Safi, N.;** Cheynier, V.; Moutounet, M. (**2002**). Role of aldehydes in the condensation of phenolic compounds with emphasis on food organoleptic properties. *Polyphenols Communications*, 577-578.

50 **Es-Safi, N.;** Cheynier, V.; Moutounet, M. (**2000**). Study of the reactions between (+)-catechin and furfural derivatives in the presence or absence of anthocyanins and their implication in food color change. *Journal of Agricultural and Food Chemistry*, *48*, 5946-5954.

51 **Es-Safi, N.;** Le Guernevé, C.; Cheynier, V.; Moutounet, M. (**2000**). New phenolic compounds formed by evolution of (+)-catechin and glyoxylic acid in hydroalcoholic solution and their implication in color changes of grape-derived foods. *Journal of Agricultural and Food Chemistry*, *48*, 4233-4240.

52 **Es-Safi, N.;** Le Guernevé, C.; Cheynier, V.; Moutounet, M. (**2000**). New phenolic compounds obtained by evolution of (+)-catechin and glyoxylic acid in hydroalcoholic medium. *Tetrahedron Letters*, *41*, 1917-1921.

53 **Es-Safi NE**, Le Guernevé, C**.;** Fulcrand, H.; Cheynier, V.; Moutounet, M. (**2000**). Xanthylium salts formation involved in wine colour changes. *International Journal of Food Science and Technology*, *35*, 63-74.

54 **Es-Safi, N.;** Le Guernevé, C.; Labarbe Benoit, Fulcrand, H.; Cheynier, V.; Moutounet, M. (**1999**). Structure of a new xanthylium salt derivative. *Tetrahedron Letters*, *40*, 5869-5872.

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BIOGRAPHICAL SKETCH

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NAME John W. Finley	POSITION TITLE Professor, School of Nutrition and Food Science, Louisiana State University, Baton Rouge, LA
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
LeMoyne College, Syracuse , NY	B.S.	1964	Chemistry
Cornell University, Ithaca, NY	Ph.D.	1969	Biochemistry and Food Science
Michigan State University, East Lansing, MI		1968 -1969	Post Doctoral Fellow

A. Personal Statement

My laboratory studies the low calorie ingredients, anti-inflammatory compounds in the diet, modified lipids and edible fiber. Previously, I developed several low calorie technologies (Nabisco) and satiety enhancing products as a fellow at Kraft Foods. Earlier, I served as chief technology officer of A.M. Todd Co. and the leader of the Food Science program at Monsanto, which was focused on delivery of intense sweeteners and development of reduced calorie ingredients. At Nabisco, I assembled and led the Fundamental Science program. Over recent years, my operation has been increasingly focusing on food ingredients to find novel avenues to combat for obesity and diabetes. The research has included the isolation of bioactive compounds including dietary fiber and anthocyanins from various sources and assessing their interaction with microbiota using human and rodent inoculum. At Monsanto I worked on purification of isoflavones and making modifications of the isolated isoflavones.

B. Positions and Honors

2008 – Fellow Institute of Food Technologists
2006 – Outstanding Alumnus Michigan State University
1993 – Leadership Award – Nabisco Foods
1990 – Fellow-Agricultural and Food Division of American Chemical Society
1984 – Fellow Royal Society of Chemistry
1969 – Sigma Xi Michigan State University
1968 - Phi Kappa Phi Cornell University

Institute of Food Technologists
2007 – Chairman Gulf Coast IFT
2008 – 2011 Board of Directors Institute

American Chemical Society National Offices:
2000 - Present Councilor
2000 - 2005 Committee on Divisional Activities
2008 - Present Committee on Science
2013 Chair Multi-Planning Program Group

Academic Positions

2013 - Professor School of Nutrition and Food Science
2007 – 2013 Present Head and Professor, Department of Food Science, Louisiana State University
1982 - 1983 Director of Microchemistry. University of Iowa, Iowa City, IA

1969 - 1982 Research Chemist. USDA Western Regional Research Center Berkeley, CA

Industry Positions
2004 – 2007 Chief Technology Officer A.M. Todd Co. Montgomeryville, PA
1999 -2004 Kraft Fellow, Kraft Foods. Glenview, IL
1996 – 1999 Director New Project Development and Leader of Food Science, Monsanto Co. St Louis, Mo
1983 - 1996 Group Director. Nabisco Foods. East Hanover, NJ
1981 – 1982 Scientist. Ralston Purina Co. ST Louis, MO

Professional Memberships
American Chemical Society
American Institute of Nutrition
Institute of Food Technologists
US Pharmacopia Expert Panel

Recent Publications:

1. Rebello CJ, Greenway FL, Finley JW.. Whole grains and pulses: a comparison of the nutritional and health benefits. J Agric Food Chem. 2014 Jul 23;62(29):7029-49.
2. Seiber JN, Finley JW. The nexus of food, energy, and water. J Agric Food Chem. 2014 Jul 9;62(27):6255-62.
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6. Bener, Mustafa; Shen, Yixiao; Apak, Resat; Finley, John W.; Xu, Zhimin (2013) Release and Degradation of Anthocyanins and Phenolics from Blueberry Pomace during Thermal Acid Hydrolysis and Dry Heating. Journal of Agricultural and Food Chemistry (2013), 61(27), 6643-6649
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10. Tomás-Barberán FA, Somoza V, Finley J Food Bioactives Research and the *Journal of Agricultural and Food Chemistry*. Symposium Introduction. *J. Agric. Food Chem.*, Article ASAP
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2. Omega-3 fatty acids: Chemistry, nutrition, and health effects. [In: ACS Symp. Ser., 2001; 788]. Shahidi, Fereidoon; **Finley, John W**.; Editors. USA. (2001), 330 pp. Publisher: (ACS, Washington, D. C.)
3. ACS Symposium Series, Vol. 484: Food Safety Assessment. Developed from a Symposium Sponsored by the Division of Agricultural and Food Chemistry at the 200th National Meeting of the American Chemical Society, Washington, D.C., August, 26-31, 1990**.** **Finley, John W.;** Robinson, Susan F.; Armstrong, David J.; Editors. USA. (1992), 478 pp. Publisher: (ACS, Washington, D.C.)
4. Basic Life Sciences, Vol. 56: NMR Applications in Biopolymers [Proceedings based on an American Chemical Society Symposium on Applications of NMR in Biopolymers, Held September 25-28, 1988, in Los Angeles, California, and an American Chemical Society Symposium on Recent Developments in NMR Spectroscopy of Carbohydrates, Held June 5-8, 1988 in Toronto, Canada]. **Finley, J. W.;** Schmidt, S. J.; Serianni, A. S.; Editors. USA. (1990), 515 pp. Publisher: (Plenum Press, New York, N.Y.)

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7. Digestibility and Amino Acid Availability in Cereals and Oilseeds. **Finley, J. W.;** Hopkins, D. T.; Editors. USA. (1985), 304 pp. Publisher: (American Association of Cereal Chemists, St. Paul, Minn.)
8. ACS Symposium Series, Vol. 277: Xenobiotic Metabolism: Nutritional Effects. [Based on a Symposium Sponsored by the Division of Agricultural and Food Chemistry at the 187th Meeting of the American Chemical Society, St. Louis, Mo. April 8-13, 1984]. Finley, John W.; Schwass, Daniel E.; Editors. USA. (1985), 382 pp. Publisher: (American Chemical Society, Washington, D. C.)

Quanyin Gao

Herbalife International of America, Inc.. Sep. 2010-present

Director， Quality Control

- Laboratory management on quality control of RM & FP release and stability sample testing.
- Laboratory compliance management for dietary supplement and functional food products.
- Formulation and manufacturing process characterization analysis.
- Method development and validation for botanical identification, assay, and limit test.
- Facilitated audits by FDA, NSF, Kosher, HACCP, and Halal without lab observations.

Irvine Pharmaceutical Services, Inc. March 2009-Sep. 2010

Director， Analytical Development

- Managed multiple CRO/CMO projects to meet goals timely such as bioanalytical and formulation development; structure analysis; compendial testing; method development and validation.
- Drug substance and drug product quality control release and stability tests.
- Impurity profiling of small molecules and biopolymers.
- Injectable and lyophilized product formulation and process development.

Watson Pharmaceuticals, Inc. (Corona, CA)

Associate Director, R&D July 2004-Feb. 2009

Manager, R&D July 2001-June 2004

Supervisor, R&D August1999-June 2001

- Successfully developed 24 generic solid dosage form drug products for ANDA filings and drug substance DMF.
- Extensive experience with FDA's QbD, QbR, QOS and related regulatory requirements for ANDAs or amendments to ensure the product CMC.
- Obtained FDA approvals for critical products for commercialization including first to file and Paragraph IV filing. Responded deficiency letters to obtain product approvals.
- Facilitated Watson's Corona, China, and Poteau Rico sites cGMP auditing by FDA. Interacted with FDA inspectors during pre-approval cGMP auditing with no 483 observation.
- Managed four teams of about 30+ R&D scientists with B.Sc. M.Sc, and PhD with high standard of performance. Mentored lab staff for their technical and career growth.
- Acquired, qualified and applied modern instrumentation for solid dosage form and inhalation product development using LC/MS, GC/MS, IR, UV/Vis, Fluorescence, Andersen Cascade Impactor (ACI), Next Generation Impactor (NGI), particle size analysis by Malvern Mastersizer, hot stage microscope, DSC, TGA, SEM, chemical imagining NIR, XRD, and Raman.

Braun/McGaw Medical Inc. (Irvine, CA)

Senior Staff Scientist, Pharmaceutical Development June1997- August 1999

- Filed NDAs for parental drug products with drug substance/drug product development, method validation and method transfer.
- Investigated leachables/extractables of parenteral plastic containers using SPE, GC, HPLC, LC/MS/MS, LC/ELSD, GC/MS, GC/FTIR, H^1 and C^{13} NMR, and x-ray diffraction.

- Developed LC/MS/MS methods for metabolite profiling for PK studies.
- Supported stability programs with HPLC, LC/MS/MS, LC/UV/MS, and LC/RI/MS techniques.

Teva Pharmaceuticals USA (Mexico, MO)

Senior Research Chemist, R&D Department May 1995-June1997

- Expertise in the structure elucidation of impurities and degradation products of drug substances (APIs) and drug products by LC/MS. Provided data for regulatory filing of 4 drug master (DMF) files.
- Conducted preparative HPLC separation of impurities from active drug ingredients.
- Characterized proteins and carbohydrates in natural products. Supported immediate and sustained release formulations.

Pacific Northwest National Laboratory (Richland, WA)

Post Doctoral Research Associate March 1994-May 1995

Bioanalytical research with characterization of proteins, DNA, RNA, and supramolecular complexes using ESI-MS, LC/MS and CE/MS techniques. Designed, constructed and characterized a novel space-focusing Time-of-Flight mass spectrometer.

EDUCATION

B. Sc. in Chemistry, Nanjing University, China, 1982

M. Sc. in Chemistry, Dalian Inst. of Chem. Phys., Chinese Academy of Sciences, 1985.

Ph. D. in Chemistry, University of California, Irvine, 1991.

Post-Doctoral Research, University of Pittsburgh and Pacific Northwest National Laboratories.

PROFESSIONAL ORGANIZATIONS

USP Expert Committee Member: Chemical Medicine Monographs 4

SELECTED PUBLICATION

1. Analytical Methods Development and Methods Validation for Solid Oral Dosage Forms, Q, Gao, D. Sanvordeker, and R. Vita, Chapter 3 of ***Generic Drug Product Development***, 2004, Marcel Dekker, New York, ed. Leon Shargel and Isadore Kanfer.
2. HPLC-Quadrupole Ion Trap Mass Spectrometry Studies of Thermal Degradation of Beclomethasone Dipropioate, Q. Gao, A. K. Sharma, W. Walter**, *J. Am. Soc. Mass Spectro***., 9(1998)387.
3. Late-infantile Ceroid-lipofuscinosis: Lysine Methylation of Mitochondrial ATP Synthase Subunit c From Lysosomal Storage Bodies, ***Biochimica et Biophysica Acta***, vol. 1361 (1997) 66, M. L. Katz, A. N. Siakotos, Q. Gao, B. Freiha, D. T. Chin.
4. Binding Specificity of Post-activated Neocarzinostatin Chromophore Drug-Bulged DNA Complex Studied Using Electrospray Ionization Mass Spectrometry, ***J. Mass Spectro.*** , 31 (1996) 31.
5. Characterization of Hydrogen-Bonded Aggregates in Chloroform by Electrospray Ionization Mass Spectrometry, ***J. Org. Chem.***, 61 (1996) 2204.

Name: Tetsuhisa Goto
Born: 1950.01.20, at Sapporo, Japan))

Retired Professor, Faculty of Agriculture, Shinshu University

Contact
Address: 7448-232 Mihara, Ina, Nagano Japan
Postal Code: 396-0113
e-mail: food_goto@yahoo.co.jp
Phone: +81-265-76-9990

College Education
1965.04-1968.03 Sakuramachi Senior High School, Tokyo, Japan
1969.04-1973.03 Rikkyo (St. Paul's) University, Tokyo, Japan
1973.03 BA (Chemistry)
1974.04-1976.03 Rikkyo (St. Paul's) University
1976.03 MS (Chemistry)
1997.03 Ph.D. (Rikkyo (St. Pual's) University) (Chemistry)

Awards
Fellow, AOAC International (2008)
2010 Community Volunteer of the Year, AOAC International(2010)
Academic achievement award, Japanese Society of Mycotoxicology (2015)

Professional Career
1976.04-1987.03 Research Scientist, Mycotoxins Laboratory, National Food Research Institute (NRFI), Ministry of Agriculture, Forestry and Fisheries (MAFF)
1987.04-1990.03 Senior Research Officer, Mycotoxins Laboratory, NFRI/MAFF
1990.04-1994.09 Head of Tea Chemistry Laboratory, National Institute Vegetable, Ornamental Plants and Tea, MAFF
1994.10-2004.03 Head of Food Safety and Quality Laboratory, NFRI, MAFF
2004.04-2015.03 Professor, Faculty of Agriculture, Shinshu University
2015.03.31 Retired from Shinshu University

Membership in Professional Organization
AOAC International,
Member, Official Method Board (2004.09-2007.09)
Chair, Method Committee D (2004.09-2007.09)
Voting member Mycotoxin Community for AOAC International
AOACI Japan Section President (2003.06-2005.06)
American Chemical Society

Institute of Food Technologists (Chicago, US)
Japanese Society of Mycotoxicology,
Editor in Chief, Mycotoxins (2000-2009)
The Chemical Society of Japan
The Japanese Society for Analytical Chemistry
Japanese Society for Food Hygiene and Safety

Recent Publications (after 2009)

The relationship between ergosterol and mycotoxin contamination in maize from various countries, Mycotoxin Research, 31, 91099(2015) Md. Zakir Hossain, Nakao Mari & Tetsuhisa Goto

Determination of sterigmatocystin in grain using gas chromatography-mass spectrometry with an on-column injector, Mycotoxin Research, 31.17-22 (2015) Md. Z. Hossain & T. Goto

Single laboratory method validation for cyanide in beans with insufficient levels of β-glucosidase activity, Quality Assurance and Safety of Crops & Foods, 7, 501-509 (2015), N. Abe, S. Kasuga, M. Okabe & T. Goto

A Rapid Determination of Ergosterol in Grains Using Gas Chromatography-Mass Spectrometry Method without Derivatization, Food Anal. Methods, 8, 1021-1026 (2015), Md. Z. Hossain & T. Goto

Near- and mid-infrared spectroscopy as efficient tools for detection of fungal and mycotoxin contamination in agricultural commodities (Review), World Mycotoxin Journal, 7 507-515 (2014), M. Z. Hossain, T. Goto

Development of an analytical method for the determination of sterigmatocystin in grains using LCMS after immunoaffinity column purification, Mycotoxin Research, 30, 123-129 (2014) R. Sasaki, M Z. Hossain, N. Abe, T. Goto

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Developments and single laboratory validation of a method for citrinin, World Mycotoxin Journal , 3, 129-134 (2010), T. Sato, H. Higashihara, A. Sasaki, D. Toth, T. Goto

Simultaneous analysis of organic acids and inorganic anions in silage by capillary electrophoresis, Animal Feed Science and Technology , 161, 58-66 (2010), H. Hiraoka, E. Ishikuro, T. Goto

Patulin distribution in decayed apple and its reduction, International Biodeterioration and

Biodegradation , 63, 379-382(2009), S. Bandoh, M. Takeuchi, K. Ohsawa, K. Higashihara, Y. Kawamoto and T. Goto

Single laboratory validation of a method for ergosterol determination in cereals, Food Additives and Contaminants , 26, 201-206(2009), H. Miyagawa, M. Umeda, T. Sato, S. Bandoh, S. Nakamura, T. Goto

Martha L. Jennens

204 E. Washington St.
Poynette, WI 53955
(608) 225-4802
mclough22@charter.net

PROFESSIONAL EXPERIENCE

2013-present: Research Chemist II-Covance Laboratories. Responsible for the development of new analytical methods and the modification of existing methodology. Involved in problem identification and resolution, including modification of existing methodology or processes. Supports staff by training less experienced staff and acting as a mentor. Involved in the evaluation and operation of newly emerging analytical technologies.

2009-2013: Technical Leader III-Covance Laboratories. Technical Leader for routine and study analyses under the direction of Nutritional Chemistry management for the Special Projects Group. Had an overall responsibility for the technical conduct of routine assays, study work, as well as validation procedures and method development. Put into place a department wide initiative to contain, control and track all HPLC columns. Had numerous client interactions which may include client visits, calls to clarify or resolve questions with the data and method development around specific samples.

2007-2009 Research Assistant III-Covance Laboratories. Provide troubleshooting, root cause analysis, and process validation expertise to multiple project areas. Work on method development/validation for client specific studies and new methods. Conduct stability studies and routine assays, including work with HPLC, GC and LCMS under GLP guidelines. Multi-departmental assay assistance across three separate groups, as needed. Travel to other sites to provide support of methods and data management and continue to provide support to other sites as issues arise. Provide final review of data before submission to clients. Discuss issues and projects with clients as the arise and work to resolve data/testing issues.

2005-2007 Research Assistant-UW Madison. Immunology research including RNA, cDNA and qPCR work. Cell culture of mammalian cell lines and viral transfection and transductions. DNA work including cloning and purification. Maintained laboratory supplies and trained undergraduate students.

2004-2005 Scientist/ Project Manager-PPD Development. HPLC, CGE testing in cGMP environment of pharmaceutical compounds. Project manager--responsible for overseeing project, data and report writing.

2003-2004 Laboratory Manager/ Research Assistant-University of Wisconsin, Madison. RT-PCR, cell culture, cell staining techniques, ordering and maintenance of laboratory supplies and equipment, oversee graduate students and give technical advice.

1997-2002 Scientist-Promega Corporation. Production of restriction enzymes utilizing various chromatography techniques. Product development and process improvement, feasibility issues for new technology, new product launches including packaging validation, writing manufacturing and QC protocols as well as SOPs.

1995-1997 Research Assistant-Agracetus/ Powderject, Inc. Working on DNA vaccines with Accell technology, specifically tropical and exotic diseases. Duties include: cloning, DNA sequencing, SDS PAGE analysis, tissue culture with several mammalian cell lines, RNA work, ELISAs, animal work, CTL assays, analyze and compile data with various computer software, upkeep of accurate notebooks, working with collaborating labs and served on radiation safety committee.

1991-1995 Molecular Biology/Biochemistry-Washington University. Use PCR techniques, DNA sequencing, tissue culture with mammalian and insect cell lines, protein production and purification with mammalian, insect and yeast cells, hybridization processes, in charge of ordering supplies, radiation safety and environmental safety for the laboratory, plan and aid in design of projects, interpret data and assist other members of my laboratory and other laboratories with technical problems and oversee the laboratory with PI is out.

EDUCATION AND AFFILIATIONS

AOAC International

Practical Statistical Methods for Improving Analytical Laboratories.

Agilent HPLC Hands-On Training (Advanced)

Advanced HPLC Method Development

Fundamental Principles and Practices of HPLC

Washington University, St. Louis, MO-Graduate work

Stephens College, Columbia, MO-BA Biology

PUBLICATIONS

Manuscripts:
H.F. Sims, M.L. Jennens, M.E. Lowe, **GENE;** 1993 Sept 15: 131(2): 281-5.
R.M. Payne, H.F. Sims, M.L. Jennens, M.E. Lowe, **AMERICAN JOURNAL OF PHYSIOLOGY**; 1994 May: 266 (5 pt 1): G914-21.
M.L. Jennens, M.E. Lowe, **JOURNAL OF BIOLOGICAL CHEMISTRY**; 1994 Oct 14: 269(41) 25470-4.
M.L. Jennens, M.E. Lowe, **JOURNAL OF LIPID RESEARCH**; 1995 May: 36 5):1029-36.
M.L. Jennens, M.E. Lowe, **JOURNAL OF LIPID RESEARCH**; 1995 Nov: 36(11):2374-82.
R. Hannah, M. Jennens-Clough, K Wood, **PROMEGA NOTES**; 1998: Number 65.
E. Hawkins, M. Jennens-Clough, K. Wood, **PROMEGA NOTES**; 1999: Number70.
M. P. Hall, M.G. Gruber, R.R. Hannah, M.L. Jennens-Clough, K.V. Wood, **Bioluminesence and Chemilumenescence: Perspectives for the 21st Century. Proceedings of the 10th International Symposium** 1998.
Jartti T, Burmeister KA, Seroogy CM, Jennens-Clough ML, Tisler CJ, Salazar LP, Dasilva DF, Evans MD, Vrtis RF, Wallace PK, Ruiz-Perez B, Gangnon RE, Lemanske RF Jr, Gern JE. **J Allergy Clin Immunol.** 2007.
Debra A Mackenzie, Jill Schartner, Jack Lin, Amanda Timmel, Martha Jennens-Clough, C Garrison Fathman, Christine M Seroogy, **J Biol Chem.** 2007

Abstracts:
M.L. Jennens, M.E. Lowe, **PEDIATRIC RESEARCH**, (1993) 33:102A.
P. Deshpande, A. Khurana, P. Hansen, M. Jennens, B. Thach, **AMERICAN PEDIATRIC SOCIETY**, (1995).
M. Seguin, C. Ockenhouse, R. Ballou, C. Elmer, M. Jennens-Clough, D. Fuller, J. Haynes, M. Sheehy; **ASBTRACTS OF THE AMERICAN ASSOCIATION OF IMMUNOLOGY**, (1996).
J. Fuller, M. Jennens-Clough, J. Haynes, G. Widera, **THE AMERICAN SOCIETY OF TROPICAL MEDICINE AND HYGIENE**, (1996).
R. Hannah, M. Jennens-Clough, K. Wood. **MipTec 1998**, (1998).

REFERENCES

Available upon request

Curriculum Vitae

Holly E. Johnson, Ph.D.
2502 5th St.#3 Santa Monica, CA 90405 holly@alkemist.com 808.631.8823

Academic Degrees

2007 Ph.D. in Pharmacognosy
Specialization: Natural Products Chemistry & Medical Ethnobotany
Department of Medicinal Chemistry & Pharmacognosy
Program for Collaborative Research in the Pharmaceutical Sciences
College of Pharmacy, University of Illinois – Chicago, IL

1997 B.S. in Environmental Biology, B.S. in Botany
Department of Biological Sciences
Humboldt State University, Arcata, CA

Professional Experience

2014 - present	**Laboratory Director**, Alkemist Labs, Costa Mesa, CA
2013 – 2014	**Senior Field Applications Chemist**, Waters Corp., Milford, MA
2011 – 2013	**Adjunct Professor**, University of Hawaii, Lihue, HI
2009 – present	**Research Associate**, National Tropical Botanic Garden, Kalaheo, HI
2009 – 2011	**Researcher**, University of Hawaii – Manoa, College of Tropical Agriculture & Human Resources, Kapaa, HI
2007 – 2011	**Visiting Assistant Professor**, Weber State University, Department of Botany, Ogden, UT
2007 – 2009	**Postdoctoral Research Fellow**, Institute for Ethnomedicine, Jackson, WY
2005 – 2007	**Senior Analytical Technician**, California State University -Fullerton Department of Biological Sciences, Fullerton, CA
2003 – 2005	**Analytical Chemistry Consultant**, Institute for Ethnobotany, Acacia Lab, National Tropical Botanic Garden, Kalaheo, HI
2000 – 2003	**Pre-Doctoral Fellow**, National Institutes of Health Center for Botanical Dietary Supplements Research, Chicago, IL
1998 – 2002	**Pharmacology/Toxicology Production Associate**, NAPRALERT™ Database, University of Illinois – Chicago, IL
1997 – 2000	**Research & Teaching Assistant**, National Cooperative Drug Discovery Group, Program for Collaborative Research in the Pharmaceutical Sciences, Chicago, IL

Honors

2001 – 2003	National Research Service Award (NIH #1F31AT000064-01 & NIH #5F31AT000064-02) National Institutes for Health - Center for Botanical Dietary Supplements Research in Women's Health
2000	Charles Wesley Petranek Memorial Scholar University of Illinois – Chicago
1997	Meredith Botany Scholar Humboldt State University

Research Interests

Botanical dietary supplements; natural products chemistry;
analytical methods development & validation for natural products;
ethnopharmacology; biologically active compounds from plants and cyanobacteria.

Field Experience

Dominican Republic, Puerto Rico, Mexico, Venezuela, El Salvador, Costa Rica, Peru, Guam, American Samoa, Western Samoa, Tonga, Fiji, Sweden, Canada, the Hawaiian Islands, continental U.S.A. including California, Wyoming, N. Carolina & Florida.

Membership in Professional Societies

American Association for the Advancement of Science
American Chemical Society
American Herbal Products Association
American Society of Pharmacognosy
AOAC International
Botanical Society of America
International Society for Ethnopharmacology
Society for Economic Botany
Phytochemical Society of North America

Selected Publications

Johnson HE, Acebes AC, Watts NE. 2014
Development and Validation of multiplex PCR bioassays for probing host-parasitoid interactions in biological control of the banana aphid (*Pentalonia nigronervosa*) in Hawaiian taro (*Colocasia esculenta)* fields. **Ecological Applications**

Kirby J, Nishimoto M, Park JG, Withers ST, Nowroozi F, Behrendt D, Fortman JL, Johnson HE, Anderson JV, Keasling JD 2010.
Cloning of casbene & neocasbene synthases from Euphorbiaceae plants and expression in *Saccharomyces cerevisiae*.
Phytochemistry 71:1466-1473.

Johnson HE, Banack SA, Cox PA. 2008
Variability in content of the anti-AIDS drug
candidate prostratin in Samoan populations of *Homolanthus nutans*.
Journal of Natural Products 71(12): 2041-2044.

Johnson HE, King SR, Banack SA, Webster C, Callanaupa WJ, Cox PA. 2008
Cyanobacteria (*Nostoc commune*) used as a dietary item in the Peruvian highlands produce the neurotoxic amino acid BMAA.
Journal of Ethnopharmacology. 118(1):159-65.

Cox PA, Johnson HE, Tavana G. 2008
Giving Samoan healers credit for prostratin.
Science. 320(5883):1589.

Banack SA, Johnson HE, Cheng R, Cox PA. 2007
Production of the neurotoxin BMAA by a marine cyanobacterium.
Marine Drugs. 5(4):180-96.

Buenz EJ, Bauer BA, Johnson HE, Tavana G, Beekman EM, Frank KL, Howe CL. 2006
Searching historical herbal texts for potential new drugs.
British Medical Journal. 333(7582):1314-5.

Buenz EJ, Johnson HE, Beekman EM, Motley TJ, Bauer BA. 2005
Bioprospecting Rumphius's Ambonese Herbal: Volume I.
Journal of Ethnopharmacology. 96(1-2):57-70.

Dr. Philip (Phil) J. Koerner is the Senior Technical Manager with Phenomenex, located in Torrance, California, USA and has more than 27 years of experience in LC, GC, and sample preparation techniques; 11 years with DuPont and 17 plus years with Phenomenex. Dr. Koerner travels extensively around the world presenting technical seminars, hands-on training, and technical assistance covering various topics in HPLC, GC, and SPE, in support of Phenomenex customers globally. He has also been an instructor for USP courses on General Chapters <467> (Residual Solvents) and <621> (Chromatography). In 2015, Dr. Koerner was appointed to the AOAC International Expert Review Panel (ERP) for the Set 2 SPDS ingredients (anthocyanins, chondroitin and PDE5 inhibitors).

Dr. Koerner received his B.S. in Chemistry at the University of California, Irvine, earned his M.S. and Ph.D. in Chemistry at the University of Illinois, and an MBA at the University of Delaware.

Professional Summary

JASEN A. LAVOIE

Jasen is currently employed at Pharmachem as a Vice President of Scientific Affairs.

Jasen has 16 years' experience working with Aloe Vera formulation, manufacturing, and regulatory affairs. He also has over 23 years of experience in research and development within the nutraceutical industry. Jasen has proven to be an effective leader within his various managerial positions. He created a team work atmosphere by working closely with Product Development, Marketing, Regulatory, Quality, Supply Chain, and Manufacturing.

Jasen studied Chemistry at the University of Massachusetts at Amherst (BS Chemistry), and Northeastern University (Masters work). He has served in the U.S. Marine Corps as a Lieutenant, Supply Officer.

Some of Jasen's interests include: Recreational Triathlethlon, Speak – Read – Write in moderate Korean. While at UMass, founded and taught Tae Kwon Do Club.

Cuiying Ma

Department of Science Dietary Supplements and
Herbal Medicines
U.S. Pharmacopeia
12601 Twinbrook Parkway,
Rockville, MD 20852

Home: (301) 963-0815
Work: (301) 230-6371
Cell: (301) 676-4685
E-mail: cm@usp.org
Fax: (301) 998-6807

Qualifications

- Extensive working experience in review of USP monograph submission and proposing botanical monographs
- In-depth knowledge of traditional Chinese herbal medicine
- Extensive hands on experience in HPLC method development and validation under GMP/GLP environment; In-depth knowledge of HPLC, GC, TLC, CE, and LC-MS in method development and validation for supporting drug development
- In-depth knowledge of unknown organic compound isolation and structure identification; Extensive working experience in structure elucidation of unknown compounds by spectrum interpretation of ^{1}H-NMR and ^{13}C-NMR (including COSY, ROESY, HMBC, HMQC, DIFNOE, NOESY, DEPT, and APT), MS, UV/VIZ, and FT-IR
- Conducted bioassay-guided fractionation, isolation of plant extracts and pure compounds
- Hands on bioassays of in vitro anti-cancer and anti-malarial, growing and maintaining cancer cell lines and malarial parasites

Education

02/97-09/00	Ph.D.	Natural Product Chemistry Department of Chemistry Hong Kong University of Science and Technology, Hong Kong
09/86-07/89	M.S.	Pharmaceutical Analytical Chemistry Department of Pharmacy Shanxi Medical University, Shanxi, China
09/78-07/82	B.S.	Pharmacy (Traditional Chinese Medicine) Beijing University of Chinese Medicine and pharmacology, Beijing, China

Professional Experiences:

10/13-present, Senior Scientific Liaison, USP, Rockville, MD

- Review USP botanical monograph submissions and propose botanical monographs for both dietary supplements and herbal medicines.

10/06-10/13, Reference Standard Scientist, USP, Rockville, MD

- Effectively managed reference standard portfolio. In my portfolio mainly includes botanical reference standards.

02/02-09/06, Postdoctoral Research Associate, University of Illinois at Chicago, Chicago, IL

- Participated drug discovery projects funded by NIH.
- Performed bioassay directed isolation and structural elucidation of bioactive compounds from tropical plants.
- Conducted in vitro anti-cancer, anti-malarial bioassay.

09/01-01/02, Research Associate, Lehman College, The City University of New York, New York, NY

- Developed and validated HPLC methods for the quantitation of catechin and epicatechin in *Theobroma gradiflorum* extracts.
- Conducted bioactivity guided isolation and structural elucidation of antioxidants from tropical fruit of *Theobroma gradiflorum* and *Manilkara zapota*.

10/00-09/01, Associate Professor, National Institute for the Control of Pharmaceutical and Biological Products, Beijing, China

- Performed extensive quality control analysis of herbal medicines by HPLC and TLC.
- Developed HPLC quality control method by quantifying multi-flavonoids in *S. baicalensis*.
- Standardized botanical reference standards by identifying the structures of the compounds based on NMR, MS, IR and UV spectral data and determining the purity of the compounds using HPLC and TLC techniques.
- Involved in HPLC fingerprint method development for *Panax ginseng*.

02/97-09/00, Research Assistant, Hong Kong University of Science and Technology, HK

- Performed bioassay guided isolation and structure determination of pure chemical compounds from *Hyoscyamus. niger, Euptelea pleiospermum* and *Rorippa montana*.
- Developed and validated HPLC and CE methods for the quantitative analysis of scopolamine and atropine in *Hyoscyamus niger* seeds.

07/95-12/96, Research Assistant, Hong Kong University of Science and Technology, HK

- Developed and validated HPLC methods for the quantitative analysis of lignans in *Schisandra chinensis*.
- Performed bioassay guided fractionation, isolation and structure determination of pure chemical compounds from *Schisandra chinensis* and *Polygonum multiflorum*.

09/89-07/95, Assistant Professor, National Institute for the Control of Pharmaceutical and Biological Products, Beijing, China

- Performed extensive quality control analysis of herbal medicines using HPLC and TLC.
- Developed and validated quality control methods for four different finished Chinese herbal medicines using HPLC and TLC-densitometry by quantifying and identifying the active compounds in the drugs.
- Standardized botanical reference standards by identifying the structures of the compounds based on NMR, MS, IR and UV spectral data and determining the purity of the compounds using HPLC and TLC techniques.

07/87-03/89, Research Assistant, Institute of Materia Medica Chinese Academy of Medical Sciences, Beijing, China

- Performed isolation and structural characterization of flavonoids isolated from *Veronica linariifolia*.

08/82-08/86, Research Assistant, Shanxi Institute of Materia Medica, Taiyuan, China

- Conducted natural product chemistry and herbal medicine quality control analysis.

Peel reviewed Publications:

1. C. Gyllenhaal, M.R. Kadushin1, B. Southavong, K. Sydara, S. Bouamanivong4, M. Xaiveu, L.T. Xuan, N.T. Hiep, N.V. Hung, P.K. Loc, L.X. Dac, T.Q. Bich, N.M. Cuong, H.M. Ly, H.J. Zhang, S.G. Franzblau, H. Xie8, M.C. Riley, B.G. Elkington1, H.T. Nguyen1, D.P. Waller1, C.Y. Ma, P. Tamez, G.T. Tan, J.M. Pezzuto, and D.D. Soejarto, "Ethnobotanical approach versus random approach in the search for new bioactive compounds: Support of a hypothesis" *Pharmaceutical Biology*, **2012**; 50(1): 30–41
2. Fred Musoke sebisubi; Olwa Odyek; William Wilberforce Anokbonggo; Jasper Ogwal-Okeng; Esperanza J. Carcache-Blanco; Cuiying Ma; Jimmy Orjala; Ghee T. Tan, "Antimalarial Activeity of *Aspilia pruliseta*, a Medicinal Plant from Uganda", *Planta Med*, **2010,** 76:1-3.
3. Ma CY; Musoke SF; Tan GT; Sydara K; Bouamanivong S; Southavong B; Soejarto DD; Fong HH; Zhang HJ, "Study of antimalarial activity of chemical constituents from *Diospyros quaesita*", *Chem Biodivers*, **2008** Nov;5(11):2442-8.
4. Ma, C. Y.; Zhang, H. J.; Tan, G. T.; Hung, N. V.; Cuong, N. M.; Soejarto, D. D.; Fong, H. H. S., "Antimalarial Compounds from *Grewia bilamellata*", *Journal of Natural Products*, **2006**, 69 (3): 346-350.
5. Zhang, H. J.; Ma, C. Y.; Hung, N. V.; Cuong, N. M.;.Tan, G. T.; Santarsiero, B. D.; Mesecar, A. D.; Soejarto, D. D.; Pezzuto, J. M.; Fong, H. H. S., "Miliusanes, A Class of Cytotoxic Agents from *Milliusa sinensis*", *Journal of Medicinal Chemistry*, **2006**, 49 (2): 693-708.
6. Soejarto, D. D.; Zhang, H. J; Fong, H. H. S.; Tan, G. T.; Ma, C. Y.; Gyllenhaal, C.; Riley, M. C.; Kadushin, M. R.; Franzblau, S. G.; Bich, T. Q.; Cuong, N. M.; Hiep, N. T.; Loc P. K.; Xuan, L. T.; Hai N. V.; Hung, N. V.; Chien, N. Q.; Binh L. T.; Vu, B. M.; Ly, H. M.; Southavong, B.; Sydara, K.; Bouamanivong, S.; Pezzuto, J. M.; Rose W. C; Dietzman, G. R.; Miller, B. E.; Thuy, T. V., " "Studies on Biodiversity of Vietnam and Laos" 1998-2005: Examining the Impact[#]" , *Journal of Natural Products*, **2006**, 69: 473-481.
7. Ma, C. Y.; Case, R. J.; Wang, Y. H; Zhang, H. J.; Tan, G. T.; Hung, N. V.; Cuong, N. M.;.Franzblau, S. G.; Soejarto, D. D.; Fong, H. H. S.; Pauli, G. F., "Anti-tuberculosis Constituents from the Stem Bark of *Micromelum hirstum*", *Planta Medica,* **2005**, 71: 261-267.
8. He, Z. D.; Ma, C. Y.; Zhang, H. J.; Tan, G. T.; Tamez, P.; Kongmany, S.; Bouamanivong, S.; Southavong, B.; Soejarto, D. D.; Pezzuto, J. M.; Fong, H. H. S., "Anti-malarial Constituents from *Nauclea orientalis*" *Chemistry and Biodiversity*, **2005**, 2: 1378-1386.
9. He, Z. D.; Ma, C. Y.; Tan, G. T.; Sydara K.; Tamez, P.; Southavong, B.; Bouamanivong, S.; Soejarto, D. D.; Pezzuto, J. M.; Fong, H. H. S., Zhang, H. J "Rourinoside and rouremin, antimalarial constituents from *Rourea minor*" *Phytochemistry*, **2006,** 67 (13):1378-84.
10. Soejarto, D. D.; Fong, H. H. S.; Tan, G. T.; Zhang, H. J.; Ma, C. Y.; Franzblau, S. G.; Gyllenhaal, C.; Riley, M. C.; Kadushin, M. R.; Pezzuto, J. M.; Xuan, L. T.; Hiep, NT.; Hung, N. V.; Vu, B. M.; Loc P. K.; Dac L. X.; Binh L. T.; Chien, N. Q.; Hai N. V.; Bich, T. Q.; Cuong, N. M.; Southavong, B.; Sydara, K.; Bouamanivong, S.; Ly HM, Thuy, T. V.; Rose W. C.; Dietzman, G. R., "Ethnobotany/ethnopharmacology and mass bioprospecting: issues on intellectual property and benefit-sharing" *Journal of Ethnopharmacology*, **2005**, 100 (1-2): 15-22.
11. Jutiviboonsuk, A.; Zhang, H. J.; Tan, G. T.; Ma, C. Y.; Hung, N. V.; Cuong, N. M.; Bunyapraphatsara, N.; Soejarto, D. D.; Fong, H. H. S., "Bioactive Constituents from the Roots of *Bursera tonkinensis*" *Phytochemistry***, 2005**, 66: 2745-2751.
12. Zhang, H. J.; Kongmany S.; Tan, G. T.; Ma, C. Y.; Southavong, B.; Soejarto, D. D.; Pezzuto, J. M.; Fong, H. H. S., "Bioactive Constituents from *Asparagus cochinchinensis*", *Journal of NaturalProducts,* **2004**, 67: 194 - 200.
13. Yang, H.; Protiva, P.; Cui, B.; Ma, C. Y.; Baggett, S.; Hequet, V.; Mori, S.; Weinstein, B.; Kennelly, E. J., "*New Bioactive Polyphenols from Theobroma gradiflorum* (Cupuacu)", *Journal of Natural Products,* **2003**, 66: 1501-1504.
14. Ma, J,; Luo, X. D.; Protiva, P.; Yang, H.; Ma, C. Y.; Basile, M. J.; Weinstein, I. B.; Kennelly, E. J., "Bioactive Novel Polyphenol from the Fruits of *Manilkara zapota* (Sapodilla)", *Journal of Natural Products,* **2003**, 66:983-986.
15. Ma, C. Y.; Dai, B. C.; Lin, R. C., "Quantitative analysis of four flavonoids by **HPLC** and fingerprint study of flavonoids in *Scutellaria baicalensis", Chinese Journal of Pharmaceutical Analysis*, **2003**, 23: 83-86.

16. Ma, C. Y.; Liu, W. K.; Che, C. T., "Lignanamides and non-alkaloidal components of *Hyoscyamus niger* seeds", *Journal of Natural Products,* **2002**, 65: 206-209.
17. Ma, C. Y.; Willianms, I. D.; Che, C. T., "Withanolides from *Hyoscyamus niger* seeds", *Journal of Natural Products,* **1999**, 62: 1445-1447.
18. Ip, S. P.; Ma, C. Y.; Che, C. T.; Ko, K. M., "Methylenedioxy group as determinant of schisandrin in enhancing hepatic mitochondrial glutathione in carbon tetrachloride-intoxicated mice", *Biochemical Pharmacology*, **1997**, 54: 317-319.
19. Ip, S. P.; Tse, A. S. M.; Ma, C. Y.; Poon, M. K. T.; Ko, K. M., "Antioxidant activities of *Polygonum multiflorum* Thunb.*, in vivo and in vitro*", *Phytotherapy Research*, 1997, 11: 42-44.
20. Ma, C. Y.; Chen, D. C., "Determination of alkaloids in *Hyoscyamus niger* by reverse phase ion-pair **HPLC** as well as TLC identification of *H. niger* and *Hygrophyla megalantha*", *Chinese Journal of Pharmaceutical Analysis*, **1996**, 16: 119-122.
21. Ma, C. Y.; Lu, J., "Quantitative analysis of geniposide in Tongkangtai* oral liquid by TLC-densitometry and identification of *Lonicera japonica* and *Scutellaria baicalensis* in the medicine by TLC", *Chinese Journal of Pharmaceutical Analysis*, **1995**, 15: 48-49.
22. Ma, C. Y., "Studies on quality control of Xiao-shi* oral liquid", *Chinese Traditional and Herbal Drugs*, **1995**, 26: 524-525.
23. Zhao, S. J.; Ma, C. Y., "Studies of quality control of Qingre-Jiedu* oral liquid", *Chinese Traditional and Herbal Drugs*, **1993**, 24: 242-243.
24. Ma, C. Y.; Yang, D. M.; Zhu, K. X.; Yang, J. S; Yu, D. Q., "Studies on chemical constituents of *Veronica linariifolia"*, *Acta Pharmaceutica Sinica*, **1991**, 26: 203-208.
25. Ma, C. Y.; Tang, Q. J., "Analysis about the bulletin of random examination results of drug quality all over the country in 1989", *Zhong Guo Yao Shi,* **1990**, 6: 28-30.
26. Ge, X. Y.; Shi, G. F.; Ma, C. Y., "General research situation on chemical compositions of *Hippophae rhamnoides*", *Chinese Traditional and Herbal Drugs*, **1986**, 17: 42-44.
27. Shi, G. F.; Wei, L. Z.; Di, T. S.; Ma, C. Y., "Studies on the preparing technology and quality control of Kele-Chongji*", *Chinese Traditional Patent Medicine,* **1985**, 7: 12-13.
28. Zhong, C. J.; Zhang, X. C.; Ma, C. Y., "Analysis of α-tocopherol and β-carotene in five vegetable oils by **HPLC**", *Shanxi Journal of Pharmaceutical Research,* **1985**, 2: 27-35.
29. Zhong, C. J.; Zhang, X. C.; Ma, C. Y., "Quantitative analysis of medical compositions in *Hippophae rhamnoides* by **HPLC**", *Shanxi Journal of Pharmaceutical Research,* **1985**, 2: 15-22.
30. Di, T. S., Ma, C. Y., ."Distingguish of white cotton material of Kuan-Dong-Hua and fungus", *Traditional Chines Medicinal Journal*, **1985**, 10: 6.

*Name of Finished Chinese Herbal Medicine

Poster and oral presentations:

1. Cuiying Ma, Nam-Cheol Kim, Gabriel I. Giancaspro, "PHARMACOPEIAL METHODS FOR POTENTIAL CONFOUNDING HERBAL MEDICINES", *ASP 2015 Annual Meeting*, July 25 to July 29, **2015,** Copper Mountain, CO, USA

2. C. Ma, S. Bhavaraju; J. Belsky; B. Jones, W. Koch, "Structural Characterization and Purity Determination of USP Vinpocetin Related Compound C Reference Standard", *ASP 52nd Annual Meeting*, July 30 to August 3, **2011,** San Diego, California, USA

3. C. Ma, G. Huang, B. Jones, W. Koch, "Characterization of Botanical Reference Standards Containing Proanthocyanidins and Anthocyanidins", *AAPS Annual Meeting and Exposition,* Nov. 14-18, **2010**, New Orleans, Louisiana, USA

4. C. Ma, "Characterization of Botanical Reference Standards Containing Proanthocyanidins and Anthocyanidins", oral presentation as a *USP RMD Seminar*, April **2010**, USP Rockville.

5. Ma, C. Y.; Musokl, F.; Tan, G. T.; Zhang, H. J.; Sydara, K.; Bouamanivong, S.; Southavong, B.; Soejarto, D. D.; Fong, H. H. S., "Anti-malarial Compounds of *Adinandra rubropunctata*" *47th Annual meeting of the ASP*, July, **2006**, Washington DC, USA.

6. Ma, C. Y.; Zhang, H. J.; Tan, G. T.; Hung, N. V.; Cuong, N. M.; Soejarto, D. D.; Fong, H. H. S., "Antimalarial Compounds from *Grewia bilamellata*", *46th Annual meeting of the ASP*, July 23-27, **2005**, Corvallis, Oregon USA.

7. Zhang, H. J.; Ma. C. Y.; Tan, G. T.; Hung, N. V.; Cuong, N. M.; Soejarto, D. D.; Fong, H. H. S., "Bioactive Constituents from *Radermachera Boniana*", *46th Annual meeting of the ASP*, July 23-27, **2005**, Corvallis, Oregon USA.

8. Ma, C. Y.; Case, R. J.; Wang, Y. H; Zhang, H. J.; Tan, G. T.; Hung, N. V.; Cuong, N. M.;.Franzblau, S. G.; Soejarto, D. D.; Fong, H. H. S.; Pauli, G. F., "Anti-tuberculosis Constituents from the Stem Bark of *Micromelum hirstum*", *45th Annual meeting of the ASP*, July, **2004**, Phoenix, UTAH, USA. **2005**, 71: 261-267.
9. He, Z. D.; Ma, C. Y.; Kongmany S.; Bouamanivong, S.; Zhang, H. J.; Tan, G. T.; Tamez, P.; Southavong, B.; Soejarto, D. D.; Pezzuto, J. M.; Fong, H. H. S., "New Anti-malarial Compounds from *Rourea minor*" *44th Annual meeting of the ASP*, July 12-16, **2003**, Chapel Hill, NC USA.
10. Yang, H.; Protiva, P.; Cui, B.; Ma, C. Y.; Baggett, S.; Hequet, V.; Mori, S.; Weinstein, I. B.; Kennelly, E. J., "New Bioactive Flavonoids from *Theobroma gradiflorum* (Cupuacu)", " *44th Annual meeting of the ASP*, July 12-16, **2003**, Chapel Hill, NC USA.
11. Li, W. K.; Xu, X. D.; Zhang, H. J.; Ma, C. Y.; Fong. H. H. S.; Van Breman, R. B.; Fitzloff, J. F., "Chemical Constituents from *Andrographis paniculata Nees*" *44th Annual meeting of the ASP*, July 12-16, **2003**, Chapel Hill, NC USA.
12. Ma, C. Y.; Che, C. T., "Constituents of *Euptelea pleiospermum*", *43rd Annual Meeting of the ASP and 3rd Monroe Wall Symposium*, July 27-31, **2002**, New Brunswick, NJ.
13. Ma, C. Y. Che, C. T., "Non-alkaloidal compositions of *Hyoscyamus niger* seeds", ***2000*** *Years of Natural Products Research –Past, Present and Future-*, July 26-30, 1999, Amasterdam, The Netherlands.
14. Ma, C. Y. "Quantitative analysis of protocatechualdehyde in Danxin capsule by TLC- densitometry", oral presentation in *Proceedings of Third National Symposium on Plate Chromatogram of Chinese Chemical Association*, Oct., **1992,** Dalian, China.

Published Books:

1. "Research for Quality Control of Finished Chinese Traditional Medicine and Standard Materials"
   Chief Editor: Baoqing Wang
   Vice Editors: Dechang Cheng; Jing Lu; Jingbin Wu; Shining Yang; Guangxiong Zhang
   Coauthors: Yan Liu; Qingsheng Zhang; Jingai Tian; Mingfeng Che; Jian Su; Sujie Zhao; Cuiying Ma; Yu Lan; Yin Yang; Shangmei Shi; Tianbin Gao; Xiaoli Su; Ming Cheng; Wei Zhang; Long Ni; Hongbo Li
   China Medicinal Science Press, March **1994**
   ISBN 7-5067-0964-3/R • 0856

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2. "Work Manual of Chemical Standard Materials Used in Chinese Traditional Medicine"
   Chief Editor: Dechang Cheng
   Vice Editors: Jing Lu; Baoqing Wang; Ping Qi;
   Coauthors: Jing Lu; Yan Liu; Xiaoli Su; Yin Yang; Wenji Su; Gangli Wang; Shuangcheng Ma; Jiandong Yu; Long Ni; Liying Zhang
   People Participated In Research Work:
   Cuiying Ma; Sujie Zhao; Qingsheng Zhang; Jian Su; Jingai Tian; Shangmei Shi; Tianbin Gao; Yu Lan; Hua Yan
   China Medicinal Science Press, November **1999**
   ISBN 7-5067-2135-X

PALMA ANN MARONE, Ph.D.

1804 Keelingwood Lane
Virginia Beach, VA 23454
(757) 450 7191
PAMarone@verizon.net

Work Experience

2014 – Present **Toxicology and Pathology Associates LLC, Virginia Beach, VA**
Independent customized full service food product safety and regulation services to the food, beverage and dietary supplement industry in compliance with FDA directorates and GRAS notification

2014 - Present **Adjunct Professor, Department of Pharmacology and Toxicology, Virginia Commonwealth University, Richmond, VA, USA**
Academic – Toxicology course lecturer and student career assistance

2013-2014 **Eurofins/Product Safety Labs: Chief Scientific Officer and Executive Director, Toxicology, Dayton, NJ, USA**

Scientific/Technical

- Head Toxicologist for Eurofins NA, major global contract research organization
- Certified European Registered Toxicologist
- Toxicologic risk assessment officer for Eurofins Scientific
- Technical/Scientific Director for Eurofins/Product Safety Labs toxicology
- Toxicological study design- specialization in food safety testing
- Direct technical oversight, program/project development and toxicologic assessment of preclinical testing for dietary supplement and food (initiated at PSL), agrochemical and industrial chemical, cosmetic, biotechnology, consumer products, and medical device (initiated at PSL) industries
- Specialization in dietary supplement and nutraceutical safety testing
- Program Director for national and inter/multi-national trade food consortia and associations
- Program Director for multi-national, Fortune 500, food, industrial and agrochemical clients
- Initiated, developed, implemented and trained personnel for chronic, reproductive/developmental, immunologic, neurologic and genetic toxicology, and endocrine disruptor *in vivo* repeated-dose toxicology capabilities
- Pathological (clinical and anatomic) evaluation determination and support
- Evaluated and implemented electronic data acquisition system (Provantis) for lab; data analysis
- Review and prepare protocols, internal and consultation reports, SOPs, peer-reviewed manuscripts
- Train and mentor technical personnel

Regulatory

- NDI and GRAS dietary supplement notifications with manuscript preparation and successful publishing record in coordination with Food Safety Modernization Act (2011)
- Specialist in Food and Beverage on-site safety testing for industry consortia (FEMA, colorants, enzymes, botanicals, additives, packaging, etc.) under FDA, ISO, OECD, EFSA, EU, JECFA, FSANZ, FAO/WHO, HACCP
- Ensure compliance with ISO 10993, ISO 17025, ISO 13485, USDA, AALAC, DEA, OSHA
- Provide technical and strategic leadership for preclinical toxicology testing for US (FDA, EPA) and global (China, Japan, EU, Brazil) regulatory submission
- FDA- approved medical device and consumer products risk assessment
- Liaison with governmental, regulatory agencies and potential partners
- Monitor changes to regulatory guidelines to insure all methods and procedures are current
- Monitor technical advancements and implement

Business Development/ Management

- Development of multi-million dollar, globally-recognized dietary ingredient and nutritional supplement (human and pet industries), consumer product and cosmetic safety testing
- Proven revenue enhancement of sister Eurofins business units
- Designated central contact for Eurofins Pharma, Food and Agrochemical Science Divisions
- Client introduction and establishment; toxicologic and nutritional industry trade show and conference representative
- Direct report to President
- Over fifty direct on-site technical reports, Toxicology
- Internal and client start-to-finish project work order process for training, implementation and documentation ; SOP review and technical finalization
- Participate in the recruitment and professional development of qualified high-level scientific personnel
- Evaluate monthly scientific performance and report to President
- Coordinate scientific business plan and projections; responsible for operating, staffing and capital spending budgets

2008-2013 Eurofins/Product Safety Labs: Executive Director of Toxicology, Dayton, NJ, USA
2006-2008 Eurofins/Product Safety Laboratories: Director of Toxicology, Dayton, NJ
2005-2006 Eurofins/Product Safety Laboratories: Senior Study Director, Dayton, NJ

2003 – 2005 BioDeliverySciences International, Inc., Newark, NJ:
Director, Physical Biochemistry and Imaging Analysis/Pathology and Toxicology

Development and characterization of biophysical determinants of cochleate structure using synchrotron, Small angle x-ray scattering TEM, SEM and confocal microscopy for preclinical and clinical drug platform of a novel phosphatidylserine-based drug delivery system leading to IND and patent of encochleated Amphotericin B.

2000-2001 Eastern Virginia Medical College, Norfolk, VA:
Director, Imaging Core Laboratory, Department of Pathology

Directed core microscopic laboratory facility for support of basic research and clinical services using fluorescent, light, confocal laser, scanning and transmission electron microscopy under CAP certification.

1993-2001 Argonne National Laboratories, Argonne, IL: Scientist, Chemistry Division

Mechanisms and characterization of membrane protein and novel drug delivery systems using Intensed Pulse Neutron Source neutron and x-ray scattering, NMR, MALDI-TOF and Advanced Photon Synchrotron Source; crystallization of photosynthetic apparatus *Rhodobacter sphaeroides* energy capture and conversion system for commercial application.

1988-1992 Aquinas College at Newton, Newton, MA:
Director, Biotechnology Assistant Program & Professor

Developed and procured funding from the state of Massachusetts for a Biotechnology continuing education certificate training program. Development of partnerships with local industry in the Boston area for internships. At completion students were qualified to work as laboratory technicians in the industry.
Grants awarded from the State of Massachusetts and Genzyme Corp. NBC Nightly News Feature, June, 1992.

1982-1987 University of Chicago & Univ. of Minnesota, Minneapolis, MN:
Postdoctoral Research Associate

Research training in Reproductive Endocrinology investigating regulation of pituitary Growth Hormone synthesis and Pro-opiomelanocortin synthesis and release in the rat. Research on the developmental effects of estrogen and nicotine on endorphin release.

1978-1982 Columbia University, New York, NY:
Graduate Research Assistant, Department of Pathology, Div. Pediatric Pathology
Research on the developmental effects of amniocentesis and oligohydramnios in the fetal rat with specific reference to limb and lung development. Invited talk of the Teratology Society, San Francisco, CA, 1981.
Thesis Title: "The Morphologic and Physiologic Effects of Oligohydramnios: A Model for Limb Development Deformities in the Rat" – Research Advisors: William A. Blanc, M.D. and Henry J. Vogel, Ph.D.

1975-1978 SmithKline and French Laboratories, Philadelphia, PA: Study Director
Scientist, Department of Reproductive and Developmental Toxicology
Conducting and reporting on toxicologic assessment of drugs for F.D.A. under G.L.P. guidelines. Duties included gavage, IV, IN, IP dosing regimens, Segments I, II, III, necropsy of mice, rats, rabbits, dogs, skeletal and visceral clearing and determination, data management. analysis and final F.D.A. report submission.

Education
Ph.D. – Pathology, Columbia University, College of Physicians and Surgeons, NY, NY
M.Phil. – Pathology, Columbia University, College of Physicians and Surgeons, NY, NY
M.A. – Pathology, Columbia University, College of Physicians and Surgeons, NY, NY
B.S. – Biology, Villanova University, Villanova, PA

Patents
"Nanoparticle Cochleates", Susan Gould Fogerite, Raphael J. Mannino, Palma A. Marone. US Provisional Application 60/578,000, filed June 7, 2004, issued, 2005.

"Cochleate Structures", Patrick Ahl, Palma Ann Marone, Sara Krause-Elsmore, Susan Gould-Fogerite, Raphael J. Mannino. Application filed May 17, 2004.

Certification
Eurotox European Registered Toxicologist (UK Registry)

Editorial Boards
Food and Chemical Toxicology (Associate Editor)
International Journal Toxicology (Editorial Board, Associate Editor)
Elsevier CRC Press Series Editor
Regulatory Toxicology and Pharmacology - Reviewer

Professional Affiliations (full member)
American Chemical Society
American College of Nutrition - Fellow
American College of Toxicology- Educational Committee (elected); STP Liaison Educational Committee; Mentor
American Society for Nutrition (ASN) – Global Nutritional Sciences Council
Food and Drug Law Institute – Contributing member/presenter Food Week; Primer Editorial Advisory Board
Institute of Food Technologists – Professional member
International Association for Food Protection, Food Chemical Hazards and Food Allergy Professional Development Group Global Harmonization Initiative
Microscopy Society of America
Society of Toxicologic Pathology (STP) – Educational Committee
Society of Toxicology (SOT) – Toxicologists without Borders; Mid-Atlantic Section; Women in Toxicology; Food Specialty Section – Elected Councilor
Teratology Society – FASEB Scientific Policy Representative

Invited Talks & Lectures
Most recent:
Villanova University, Your career in Toxicology, April, 2007
Supply Side West, Vendorworks, Nutritional Product Development, November, 2010
Institute of Food Technologists, Panel Session, Global Products Require Global Strategies, June, 2011
Supply Side West, Vendorworks, Nutritional Product Development, November, 2011
Supply Side West, Vendorworks, Implementing an Effective Testing Program for Salmonella Control, Food Safety and Identity Verification, October, 2011
Food Drug Law Institute, New Dietary Ingredient (NDI) Regulation and Compliance: An FDLI Workshop, December 12, 2011
Supply Side West, Making the Switch from Supplements to Food, November 8, 2012
Panelist, Women in Leadership, Villanova School of Business, March 17, 2014
Food Drug Law Institute, Food Week, Marketing Trends – How America's Food Choices are Changing, February 24, 2015

Advisory Boards, GRAS Panels and Honors
Consultant, Scientific Advisor and GRAS panelist for Nutrition Divisions of several Fortune 500 companies, 2012-present
EPA Science Advisory Board, Chemical Safety Subcommittee, 2013-present
FDA Science Advisory Board, 2013-present
American Society of Nutrition, Global Nutrition Council, 2013-present
Life Science Leader Award for Excellence/Quality in Contract Research - 2013
Food Drug Law Institute – Editorial Advisory Board, 2015-present
NSF International Joint Committee on Generally Recognized as Safe Publicly Available Standard, Voting Member, 2015-present; GMA Affiliate
Teratology Society – Federation of American Society for Experimental Biology (FASEB) Science Policy Representative, 2015 - present

Continuing Education; Roundtable Discussions
Study Director Training, American College of Toxicology, Williamsburg, VA, November, 2005
Radiation Safety Training (DOE), Argonne National Laboratory, Argonne, IL, November, 2004
Food and Drug Law Institute, Introduction to Food Law, Washington, DC, February 5-8, 2013
Pathology Endpoints in Endocrine Disruptor Screening-Society of Toxicologic Pathology, NTP, March 21, 2013
Inhalation Toxicology: Current Risk Perspectives, Mid-Atlantic Society of Toxicology, Edison, NJ, October 23, 2013
FutureTox II, Society of Toxicology, Raleigh, NC, January 16-17, 2014
Analyzing Risk: Principles, Concepts and Applications, Harvard School of Public Health, March 10-13, 2014
International Organization for Standardization (ISO) 17025, March 18-20, 2014
State-of-the-Science Workshop to Discuss Issues Relevant for Assessing the Health Hazards of Formaldehyde Inhalation, EPA, NCEA, April 30-May 1, 2014
What are the independent and interactive roles of GI microbiota and nutrition in modifying chronic disease,. Nuritional Sciences Council, ASN, June 17, 2015.
FASEB Roundtable on Scientific Rigor and Reproducibility of Research Using Mouse Models, Bethesda MD, August 12, 2015
Recent Developments in EMA/Food Fraud Research and Tools, National Center for Food Protection and Defense, September 11, 2015
FSMA Final Rule for Preventive Controls for Human Food, IFT/FDA, September 24, 2015
FASEB Roundtable on Rigorous and Reproducible Research, Community Stakeholders, Bethesda, MD, October 7, 2015
FDA/SOT, Colloquium-A Path Forward for Computational and In Vitro Methods for Food Ingredient Assessments, College Park, MD, October 13, 2015
USDA Food Allergens, October 14-15, 2015
Joint Committee on Generally Recognized as Safe Publicly Available Standard, NSF International, Washington DC, October 29, 2015

Pathology Peer Review and the OECD Guidance on the GLP Requirements: A Review of the Review: ACT December 16, 2015.
FASEB: Capitol Hill Day. March 2-3, 2016.

Cooperative Development
Internship Mentor and Sponsor, Rutgers University, and Villanova University 2006-present
Women's Professional Network, Villanova University
SciPinion –Toxicology Selected Peer Reviewer

Publications

Most recent/relevant:

Marone, P.A. (2016). Food Safety: Marketing Trends Intended for Consumer Awareness and Partnership. In: Developing Functional Food and Nutraceutical Products, D. Bagchi, S. Nair, Eds. Academic Press, Elsevier, in press.

Marone, P.A. (2016). Food Safety and Regulatory Concerns, Chap 7. In: Insects as Sustainable Food Ingredients: Production, Processing and Applications. A. T. Dossey, J. A. Morales-Ramos, M. Guadalupe Rojas, Eds. Elsevier, in press.

Marone, P.A., V.L. Birkenbach, A.W. Hayes (2015). Newer approaches to identify potential untoward effects in functional foods. Int J Toxicol. Epub 9 December 2015. Doi: 10.1177/1091581815616781.

Marone, P.A., K.E. Birkenbach (2016). Safety of Functional Foods, Chap 2. In: Nutraceuticals and Functional Foods in Human Health and Disease Prevention, D. Bagchi, H.G. Preuss, A. Swaroop, Eds. CRC Press, Francis and Taylor, Boca Raton, FL. Pp9-42.

Marone, P.A. (2016). Nutraceuticals in Cosmeceuticals, Chap 32. In: Nutraceuticals and Functional Foods in Human Health and Disease Prevention, D. Bagchi, H.G. Preuss, A. Swaroop, Eds. CRC Press, Francis and Taylor, Boca Raton, FL. Pp593-605.

Swaroop, A., M. Bagchi, P. Kumar, H.G. Preuss, K. Tiwari, P.A. Marone, D. Bagchi (2014). Safety, efficacy and toxicological evaluation of a novel, patented anti-diabetic extract of *Trigonella Foenum-Graecum* seed extract (Fenfuro^{TM})**.** Tox. Mech. Meth. 24(7):495-503. Doi: 10.3109/15376516.2014.943443.

Szabo N.J., R.A. Matulka, P.A. Marone, M.R. Bauter, T. Chan, S. Franklin, J.R. Carney, S.L. McQuaid, W. Rakitsky, R. Green, P. Licari (2014) Safety evaluation of oleic-rich triglyceride oil produced by a heterotrophic microalgal fermentation process. Food Chem. Tox. 65:301-311.

Marone, P.A., W.C. Hall, A. W. Hayes (2014). Reassessing the two-year rodent carcinogenicity bioassay: A review of the applicability to human risk and current perspectives. Reg. Tox. Pharm. 68:108-118**.** Doi: 10.1016/j.yrtph.2013.11.011.

Heimbach, J.T., H. Egawa, P.A. Marone, M. R. Bauter and E. Kennepohl (2013). Tamarind seed polysaccharide: A 28-day dietary study in Sprague-Dawley rats. Int. J. Tox. 32(3):198-208.

Moran, D.L., P. A. Marone, M.R. Bauter, and M.G. Soni (2013).Safety assessment of Apoaequorin, a protein preparation: Subchronic toxicity study in rats. Food Chem. Tox. 57:1-10.

Lynch, B., A. Lau, N. Baldwin, H. Hofmann-Huther, M.R. Bauter and P.A. Marone (2013). Subchronic and reproductive toxicity of whole dried Hoodia parviflora aerial parts in the rat. Food Chem. Tox. 56:313-324.

Lynch, B., A. Lau, N. Baldwin, H. Hofmann-Huther, M.R. Bauter and P.A. Marone (2013). Genotoxicity of dried Hoodia parviflora aerial parts. Food Chem. Tox.55:272-278.

Schmitt, D., N. Tran, J. Peach, M. Bauter and P. Marone. (2012) Toxicological evaluation of DHA-rich algal oil Genotoxicity, acute and subchronic toxicity in rats. Food Chem Tox. 50(10):3567-3576.

Marone, P.A., M. Bauter, H. Hofman-Huther, R.J. Gahler and S. Wood. (2012) Toxicologic evaluation of oregano oil. Int. J. Nutr. Met. 46(6):83-89.

Dolan, L.C., E. Gietl, U.LaCognata, V. Landschutze, P.A. Marone and R.A Matulka. (2012) Safety evaluation of fibermalt. Food Chm. Tox. 50:2515-2523.

Henderson, R.G., J. Durando, A. Oller, D.J. Merkel, P.A. Marone and H. Bates. (2012) Acute toxicity of nickel compounds. Reg. Tox. Pharm. 62:425-432.

Marone, P.A., M. Bauter, H. Hofman-Huther, R.J. Gahler and S. Wood. (2011) Toxicologic evaluation of a plant food concentrate. Int J. Nut. Met. 3(5):58-64.

Fedorova-Dahms, I. P.A. Marone, M. Bauter and A.S. Ryan (2011) Safety evaluation of DHA-rich algal oil from Schizochytrium sp. Food Chem. Tox. 49:3310-3318.

Fedorova-Dahms, I. P.A. Marone, E. Bailey-Hall and A.S. Ryan (2011) Safety evaluation of algal oil from Schizochytrium sp. Food Chem. Tox. 49:70-77.

Bagchi, D. Gupta, M,Yasmin and P. Marone.(2010) Safety and toxicological evaluation of AlgaeCal, a novel plant based calcium supplement. Toxicol. Mech. Meth. 20(6):234-244.

Sreejayan, N., P.A. Marone, F.C. Lau, T. Yasmin, M. Bagchi and D. Bagchi (2010). Safety and toxicological evaluation of a novel chromium (III) dinicocysteinate complex. Toxicol. Mech. Meth. 20(6):321-333.

Heimbach, J.T., P.A. Marone, J.M. Hunter, B.V. Nemzer, S.M. Stanley and E. Kennepohl (2010). Safety studies on products from whole coffee fruit. Food Chem. Tox. 48(8-9):2517-2525.

Marone, P.A., F.C. Lau, R.C. Gupta , M. Bagchi and D. Bagchi (2010). Safety and toxicological evaluation of undenatured type II collagen. Toxicol. Mech. Meth. 20: 175-189.

Marone, P.A., M. Lyon, R. Gahler, C. Donath, H. Hofman-Huther, and S. Wood (2009). Genotoxicity studies of polyglycoplex (PGX): A novel dietary fiber. Int. J. Tox. 28:318-331.

Matulka, R.A., M. Lyon, S. Wood, P.A. Marone, D. J. Merkel and G.A. Burdock. (2008). The safety of polyglycoplex® (PGX®) as shown in a 90-day rodent feeding study. Nut. Jour. 8:1-11.

Grover, G.J., P.A. Marone, L. Koeztner and D.Seto-Young. (2008) Physiological function, structure, and control of the mitochondrial F1F0 ATP synthase in normal and ischemic myocardium. Int. J. Biochem. Cell Biol. 40:2698-2701.

Marone, P.A, J. F. Borzelleca, D. Merkel, J. T. Heimbach and E. Kennepohl. (2008) 28-Day toxicity study of luo han fruit concentrate in Hsd:SD® rats. Food Chem. Tox. 46:910-919.

Schmitt, D., N. Tran, S. Riefler, J. Jacoby, D. Merkel, P. Marone and N. Naouli. (2008) Toxicologic evaluation of modified gum acacia: Mutagenicity, acute and subchronic toxicity. Food Chem. Tox. 46/3; 1048-1054.

Grover, G,, and P.A. Marone. (2007) Pharmacological studies with the selective mitochondrial F1F0 ATP hydrolase inhibitor BMS-199264 in ischemic myocardium: Is the switch from an ATP synthase to a hydrolase merely a chemical reaction run in reverse? Recent Res. Devel. Physiol, 4: 4:45-64.

Marone, P.A., S.K. Elsmore, R. Lu and R. J. Mannino. (2004) Cochleate ultrastructure is dependent upon phospholipids composition and drug-PS molecular interaction. Micros. Microanal. 10(1) Suppl.

Tiede, D.M., K. Littrell, P.A. Marone, R. Zhang, P. Thiyagarajan (2000). Solution structure of a biological bimolecular electron transfer complex: Characterization of the photosynthetic reaction center-cytochrome c2 protein complex by small angle neutron scattering. J. Appl Crystallog. 33: 560-564.

Zhang, R., P. A. Marone, P. Thiyagarajan, D. M. Tiede (1999). Structure and structural fluctuations of n-alkyl-B-D-glucopyranoside micelle determined by X-ray and neutron scattering. Langmuir. 15 (22):7510-7519.

Marone, P. A., P. Thiyagarajan, A. Wagner, D. M. Tiede (1999). Effect of detergent alkyl chain length on crystallization of a detergent-solubilized membrane protein: Correlation of protein-detergent particle size and particle-particle interaction with crystallization of the photosynthetic reaction center from Rhodobacter spheroides. Journal of Crystal Growth. 207:214-225.

Marone, P. A., P. Thiyagarajan, A. Wagner, D. M. Tiede (1998). The association state of a detergent-solubilized membrane protein measured during crystal nucleation and growth by small angle neutron scattering. Journal of Crystal Growth. 191:811-819.

Tiede, D. M., P. A. Marone, P. Thiyagarajan (1997). Structure of the Rhodobacter sphaeroides reaction center-cytochrome C2 complex in solution. Biophysical Journal. 72, 248a.

Tiede, D.M, Vazquez, J., Cordova, J., Marone, P.A. (1996). Time-Resolved Electrochromism Associated with the Formation of Quinone Anions in the Rhodobacter sphaeroides R26 Reaction Center. Biochem. 35(33):10763-10775.

Tiede, D., P .Marone, A. M. Wagner, P. Thiyagarajan (1995). Characterization of photosynthetic supramolecular assemblies using small angle neutron scattering. In “Photosynthesis: From Light to Biosphere I” pp. 431-436. P. Mathis ed. Kluwer Academic Publishers, Dordrecht.

Cuttler, L., B. J. Collins, P. A. Marone, and M. Szabo. (1993) The effect of isobutylmethylxanthine, forskolin and cholera toxin on growth hormone release from pituitary cell cultures of perinatal and mature rats. Endocrine Research. 19:33-46.

Cuttler, L., P. A. Marone and M. Szabo. (1989) The effect of age on prostaglandin E2 stimulation of growth hormone release from cultured rat pituitary cells. Endocrinology. 124:661-666.

Cuttler, L., P. Marone, J. Welsh, B. Collins and M. Szabo. (1988) Perinatal changes in pituitary susceptibility to desensitization by growth hormone-releasing factor. Endocrinology. Abstract of 70th Annual Meeting.

Cuttler, L., P. Marone and M. Szabo. (1989) The effect of age on prostaglandin E2 stimulation of growth hormone release from cultured rat pituitary cells. Endocrinology. 124: 661-666.

Sharp, B., P. Marone, A. S. Levine and J. E. Morley. (1983) Chronic nicotine administration alters neurohypophyseal dynorphin-immunoreactivity levels. Clinical Research. 31:720A.

Sharp, B., P. Marone, K. McAllen and R. Ross. (1983) Age and sex modify the tissue levels and chromatographic profile of rat gamma-3-melanocyte stimulating hormone immunoreactivity. Endocrinology. 318.

Moessinger, A.C., W.A. Blanc, P.A. Marone and D.C. Polsen. (1982) Umbilical cord length as an index of fetal activity: Experimental study and clinical implications. Pediatric Research. 16:109-112.

Marone, P.A., A.C. Moessinger and W.A. Blanc. (1981) Fetal hemorrhages following amniocentesis (AC). Teratology. 23:2.

Moessinger, A.C., P. Marone, L. S. James and W.A. Blanc. (1980) Fetal akinesia and lung growth. Laboratory Investigation. 42, 1:7.

6706 Francis Marion Avenue Dalzell, SC 29040 •803.499.4469 •calabs@webcom.com

Charles Metcalfe

Objective

To operate an independent analytical testing laboratory.

Experience

1998-Present — **Custom Analytics** — Sumter, SC

President & Analytical Chemist

- Analytical method development
- Management of analytical testing facility for OTC, Rx, botanicals and dietary supplement products
- Management of quality control system
- Business development

1995-1998 — **Phibrotech & Custom Analtyics** — Sumter, SC

Analytical Chemist (Phibrotech), President (Custom Analytics)

- Analytical method development for EPA product registrations
- Owner chief analytical chemist for Custom Analytics

1984 – 1995 — **Sara Lee Corporation** — Douglassville, PA

Manager of Analytical Services

- Managed analytical and microbiology services
- Method development and validation
- Competitive product analysis

1981 - 1984 — **Exxon Chemical** — Houston, TX

Synthetic Chemist & Formulator

- Synthesized new organic molecules for enhanced oil recovery
- Developed formuations for enhanced oil recovery

1976 - 1981 — **Oak Ridge National Laboratory** — Oak Ridge, TN

Chemist

- Developed methodology for measuring indoor air pollution
- Monitored air pollutants from coal gasification production
- Biomedical studies on mammals relating to coal gasification pollutants

6706 Francis Marion Avenue Dalzell, SC 29040 •803.499.4469 •calabs@webcom.com

Charles Metcalfe

Education

1975 - 1976 University of Nebraska Lincoln, NE

- Graduate research program in radiochemistry

1971 – 1975 Virginia Polytechnic University Blacksburg, VA

Bachelor of Science, Chemistry

- Undergraduate research programs in radiochemistry & organic synthesis

Professional Associations

- International Aloe Society Council, www.iasc.org
- American Herbal Products Association, www.ahpa.org
- Society of Cosmetic Chemists, www.scconline.org
- AOAC International, www.aoac.ofg

Melissa Meaney Phillips

3907 Joliet Street
Silver Spring, MD 20906
Phone: (517) 214-6967
Email: melmphillips@gmail.com

EDUCATION

Postdoctoral Research Chemist **January 2008 – January 2010**
Organic Chemical Metrology Group, Analytical Chemistry Division, National Institute of Standards and Technology, Gaithersburg, MD
Project: Determination of Marker Compounds in *Vaccinium* Berries
Advisor: Dr. Lane C. Sander

PhD in Chemistry (Analytical) **December 2007**
Department of Chemistry, Michigan State University, East Lansing, MI
Project: Analytical Applications of Fluorescence Quenching
Advisor: Dr. Victoria L. McGuffin

MS in Forensic Chemistry **October2007**
School of Criminal Justice, Michigan State University, East Lansing, MI
Project: Quantitation of Nitrated Explosives by Fluorescence Quenching following Thin-Layer Chromatography
Advisors: Dr. Victoria L. McGuffin, Dr. Jay A. Siegel, Dr. Ruth J.H. Waddell

BS in Lyman Briggs School – Chemistry, *cum laude* **May 2002**
Michigan State University, East Lansing, MI

RESEARCH EXPERIENCE

Program Coordinator, Food& Nutrition **2013 – present**
Organic Chemical Metrology Group, Chemical Sciences Division, National Institute of Standards and Technology, Gaithersburg, MD
- Responsible for development of food Standard Reference Materials (SRMs), including identification and acquisition of materials, coordination of analytical measurements, and documentation of results
- Responsible for oversight of food and nutrition-related research projects

Research Chemist **2008 – present**
Organic Chemical Measurement Science Group, Chemical Sciences Division, National Institute of Standards and Technology, Gaithersburg, MD
- Evaluated various approaches for integration of data from two-dimensional liquid chromatography (LCxLC) for purposes of comparing quantitative data.
- Certified concentrations forwater-soluble vitamins in food and dietary supplement SRMs (e.g.,infant formula, baby food, whole milk powder, whole egg powder, soy flour, and fortified breakfast cereal) using various extraction techniques and analytical methods such asliquid chromatography with isotope-dilution mass spectrometric detection (LC-ID-MS and LC-ID-MS/MS).
- Developed a method for high-precision determination and certified concentrations of choline and carnitine in food-matrix SRMs using microwave digestion and LC-ID-MS.
- Developed methods for high accuracy and high precision determination of ammonium and phosphate in a fertilizer SRM by ion chromatography with conductivity detection (IC-CD).
- Developed methods and certified concentrations ofrelevant active and marker compounds in botanicaldietary supplement and natural product SRMs (e.g. *Vaccinium* berries, soy, St. John's wort) using various

extraction techniques and analytical methods such as liquid chromatography with absorbance (LC-Abs), gas chromatography with ID-MS, IC-CD, and LC-ID-MS.
Developed methods for separation of biomarker isomers by LC-Abs.
Administered a quality assurance program for dietary supplement laboratories, including selection and shipment of samples, communication with participants, collection and analysis of data, and formulation and distribution of final reports.
Tested and catalogued the performance (e.g. selectivity, number of theoretical plates, pressure) of over 300 liquid chromatography (LC) columns.

Research Assistant **2002 – 2007**
Department of Chemistry, Michigan State University
Investigated fluorescence quenching-based methods for detection of nitrated explosives by screening fluorophores based on sensitivity and incorporating them into potential field-ready devices for explosives detection.
Utilized the pH-dependent fluorescence of fluorescein for determination of acids in solution and applied this method to analysis of foods and beverages (juices, wines, and vinegars) and drugs of abuse (γ-hydroxybutyric acid or GHB) by HPLC.
Developed a less toxic method for the separation of explosives by thin-layer chromatography and quantitation based on CCD camera imaging.

TEACHING EXPERIENCE

Teaching Assistant **2002 – 2007**
Department of Chemistry, Michigan State University
Introductory Physical Chemistry I (Recitation Instructor) Physical chemistry of macroscopic systems including gases, liquids, phase diagrams, classic thermodynamics, chemical equilibrium, kinetics, electrolytic solutions and electrochemistry. Fall 2007. Instructor: Dr. John L. McCracken, enrollment: 280.
Advanced Analytical Chemistry (Teaching Assistant) Basic electronics and data acquisition/analysis, electrochemistry, and statistics for chemists. Fall 2006. Instructors: Dr. Merlin L. Bruening and Dr. Gary J. Blanchard, enrollment: 20.
Advanced Analytical Chemistry (Teaching Assistant) Principles of equilibria and applications in analytical methodology including acid-base, complexation, redox reactions, potentiometry and conductometry, solute partitioning in extraction and chromatography, and kinetic methods of analysis. Fall 2005. Instructor: Dr. Victoria L. McGuffin, enrollment: 12.
Quantitative Analysis (Recitation and Laboratory Instructor) Preparation and quantitative analysis of chemical compounds, including solution descriptions, solution chemistry (acid/base, solubility, complexation, oxidation-reduction reactions), titrimetry, volumetric calculations, statistics, chemical equilibrium, activity, buffers, indicators, gravimetric analysis, equilibrium, introductory spectroscopy, and calibration curves. Summer 2003, 2004, 2005, 2006, 2007. Instructor: Dr. Kathryn G. Severin, enrollment: 30.
Analytical Laboratory (Laboratory Instructor) A project-based capstone course in which students solve analytical chemical problems including chromatographic separations (GCMS or HPLC), spectroscopic (AA or XRF) and electrochemical methods (potentiometry or stripping voltammetry), deformulation of a household product using available techniques, computer programming using Labview, and surface and interface analysis. Spring 2003, 2004, 2005, 2006, 2007. Instructors: Dr. Merlin L. Bruening and Dr. Kathryn G. Severin, enrollment: 15-30.
Introductory Physical Chemistry I (Recitation Instructor) Physical chemistry of macroscopic systems including gases, liquids, phase diagrams, classic thermodynamics, chemical equilibrium, kinetics, electrolytic solutions and electrochemistry, and statistical mechanics. Fall 2002, 2003, 2004. Instructor: Dr. Paul F. Mantica, enrollment: 280.

Undergraduate Research Mentor **2004 – 2007**
Department of Chemistry, Michigan State University
Heidi L. Bonta, Michigan State University: Incorporation of Selected Fluorophores into Field-Ready Devices for the Detection of Nitrated Explosives. Fall 2006-Fall 2007.

Jenny M. Borowitz, Michigan State University: Quantitation of Nitrated Explosives by Fluorescence Quenching following Thin-Layer Chromatography. Summer 2005-Spring 2006.
Victoria J. Hall, Huntington University: Selectivity of Fluorescein Quenching by Nitroaromatic Compounds. Summer 2004.

Guest Lecturer **2005**
Forensic Science Workshop, Portage Northern High School, Portage, MI
Developed and presented forensic science-based laboratory experiments to 25 high school science teachers interested in incorporation of such materials into the classroom. Experiments included determination of blood alcohol content using visible spectrophotometry following reaction with a chromophore as well as comparison of soil composition (e.g. limestone, chloride, iron) using observation and visible spectrophotometry following addition of appropriate indicator solutions.

Guest Lecturer **2004**
School of Criminal Justice, Michigan State University
Survey of Forensic Science. Scientific analysis of physical evidence. Four major aspects of physical evidence using real criminal and civil cases: generation of physical evidence by criminal activity; collection and preservation of physical evidence; analysis of physical evidence by forensic science laboratory; presentation of scientific expert testimony in court. Topics covered: Fire/arson and explosives analysis. Fall 2004. Instructor: Dr. David R. Foran, enrollment: 15.

Tutor **2003 – 2005**
Department of Chemistry, Michigan State University
General Chemistry II and Introductory Physical Chemistry.

Undergraduate Teaching Assistant **2001**
Department of Mathematics, Michigan State University
Multivariable Calculus (Recitation Instructor) Vectors in space, functions of several variables and partial differentiation, multiple integrals, line and surface integrals, and Green's and Stokes's theorems. Spring 2001. Instructor: Dr. Khodr M. Shamseddine, enrollment: 600.

PROFESSIONAL AFFILIATIONS

American Chemical Society (ACS)	2004-present
ACS Subdivision on Chromatography and Separations Chemistry	2009-present
AOAC International	2008-present
AOAC International Technical Division on Reference Materials	2011-present
Washington Chromatography Discussion Group	2008-present
American Academy of Forensic Sciences	2004-2008
Society of Electroanalytical Chemistry	2004-2008
Midwestern Association of Forensic Scientists	2007-2008
Society for Applied Spectroscopy	2007-2008

PROFESSIONAL DEVELOPMENT

Participant, The New ISO 13528:2015Workshop on updated statistical methods for PT, Training Course, QuoData GmbH (2016).

Participant, Introduction to Chemometrics, Short Course, Washington Chromatography Discussion Group (2013).

Participant, Comprehensive Two-Dimensional Liquid Chromatography (LCxLC) Short Course, HPLC 2013 (2013).

Participant, Fundamentals of Uncertainty Analysis, National Institute of Standards and Technology Short Course (2012).

Participant, ISO 17043 Proficiency Testing Workshop, National Voluntary Laboratory Accreditation Program (NVLAP) (2011).

Participant, Introduction to Mass Spectrometry and Interpretation of Mass Spectra, Baltimore-Washington Mass Spectrometry Discussion Group Short Course (2010).

Participant, Single Laboratory Validation of Analytical Methods for Dietary Supplements, AOAC Training Course (2008).

Participant, Advanced HPLC Method Development, Washington Chromatography Discussion Group Short Course (2008).

Participant, Creating a Teaching Philosophy You Can Use, Workshop, Teaching Assistant Programs, Michigan State University (2007).

Participant, Talking about Teaching in the Interview, Workshop, Teaching Assistant Programs, Michigan State University (2007).

Participant, Understanding and Handling Classroom Incivility, Workshop, Teaching Assistant Programs, Michigan State University (2007).

Participant, Using Demonstrations to Promote Conceptual Understanding in Chemistry: Making Connections on the Macroscopic, Microscopic, and Symbolic Levels, Lilly Seminar Series, Office of Faculty and Organizational Development, Michigan State University (2006).

Participant, Making Classroom Lectures Interactive and Effective: Engaging Students in Course Content through Interactive Lecturing, Lilly Seminar Series, Office of Faculty and Organizational Development, Michigan State University (2006).

ACADEMIC AND PROFESSIONAL SERVICE

Member, AOAC INTERNATIONAL Editorial Board (2014-present)

Co-Chair, International Vitamin Conference (IVC), Washington, DC (2014)

Member, General Chapters Chemical Analysis Expert Committee, United States Pharmacopeia, Rockville, MD (2010-2015)
Review and approve changes to USP guidelines related to chemical analysis.
Member of Subcommittee on Dietary Supplements.
Member of Expert Panel on Elemental Impurities.

Stakeholder, Working Group Member, and Expert Review Panel Member, Stakeholder Panel on Infant Formula and Adult Nutritionals, AOAC International, Gaithersburg, MD (2010-present)
Provided expert guidance on method performance requirements for determination of vitamins in infant formulas.

Co-Chair, Proficiency Testing Task Force, Stakeholder Panel on Infant Formula and Adult Nutritionals, AOAC International, Gaithersburg, MD (2015-present)
Provided expert guidance in establishing a proficiency testing program for infant formulas and adult nutritionals. Designed studies, including analyte and matrix selection, and established protocols for new program.

Stakeholder, Working Group Member, and Expert Review Panel Member, Stakeholder Panel on Strategic Food Analytical Methods, AOAC International, Gaithersburg, MD (2014-present)
Provided expert guidance on method performance requirements for determination of analytes of interest in foods.

Stakeholder,Working Group Member, and Expert Review Panel Member,Stakeholder Panel on Dietary Supplements, AOAC International, Gaithersburg, MD (2014-present)
Provided expert guidance on method performance requirements for determination of analytes of interest in dietary supplements.

Poster Committee, HPLC Conference, Boston, MA (2010)
Judged poster presentations to help identify a contest winner.

Presenter,Kids Adventures, Carderock Springs Elementary School, Bethesda, MD (2014)
Presented science demonstrations to elementary children.

Presenter,Kids Adventures, Rock Creek Forest Elementary School, Chevy Chase, MD (2009, 2013)
Presented science demonstrations to elementary children.
Developed a lab to demonstrate pH using red cabbage indicator and household chemicals.

Presenter,Kids Adventures, Candlewood Elementary School, Derwood, MD (2013)
Presented science demonstrations to elementary children.

Presenter, USA Science and Engineering Festival, Washington, DC (2012)
Presented science demonstrations to elementary children.

Presenter,Take your Daughters and Sons to Work Day**,** NIST, Gaithersburg, MD (April 2008-2010)
Developed a hands-on activity for 11 – 12 year olds.
Demonstrated chromatography principals using paper chromatography and separating food dye in grape soda.

Secretary, Washington Chromatography Discussion Group (2009-2015)

Board Member, Washington Chromatography Discussion Group (2008-2009)

Poster Committee, HPLC Conference, Baltimore, MD (2008)
Judged poster presentations to help identify a contest winner.

Co-chair and Member, ACS Women in Chemistry, Michigan State Local Section American Chemical Society (Member 2002-2007; Co-Chair 2004-2005)
American Chemical Society's National Chemistry Week. Performed demonstrations. Coordinated 30 demonstration teams in 2004.
Girls Math/Science Conference. Coordinated a hands-on session entitled "Solving Murder with Makeup" for sixth-grade girls. Sponsored by the Capital Area Science and Math Center.
Awards
Sustained Effort toward Excellence in Diversity, Office of Affirmative Action, Michigan State University, 2006.
Outstanding Overall Local Section Women Chemist Committee, American Chemical Society, 2003, 2004, 2005.
Outstanding Outreach to Girls or Young Women Finalist, American Chemical Society, 2003.

Co-chair and Member, Orientation Committee, Department of Chemistry, Michigan State University
Coordinated the orientation schedule for incoming graduate students. Organized and raised funds for a department-wide picnic. (Member 2003, 2004; Co-Chair 2005, 2006)

Graduate Student Representative, Educational Policies Committee, Department of Chemistry, Michigan State University
Modified graduate program course requirements and the written component for Ph.D. candidacy. Integrated a biological chemistry area into the department beginning Fall 2006. (2004-2007)

Co-editor, Teaching Assistant Manual, Department of Chemistry, Michigan State University
Prepared a document to assist incoming graduate students in their first experiences with teaching, including sections on learning styles, the types of students at MSU, tips on being an effective instructor, and a resource guide. (2004, 2006)

Co-author and Presenter, University Policies and Procedures on Teaching, Department of Chemistry, Michigan State University
Authored and delivered presentations designed to supplement the Teaching Assistant Manual, including skits and sections on learning styles, sexual harassment, academic dishonesty, and potential classroom situations. (2004-2006)

Coordinator and Volunteer, Scout Chemistry Merit Badge Day, Michigan State University
Coordinated a series of hands-on experiments and demonstrations in which 50 boy and girl scouts fulfill the requirements for the Chemistry Merit Badge. Administered a web-based sign up, communicated with scout leaders and parents, and organized volunteers. (Coordinator 2005-2006; Volunteer 2004)

State Event Supervisor and Volunteer, Chemistry Lab, Michigan Science Olympiad
Wrote and administered a laboratory practical for high school competition. Topics included thermodynamics, molecular structures, colligative properties, and redox reactions. Coordinated volunteers to set-up, proctor, and grade exams. (State Event Supervisor 2005, 2007; Volunteer 2006)

Graduate Student Representative, Advisory Committee to the Chair, Department of Chemistry, Michigan State University
Advised on departmental issues important to graduate students. Developed goals for other departmental committees. (2005-2007)

Graduate Student Representative, Anti-Discrimination Judicial Board, Michigan State University
Advised the President on issues related to discrimination in policy and procedure. (2005-2007)

Coordinator, "Things Every Scientist Should Know – Outside the Laboratory", Women in Chemistry, Michigan State University
Coordinated speakers on topics including intellectual properties, alternative careers in the sciences, conflict resolution, health and wellness, scientific writing, and financial planning. Received a Local Section Innovative Grant from the American Chemical Society to support the seminar series. (2005)

HONORS AND AWARDS

2015 William P. Slichter Award, NIST
2015 Expert Review Panel of the Year Member, AOAC International
2015 Best Poster Award, Scripps 12th Annual Natural Supplements: An Evidence Based Update
2013 Best Poster Award, HPLC 2013
2007 Educational Merit Fellowship, Department of Chemistry, Michigan State University
2007 Travel Fellowship, School of Criminal Justice, Michigan State University
2007 Travel Fellowship, American Chemical Society Michigan State University Local Section
2006 Educational Merit Fellowship, Department of Chemistry, Michigan State University
2006 Outstanding Graduate Student Woman, Faculty-Professional Women's Association, Michigan State University
2006 Excellence-in-Teaching Citation, College of Natural Science, Michigan State University
2006 Travel Fellowship, The Graduate School, Michigan State University
2005 Tracy A. Hammer Outstanding Graduate Student Award, College of Natural Science, Michigan State University
2005 Educational Merit Fellowship, Department of Chemistry, Michigan State University
2005 Travel Fellowship, Council of Graduate Students, Michigan State University
2002 Recruitment Fellowship, Department of Chemistry, Michigan State University

INVITED PUBLICATIONS

Catherine A. Rimmer, Melissa M. Phillips. "Solution to Certified Reference Material Recipe Challenge." *Anal. Bioanal. Chem.*405 (2013) 6899-6900.

Catherine A. Rimmer, Melissa M. Phillips. "Certified Reference Material Recipe Challenge." *Anal. Bioanal. Chem.* 405 (2013) 4321-4322.

Melissa M. Phillips, Catherine A. Rimmer. "Functional Foods and Dietary Supplements." *Anal. Bioanal. Chem.* 405 (2013) 4323-4324.

Melissa M. Phillips. "Analytical Approaches to Determination of Total Choline in Foods and Dietary Supplements." *Anal. Bioanal. Chem.*403 (2012) 2103-2112.

Hendrik Emons, Jane Weitzel, John Budin, Melissa Phillips, Catherine Rimmer, Donna Zink. "TDRM/TDLM Workshop on Reference Materials and Laboratory Accreditation at the AOAC Annual Meeting 2011." *Inside Laboratory Management*. (Nov/Dec 2011) 6-7.

Melissa M. Phillips. "André M. Striegel, Wallace W. Yau, Joseph J. Kirkland, and Donald D. Bly (Eds.): Modern size-exclusion liquid chromatography. Practice of gel permeation and gel filtration chromatography, 2nd ed." *Anal. Bioanal. Chem.* 399 (2011) 1571-2.

Catherine A. Rimmer, Melissa M. Phillips. "Analytical Tools for the Dietary Supplement and Food Laboratory." *Natural Products Insider* (Mar 7, 2011).

Paula Brown, Melissa Phillips, Catherine Rimmer, Laura Wood. "Quality Focus: GMPs: The Other Pieces of the Puzzle." *Nutraceuticals World*. (Jan/Feb 2011) 28-29.

Paula Brown, Catherine Rimmer, Melissa Phillips, Laura Wood. "Quality Focus: The GMP Puzzle: What's in Your Box?" *Nutraceuticals World*. (Nov 2010) 28-29.

PEER-REVIEWED SCIENTIFIC PUBLICATIONS

Melissa M. Phillips, Mary Bedner, Manuela Gradl, Carolyn Q. Burdette, Michael A. Nelson, James H. Yen, Lane C. Sander, Catherine A. Rimmer. "Liquid Chromatography with Absorbance Detection and with Isotope-Dilution Mass Spectrometry for Determination of Isoflavones in Soy Standard Reference Materials." (in preparation)

Lynn X. Zhang, Carolyn Q. Burdette, Melissa M. Phillips, Catherine A. Rimmer, R. Kenneth Marcus. "Determination of Isoflavone Content in SRM 3238 UsingLiquid Chromatography-Particle Beam/Electron IonizationMass Spectrometry." *J. AOAC Int.* 98 (2015) 1483-1490.

Melissa M. Phillips. "Liquid Chromatography with Isotope-Dilution Mass Spectrometry for Determination of Water-Soluble Vitamins in Foods." *Anal. Bioanal. Chem.* 407(2015) 2965-2974.

Benjamin J. Place, Mallory J. Morris, Melissa M. Phillips, Lane C. Sander, Catherine A. Rimmer. "Evaluation of the Impact of Peak Description on the Quantitative Capabilities of Comprehensive Two-Dimensional Liquid Chromatography." *J. Chromatogr. A* 1368 (2014) 107-115.

Laura J. Wood, Katrice A. Lippa, Melissa M. Phillips, Catherine A. Rimmer, N. Alan Heckert, Stefan D. Leigh, Amanda J. Moors, Rebecca S. Pugh, and Lauren B. Rust. "Breakfast Cereal Sampling Study for Nutritional Elements." *Anal. Bioanal. Chem.*405 (2013) 4569-4578.

Mark S. Lowenthal, Melissa M. Phillips, Catherine A. Rimmer, Paul A. Rudnick, Yamil Simón-Manso, Stephen E. Stein, Dmitrii Tchekhovskoi, Karen W. Phinney. "Developing Qualitative LC-MS Methods for Characterization of *Vaccinium* Berry Standard Reference Materials." *Anal. Bioanal. Chem.* 405 (2013) 4451-4465.

Lane C. Sander, Mary Bedner, David L. Duewer, Katrice A. Lippa, Melissa M. Phillips, Karen W. Phinney, Catherine A. Rimmer, Michelle M. Schantz, Katherine E. Sharpless, Susan Tai, Jeanice B. Thomas, Stephen A. Wise, Laura J. Wood. "The Development and Implementation of Quality Assurance Programs to Support Nutrient Measurements." *Anal. Bioanal. Chem*. 405 (2013) 4437-4441.

Melissa M. Phillips, Katherine E. Sharpless, Stephen A. Wise. "Standard Reference Materials for Foods: A Program Update." *Anal. Bioanal. Chem.* 405 (2013) 4325-4335.

Melissa M. Phillips, Lane C. Sander. "Microwave-Assisted Extraction and Quantitative LC/IDMS Measurement of Total Choline and Free Carnitine in Foods." *J. AOAC Int.* 95 (2012) 1479-1486.

Hendrik Emons, Jane Weitzel, John Budin, Melissa Phillips, Catherine Rimmer, Donna Zink. "TDRM/TDLM Workshop on Reference Materials and Laboratory Accreditation at the AOAC Annual Meeting 2011." *Accred. Qual. Assur.*17 (2012) 101-105.

Melissa M. Phillips, Catherine A. Rimmer, Laura J. Wood, Katrice A. Lippa, Katherine E. Sharpless, David L. Duewer, Lane C. Sander, Joseph M. Betz. "NIST/NIH Dietary Supplement Laboratory Quality Assurance Program: The First Five Exercises." *J. AOAC Int.*94 (2011) 803-814.

Ryan G. Brennan, Melissa M. Phillips, Liang Y.O. Yang, Thomas P. Moffat. "Characterization and Purification of Commercial SPS and MPS by Ion Chromatography and Mass Spectrometry." *J. Electrochem. Soc.* 158 (2011) D178-86.

Melissa M. Phillips, Ryan J. Case, Catherine A. Rimmer, Katherine E. Sharpless, Stephen A. Wise, Lane C. Sander. "Determination of Organic Acids in *Vaccinium* Berry Standard Reference Materials." *Anal. Bioanal. Chem.*398 (2010) 425-434.

Melissa S. Meaney, Victoria L. McGuffin. "Investigation of Common Fluorophores for the Detection of Nitrated Explosives by Fluorescence Quenching." *Anal. Chim. Acta* 610(2008) 57-67.

Melissa S. Meaney, Victoria L. McGuffin. "Luminescence-Based Methods for Sensing and Detection of Explosives." *Anal.Bioanal. Chem.* 391 (2008) 2557-2576.

NIST SPECIAL PUBLICATIONS

Melissa M. Phillips, Catherine A. Rimmer, Laura J. Wood. "Dietary Supplement Laboratory Quality Assurance Program: Exercise K Final Report." NIST Interagency Report 8032. Gaithersburg, MD, USA. DOI: 10.6028/NIST.IR.8032. http://dx.doi.org/10.6028/NIST.IR.8032(November 2014).

Melissa M. Phillips, Catherine A. Rimmer, Laura J. Wood, Mary Bedner, Kaitlyn D. Chieh, Rick L. Paul. "Dietary Supplement Laboratory Quality Assurance Program: Exercise J Final Report." NIST Interagency Report 7997. Gaithersburg, MD, USA. DOI: 10.6028/NIST.IR.7997. http://dx.doi.org/10.6028/NIST.IR.7997(April 2014).

Melissa M. Phillips, Catherine A. Rimmer, Laura J. Wood, Karen E. Murphy, Thomas W. Vetter. "Dietary Supplement Laboratory Quality Assurance Program: Exercise I Final Report." NIST Interagency Report 7955. Gaithersburg, MD, USA. DOI: 10.6028/NIST.IR.7955. http://dx.doi.org/10.6028/NIST.IR.7955(August 2013).

Melissa M. Phillips, Catherine A. Rimmer, Laura J. Wood, Anthony F. Marlow, Michele M. Schantz, John R. Sieber. "Dietary Supplement Laboratory Quality Assurance Program: Exercise H Final Report." NIST Interagency Report 7903. Gaithersburg, MD, USA. DOI: 10.6028/NIST.IR.7903. http://dx.doi.org/10.6028/NIST.IR.7903 (Dec 2012).

PUBLISHED ABSTRACTS

Melissa M. Phillips. "NIST Tools for Quality Assurance in Botanical Dietary Supplement Measurements." *Planta Med.*, 77 (2011).

INVITED PRESENTATIONS

Melissa M. Phillips, Laura J. Wood, Katherine E. Sharpless, Stephen A. Wise. "Food Reference Materials for Nutritional Assessment." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M. Phillips. "The Role of Standard Reference Materials in Method Performance Verification Studies." 128th AOAC INTERNATIONAL Annual Meeting and Exposition, Boca Raton, FL, September 2014.

Melissa M. Phillips. "Metrology 101: No Umbrella Required." Penn State Erie, The Behrend College, Erie, PA, December 2013.

Melissa M. Phillips. "Eggs, Milk, Cereal, and Meat: SRMs for Breakfast." The Pittsburgh Conference, Philadelphia, PA, March 2013.

Melissa M. Phillips. "Challenges in the Certification of Dietary Supplement Standard Reference Materials." The Pittsburgh Conference, Orlando, FL, March 2012.

Melissa M. Phillips. "NIST Tools for Quality Assurance in Botanical Dietary Supplement Measurements." 10th Annual International Conference on the Science of Botanicals, Oxford, MS, April 2011.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "The Journey of a Standard Reference Material." College of the Holy Cross, Worcester, MA, June 2010.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Development of Cranberry Juice Cocktail and Other Related Reference Materials." 123rd AOAC Annual Meeting and Exposition, Philadelphia, PA, September 2009.

Melissa S. Meaney, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Characterization of NIST Dietary Supplement SRMs." Chromatography Forum of the Delaware Valley Spring Symposium, Fort Washington, PA, April 2009.

ORAL PRESENTATIONS

Melissa M. Phillips, Catherine A. Rimmer. "NIST Tools for the Analysis of Dietary Supplements and Foods." SupplySide East, Secaucus, NJ, May 2011.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, and Stephen A. Wise. "Determination of Water-Soluble Vitamins in NIST Food Matrix SRMs." The Pittsburgh Conference, Atlanta, GA, March 2011.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, and Stephen A. Wise. "Determination of Vitamins in NIST Food Matrix SRMs." The Pittsburgh Conference, Orlando, FL, March 2010.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Certification of Organic Acid and Flavonol Concentrations in *Vaccinium* Berry Standard Reference Materials (SRMs)." 238th American Chemical Society National Meeting and Exposition, Washington, DC, August 2009.

Melissa S. Meaney, Victoria L. McGuffin. "Fluorescence Quenching of Fluorescein for the Detection of Acids in Forensic Samples." The Pittsburgh Conference, Chicago, IL, March 2007.

Melissa S. Meaney, Victoria L. McGuffin. "Fluorescence Quenching of Fluorescein for the Detection of Carboxylic Acids." The Pittsburgh Conference, Orlando, FL, March 2006.

Melissa S. Meaney, Victoria L. McGuffin. "Investigation of Common Fluorophores for the Detection of Nitrated Explosives by Fluorescence Quenching." The Pittsburgh Conference, Orlando, FL, March 2005.

POSTER PRESENTATIONS

Melissa M Phillips, Catherine A Rimmer, Laura J Wood, Joseph M Betz. "NIST Tools for Dietary Supplements Testing: Ensuring Quality in Commercial Products." 13th Annual Natural Supplements: An Evidence-Based Update, San Diego, CA, January 2016.

Catherine A Rimmer, Melissa M Phillips, Michele M Schantz, Laura J Wood, Lee Yu, Joseph M Betz. "Marine Reference Materials for Dietary Supplement Analysis." 13th Annual Natural Supplements: An Evidence-Based Update, San Diego, CA, January 2016.

Melissa M Phillips, Catherine A Rimmer, Laura J Wood, Joseph M Betz. "Interlaboratory Studies for Dietary Supplements: Fundamentals for Understanding Supplement Composition." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M. Phillips, Benjamin J. Place, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Characterization of Polyphenols in Vaccinium Berry Dietary Supplement Standard Reference

Materials." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Laura J. Wood, Melissa M. Phillips, Joseph F. Browning, Johanna E. Camara, Kaitlyn D. Chieh, Siva K. R. Chinthalapati, Grace E. Hahm, John Molloy, Rick L. Paul, Savelas A. Rabb, Michele M. Schantz, Katherine E. Sharpless, John R. Sieber, Lee L. Yu. "Characterization of a New Total Nutrient Standard Reference Material: Dry Cat Food." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M. Phillips, Laura J. Wood, Joseph F. Browning, Johanna E. Camara, Kaitlyn D. Chieh, W. Clay Davis, Grace E. Hahm, Jeanita S. Pritchett, Michele M. Schantz, Katherine E. Sharpless, John R. Sieber, Lorna T. Sniegoski, Michael J. Welch. "Characterization of a New Total Nutrient Standard Reference Material: Protein Drink Mix." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Brittany L. Catron, Kaitlyn D. Chieh, Peter B. Howell, Stephen E. Long, Karen E. Murphy, Michael A. Nelson, Rick L. Paul, Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise, Laura J. Wood. "Characterization of St. John's Wort Standard Reference Materials (SRMs)." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M. Phillips, Laura J. Wood, Catherine A. Rimmer, Mary Bedner, Jeanice B. Thomas, Katherine E. Sharpless, Lane C. Sander, Stephen A. Wise. "Soy Standard Reference Materials (SRMs) for Quality Assurance in Nutrition Measurements." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M. Phillips, Johanna E. Camara, Grace E. Hahm, Karen W. Phinney, Lane C. Sander, and Stephen A. Wise. "Using Isotope Dilution with LC/MS and LC/MS/MS to Measure Water-Soluble Vitamins in NIST Unfortified and Fortified Food-Matrix SRMs." 14th Biological and Environmental Reference Material (BERM) Symposium, Washington, DC, October 2015.

Melissa M Phillips, Catherine A Rimmer, Laura J Wood, Joseph M Betz. "Interlaboratory Studies for Dietary Supplements: Fundamentals for Understanding Supplement Composition." 129th AOAC INTERNATIONAL Annual Meeting and Exposition, Los Angeles, CA, September 2015.

Hannah Simon, Melissa M. Phillips, Catherine A. Rimmer, Caleb J. Porter. "Value Assignment of Curcuminoids in Turmeric Standard Reference Materials." 129th AOAC INTERNATIONAL Annual Meeting and Exposition, Los Angeles, CA, September 2015.

Melissa M. Phillips, Laura J. Wood, Joseph F. Browning, Johanna E. Camara, Kaitlyn D. Chieh, W. Clay Davis, Grace E. Hahm, Jeanita S. Pritchett, Michele M. Schantz, Katherine E. Sharpless, John R. Sieber, Lorna T. Sniegoski, Michael J. Welch. "Characterization of a New Total Nutrient Standard Reference Material: Protein Drink Mix." 129th AOAC INTERNATIONAL Annual Meeting and Exposition, Los Angeles, CA, September 2015.

Brittany L. Catron, Kaitlyn D. Chieh, Peter B. Howell, Stephen E. Long, Karen E. Murphy, Michael A. Nelson, Rick L. Paul, Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise, Laura J. Wood. "Characterization of St. John's Wort Standard Reference Materials (SRMs)." 129th AOAC INTERNATIONAL Annual Meeting and Exposition, Los Angeles, CA, September 2015.

Melissa M. Phillips, Laura J. Wood, Catherine A. Rimmer, Mary Bedner, Jeanice B. Thomas, Katherine E. Sharpless, Lane C. Sander, Stephen A. Wise. "Soy Standard Reference Materials (SRMs) for Quality Assurance in Nutrition Measurements." 129th AOAC INTERNATIONAL Annual Meeting and Exposition, Los Angeles, CA, September 2015.

Melissa M Phillips, Catherine A Rimmer, Laura J Wood, Joseph M Betz. "Interlaboratory Studies for Dietary Supplements: Fundamentals for Understanding Supplement Composition." 12th Annual Natural Supplements: An Evidence-Based Update, San Diego, CA, January 2015.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander. "LC-MS and LC-MS/MS for Determination of Water-Soluble Vitamins in Foods." 127th AOACINTERNATIONAL Annual Meeting and Exposition, Chicago, IL, August 2013.

Melissa M. Phillips, Mallory J. Morris, Benjamin J. Place, Catherine A. Rimmer, Lane C. Sander. "Comparison of Commercial Software Approaches for Quantitation in Two-Dimensional Liquid Chromatography." HPLC2013, Amsterdam, the Netherlands, June 2013.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander. "LC-MS and LC-MS/MS for Determination of Water-Soluble Vitamins in Foods." HPLC2013, Amsterdam, the Netherlands, June 2013.

Melissa M. Phillips, Lane C. Sander, and Stephen A. Wise. "Using LC/MS/MS to Measure Water-Soluble Vitamins in NIST Unfortified Food-Matrix SRMs." 126th AOAC INTERNATIONAL Annual Meeting and Exposition, Las Vegas, NV, October 2012.

Catherine A. Rimmer, Melissa M. Phillips, Laura J. Wood. "Improving Measurement Capabilities: NIST Interlaboratory Studies for Food and Dietary Supplements." 126th AOAC INTERNATIONAL Annual Meeting and Exposition, Las Vegas, NV, October 2012.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander. "Microwave-Assisted Extraction and LC-MS Analysis of Total Choline and Free Carnitine in Foods." The Second International Vitamin Conference, Copenhagen, Denmark, May 2012.

Melissa Phillips, Mary Bedner, Johanna Camara, Danielle Cleveland, Candice Jongsma, Mark Lowenthal, Bryant Nelson, Karen Phinney, Karsten Putzbach, Catherine Rimmer, Lane Sander, Katherine Sharpless, Susan Tai, Jeanice Thomas, Stephen Wise. "Standard Reference Materials for the Determination of Vitamins in Food, Supplement, and Clinical Samples." The Second International Vitamin Conference, Copenhagen, Denmark, May 2012.

Catherine A. Rimmer, Melissa M. Phillips, Laura J. Wood, Katherine E. Sharpless, Stephen A. Wise, Lane C. Sander. "NIST Dietary Supplement Laboratory Quality Assurance Program: A Tool for Improving Vitamin Measurements in Foods and Dietary Supplements." The Second International Vitamin Conference, Copenhagen, Denmark, May 2012.

Melissa M. Phillips, Lane C. Sander, Stephen A. Wise. "Microwave-Assisted Extraction and LC-MS Analysis of Total Choline in Foods." 125th AOAC INTERNATIONAL Annual Meeting and Exposition, New Orleans, LA, September 2011.

Catherine A. Rimmer, Mary Bedner, Manuela K. Gradl, Mariana Arce-Osuna, Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Klaus Albert. "Determination of Soy Isoflavones in Foods and Dietary Supplements." 125th AOAC INTERNATIONAL Annual Meeting and Exposition, New Orleans, LA, September 2011.

Catherine A. Rimmer, Melissa M. Phillips, Laura J. Wood, Katrice A. Lippa, Stephen A. Wise, Lane C. Sander. "NIST Dietary Supplement Laboratory Quality Assurance Program: The First Five Years." 125th AOAC INTERNATIONAL Annual Meeting and Exposition, New Orleans, LA, September 2011.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Determination of B-Vitamins, Choline, and Carnitine in NIST Food-Matrix SRMs." HPLC, Budapest, Hungary, June 2011.

Mary Bedner, Manuela K. Gradl, Mariana Arce-Osuna, Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, Klaus Albert. "Determination of Soy Isoflavones in Foods and Dietary Supplements." HPLC, Budapest, Hungary, June 2011.

Melissa M. Phillips, Ryan G. Brennan, Thomas P. Moffat. "Analytical Characterization of Commercial SPS and MPS by Ion Chromatography and Mass Spectrometry." The Pittsburgh Conference, Atlanta, GA, March 2011.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, and Stephen A. Wise. "Determination of Water-Soluble Vitamins in NIST Food-Matrix SRMs." 124th AOACINTERNATIONAL Annual Meeting and Exposition, Orlando, FL, September 2010.

Lisa Steinhauser, Melissa M. Phillips, Catherine A. Rimmer, Klaus Albert, Lane C. Sander. "Method Development for the Determination of Yohimbine in Dietary Supplements." 124th AOACINTERNATIONAL Annual Meeting and Exposition, Orlando, FL, September 2010.

Melissa M. Phillips, Catherine A. Rimmer, Kevin D. Krueger, Mark S. Lowenthal, Rachel A. Lieberman, Lane C. Sander. "Characterization of *Vaccinium* Berry Standard Reference Materials (SRMs)." HPLC, Boston, MA, June 2010.

Melissa M. Phillips, Catherine A. Rimmer, Karen W. Phinney, Jeanice B. Thomas, Bryant C. Nelson, Lane C. Sander. "Determination of Water-Soluble Vitamins in NIST Food-Matrix SRMs." The First International Vitamin Conference, Copenhagen, Denmark, May 2010.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Karen W. Phinney, Jeanice B. Thomas, Bryant C. Nelson, Karsten Putzbach, Katherine E. Sharpless, Stephen A. Wise. "Standard Reference Materials for the Determination of Vitamins in Foods and Dietary Supplements." The First International Vitamin Conference, Copenhagen, Denmark, May 2010.

Catherine A. Rimmer, Melissa M. Phillips, Laura J. Wood, Katrice A. Lippa, Lane C. Sander. "NIST Dietary Supplements Laboratory Quality Assurance Program: A Focus on Vitamin Exercises." The First International Vitamin Conference, Copenhagen, Denmark, May 2010.

Melissa M. Phillips, Catherine A. Rimmer, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Determination of Vitamins in NIST Food Matrix SRMs." NIST Sigma Xi Postdoctoral Poster Session, Gaithersburg, MD, February 2010.

Catherine Rimmer, Katrice Lippa, Melissa Phillips, David Duewer, Lane Sander, Katherine Sharpless, Stephen Wise, Laura Wood. "Dietary Supplement Laboratory Quality Assurance Program." 123rd AOAC INTERNATIONALAnnual Meeting and Exposition, Philadelphia, PA, September 2009.

Melissa M. Phillips, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Development of *Vaccinium* Berry Dietary Supplement Standard Reference Materials (SRMs)." 12th Biological and Environmental Reference Material (BERM) Symposium, Oxford, UK, July 2009.

Catherine A. Rimmer, Katrice A. Lippa, Laura J. Wood, Melissa M. Phillips, Katherine E. Sharpless, Stephen A. Wise, Lane C. Sander, David L. Duewer. "NIST Quality Assurance Program for Dietary Supplements." 12th Biological and Environmental Reference Material (BERM) Symposium, Oxford, UK, July 2009.

Melissa S. Meaney, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Characterization of Organic Acid and Flavonoid Profiles in *Vaccinium* Berry Dietary Supplement Standard Reference Materials (SRMs)." The Pittsburgh Conference, Chicago, IL, March 2009.

Melissa S. Meaney, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Characterization of Organic Acid and Flavonoid Profiles in *Vaccinium* Berry Dietary Supplement Standard Reference Materials (SRMs)." NIST Sigma Xi Postdoctoral Poster Session, Gaithersburg, MD, February 2009.

Melissa S. Meaney, Lane C. Sander, Katherine E. Sharpless, Stephen A. Wise. "Development of *Vaccinium* Berry Dietary Supplement Standard Reference Materials (SRMs)." HPLC, Baltimore, MD, May 2008.

Melissa S. Meaney, Victoria L. McGuffin. "Fluorescence Quenching Detection of Nitrated Explosives." The Pittsburgh Conference, Chicago, IL, March 2004.

SRM ACTIVITIES

RM 8441a	Wheat Hardness (TPL/TC)
RM 8445	Spray-Dried Whole Egg for Allergen Detection (TPL/TC) Extended certification date based on FDA data.
RM 8642a	FDA Saxitoxin Dihydrochloride Solution (TPL/TC) Acquired material from FDA.
SRM 194a	Ammonium Dihydrogen Phosphate Measured ammonium and phosphate by IC-CD.
SRM 916b	Bilirubin Method developed for stabilization and measurement of bilirubin isomers XIIIα, IXα, and IIIα by LC-Abs.
SRM 1544	Fatty Acids and Cholesterol in a Frozen Diet Composite (TPL/TC) To be discontinued when out of stock. To be replaced by SRM 1548b Typical Diet.
SRM 1546a	Meat Homogenate (TPL/TC) Measured water-soluble vitamins by ID-LC/MS/MS. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.Prepared additional data for submission to SED. Updated and finalized Certificate of Analysis.
SRM 1548a	Typical Diet (TPL/TC) Planned and purchased material to prepare renewal SRM.
SRM 1549a	Whole Milk Powder (TPL/TC) Measured water-soluble vitamins, choline, and carnitine by ID-LC-MS.
SRM 1577c	Bovine Liver Prepared additional data for submission to SED.
SRM 1845a	Whole Egg Powder (TPL/TC) Measured water-soluble vitamins by ID-LC/MS/MS. Measured choline and carnitine by ID-LC-MS. Prepared data for submission to SED.
SRM 1849a	Infant/Adult Nutritional Formula (TPL/TC) Measured water-soluble vitamins, choline, and carnitine by ID-LC-MS. Prepared additional data for submission to SED. Drafted and finalized updated Certificate of Analysis.
SRM 1869a	Infant/Adult Nutritional Formula (TPL/TC)
SRM 1974c	Organics in Mussel Tissue (*Mytilus edulis*) Prepared updated Certificate of Analysis.
SRM 2383a	Baby Food Composite (TPL/TC) Measured water-soluble vitamins by ID-LC-MS. Obtained additional carotenoid data from contracting laboratory. Prepared data for submission to SED. Drafted and finalized updated Certificate of Analysis.
SRM 2384	Baking Chocolate (TPL/TC) Measured water-soluble vitamins by ID-LC-MS/MS. Coordinated stability for 5 additional analyte groups. Prepared data for submission to SED. Drafted and finalized updated Certificate of Analysis.
SRM 2385	Slurried Spinach (TPL/TC)

SRM 2386 Avocado Powder (TPL/TC)
Acquired material and stratified samples. Coordinated measurement of total nutrients through Grocery Manufacturer's Association.

SRM 2387 Peanut Butter (TPL/TC)
Measured water-soluble vitamins by ID-LC-MS/MS. Coordinated stability for 3 additional analyte groups. Prepared data for submission to SED. Drafted and finalized updated Certificate of Analysis.

SRM 3180 Iodide Anion Standard Solution
Measured iodide by IC-CD.

SRM 3233 Fortified Breakfast Cereal (TPL/TC)
Measured water-soluble vitamins by ID-LC-MS.

SRM 3234 Soy Flour (TPL/TC)
Measured water-soluble vitamins by ID-LC/MS/MS. Measured choline and carnitine by ID-LC-MS. Measured isoflavones by LC-UV. Prepared isoflavones data for submission to SED. Drafted and finalized updated Certificate of Analysis.

SRM 3235 Soy Milk (TPL/TC)
Measured isoflavones by LC-UV. Prepared data for submission to SED. Drafted Certificate of Analysis. Coordinated measurement of total nutrients by Grocery Manufacturer's Association.

SRM 3236 Soy Protein Isolate (TPL/TC)
Measured isoflavones by LC-UV. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3237 Soy Protein Concentrate (TPL/TC)
Measured isoflavones by LC-UV. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3238 Soy-Containing Solid Oral Dosage Form (TPL/TC)
Measured isoflavones by LC-UV. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3239 Isoflavones Calibration Solution (TPL/TC)
Prepared solutions. Measured isoflavones by LC-UV.

SRM 3252 Protein Drink Mix (TPL/TC)
Measured water-soluble vitamins by ID-LC/MS/MS. Measured choline and carnitine by ID-LC-MS (via Grace Hahm, student intern). Coordinated measurement of total nutrients through Grocery Manufacturer's Association. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3253 Yerba Mate (TPL/TC)
Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3262 St. John's Wort Aerial Parts
Measured chlorogenic acid, flavonoids, and naphthodianthrones by LC with absorbance and fluorescence detection.

SRM 3264 St. John's Wort Methanol Extract
Measured chlorogenic acid, flavonoids, and naphthodianthrones by LC with absorbance and fluorescence detection.

SRM 3276 Carrot Extract in Oil (TPL/TC)

SRM 3277 Krill Oil
Coordinated measurement of fatty acids and astaxanthin through Grocery Manufacturer's Association.

SRM 3278 Tocopherols in Edible Oils (TPL/TC)
Certification range extended based on stability data.

SRM 3281 Cranberry (Fruit)
Measured organic acids by ID-LC-MS and ID-GC-MS. Method developed for measurement of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3282 Low-Calorie Cranberry Juice Cocktail
Measured organic acids by IC-CD and LC-UV, method developed for measurement of anthocyanidins and flavonols by LC-Abs. Conducted stability testing of organic acids by LC-MS.

SRM 3283 Cranberry Extract
Measured organic acids by IC-CD and ID-LC-MS, method developed for measurement of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3284 Cranberry-Containing Solid Oral Dosage Form
Measured organic acids by IC-CD and ID-LC-MS, method developed for measurement of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3285 Mixed Berry-Containing Solid Oral Dosage Form
Measured organic acids by IC-CD and ID-LC-MS, method developed for measurement of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3286 Organic Acids Calibration Solution (TPL/TC)
Prepared and measured organic acids by LC-UV. Drafted and finalized Certificate of Analysis. Conducted stability testing of organic acids by LC-MS.

SRM 3287 Blueberry (Fruit)
Measured organic acids by IC-CD and ID-LC-MS, method developed for measurement of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Measured water-soluble vitamins by ID-LC-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3290 Dry Cat Food (TPL/TC)
Measured water-soluble vitamins by ID-LC/MS/MS. Measured choline and carnitine by ID-LC-MS (via Grace Hahm, student intern). Coordinated measurement of total nutrients, gravimetric fat, and crude fiber through Grocery Manufacturer's Association. Collected final data and prepared Report of Analysis summary for total nutrients. Prepared data for submission to SED. Drafted and finalized Certificate of Analysis.

SRM 3291 Bilberry Extract
Measured organic acids by ID-LC-MS, method developed for measurement of organic acids by

IC-CD and of anthocyanidins and flavonols by LC-Abs. Method developed for measurement of anthocyanins by LC-Abs. Method developed for fingerprinting of proanthocyanidins by LC-FL-MS. Conducted stability testing of organic acids by LC-MS.

SRM 3951 Vitamin B_{12} in Frozen Human Serum
Attempted to develop an ID-LC-MS/MS method for cyanocobalamin. Detection limits are not low enough for the SRM.

Tommy D. "Tom" Phillips

6585 Sweet Fern ✖ Columbia, MD 21045 (443) 631-6959
phillitd@msn.com

Education: **Pikeville College, Pikeville Kentucky**
Degree Awarded: B.S. 1979-1982
Major: Biology
Major: Chemistry
Major: Mathematics

Academic Activities and Awards

Presidential Scholar	1978-1982
Kentucky Academy of Sciences	1979-1982
Pikeville College Judicial Board	1980-1982

Professional Memberships and Associations

American Chemical Society
American Society of Mass Spectrometry
Association of Official Analytical Chemists
Royal Society of Chemistry
Committee on Mine Water Quality
Association of Public Health Laboratories
Association of Food and Drug Officials
Association of Feed Control Officials

Professional Experience

State of Maryland, Department of Agriculture, Annapolis, MD
Supervisory Chemist, State Chemist Section **2002 -present**

Supervision and training of scientists and technicians performing pesticide methods, both formulation and residue. Method development and validation of pesticide methods for new and emerging pesticides. Responsible for study design for validation and development. Responsible for assigning work, reviewing work, reviewing QuAPP's and reviewing data from submitted from chemists.

Analyses include sample preparation, method determination, validation, and implementation. Lead chemist for routine pesticide and veterinary drug analyses in foods, and animal feed, including pet food. Lead chemist for the development of new methods for contaminants and veterinary drug residues in animal feed. Other investigations include complex and non-routine formulation analyses of chlorinators, quaternary ammonium compounds, mixed formulation pesticides, aerosols, mycotoxins, toxins, and biological analyses of large animal feeds and feed ingredients. All samples require data analyses and technical reports; proficient with SAS, SPSS, and Excel packages and experiment-specific VBA codes.

Principal Chemist responsible for the provision of technical evaluation, calibration, repair and all other phases of analytical instrument maintenance in all laboratories. Section instruments include Agilent GC's (6890n) with NPD, μECD, XSD and PFPD, Agilent 6890 n GC-5973 B MSD, Varian GC-ITD, Bruker(Varian) GC-MS/MS, Water's Acquity,

and Alliance HPLC's with PDAD, Fluorescence, Pickering Pinnacle, MS/MS, Dionex ASE with solvent programming, Cepheid RT-PCR, and a Perkin-Elmer UV-Visible Spectrophotometer.

Analytical Chemical Services of Columbia, Inc., Columbia, MD
Assistant Chief Chemist **1997-2002**

Training and supervision of all scientific staff (i.e., chemists, technicians); oversight of $400k annual laboratory budget. Other responsibilities included establishment of QA/QC protocols, laboratory safety, resolving client issues, report writing, and method/experimental design.

Responsible for agricultural and food analyses which included product deformulation, product matching and non-routine analyses of food ingredients. Responsible for method development and validation for non-routine analysis of food and food ingredients for adulterants and contaminants. Scientific evaluations included statistical evaluation of data, technical report writing, and method evaluation.

Primary scientist responsible for all analytical instruments, including Perkin-Elmer GC with dual-FID, Agilent 6890 GC-5973 MS, SSI HPLC's with UV/Visible detectors, Cepheid RT-PCR, and a Perkin-Elmer UV-Visible Spectrophotometer.

Department of Public Health, Frankfort KY
Chemist III, Division of Laboratory Services **1989 –1997**

Training and supervision of analytical science team as well as inspectors in the Food Safety and Cosmetic Division of the Department of Public Health. Developed training protocols for inspectors relative to efficient and GLP/GMP sampling methods, entomological ecology, environmental contaminants and contaminant sources, which required staff cross-training. As QA Officer for the Instrumentation Section, responsibilities included adherence to AIHA, OSHA, and EPA standards of operation, accreditation, and certification. As liaison between scientists and administrators, provided evaluation and recommendations regarding employee relations, departmental policies, and interagency relations.

Principal chemist for routine analyses of environmental contaminants in food, water, soil, and air, as well as evaluation of fluoride in drinking water. Principal chemist for the routine analyses of filth and foreign matter in foods. Principal chemist responsible for methods development for contaminants, toxins, minerals and metals, adulterants, and additives in food. Experimental methods included method determination, method validation, data analysis, and technical report writing.

Primary chemist responsible for all analytical instruments, including Varian 3400 GC with dual-FID's, Varian 3400 GC-Finnigan ITD, Lachat Quikchem IV autoanalyzer with Nitrate/Nitrite modules and ISE module, Dionex IC with Sieman's detector, Waters 3695 HPLC with PDAD, RI and Fluorescence detectors.

Pharmacology and Toxicology Research Laboratories, Inc., Clays Ferry, KY
Analytical Chemist II **1986 –1989**

Provided chemical and biological analyses of drugs and their metabolites in serum; developed and validated chemical analyses of pesticides and their metabolites in air, water, soil, plant, and animal tissues in accordance to FDA and EPA guidelines. Other responsibilities included experimental method development and in-house validation certifications. Administrative Responsibilities included enforcement of in-house regulations for radiological safety and decontamination of biohazards and/or radioactive materials.

Primary chemist responsible for all analytical instruments, including Agilent 5890 GC with ECD and NPD detectors, Agilent 5890 GC-MSD, HP 1010 HPLC with UV/Visible and Fluorescence detectors, and various scintillation counters.

University of Kentucky, College of Agriculture, Lexington, KY
Principal Laboratory Technician, Agronomy Department **1985 –1986**

Analytical responsibilities for routine analyses of soils for classification (e.g., particle size, CEC, mineralogy); and fulfillment of experiments required by doctoral candidates. Undergraduate teaching requirements included laboratory preparation, preparation of handout materials, grading, and academic tutoring.

Publications:

"Single laboratory validation of a method for the determination of phenols and phenates in disinfectant formulations by liquid chromatography with UV detection," JAOACI 93(3):1039-1045, 2010.

"Determination of Phenols and Phenates in Disinfectant Formulations by Liquid Chromatography with UV Detection: Collaborative Study," JAOACI 95(2): 411-418, 2012.

"Building an Integrated Laboratory System to Advance the Safety of Food and Animal Feed," International Journal of Regulatory Science, 2(1): 1-6, 2014.

"Determination of nightshade alkaloids in a "stew" by HPLC-MS/MS," submitted Journal of Food Protection, 2015.

"A comparison of ELISA and HPLC-MS/MS in the determination of melamine in canned and dry pet foods," submitted JAOACI, 2015.

References: Available upon request.

Curriculum vitae

Dr. Klaus Reif, *10.01.1962, Dr. rer. nat.,

Studies:	
1983 - 1989	chemistry, diploma at the Friedrich-Alexander-University Erlangen
1989	university degree as chemist
1989 - 1991	PhD at Friedrich-Alexander-University Erlangen, Institute for physical chemistry (group Prof. Dickert) and in the research center of Siemens AG Erlangen (development of chemosensors for solvent vapours)
Sep. 1991	PhD of natural science (Dr. rer. nat.)
since Oct. 1991	employed by PhytoLab GmbH, Vestenbergsgreuth, Germany
field of activity:	head of method development and HPLC
responsible for:	method development and method validation for the registration procedure of phytopharmaceuticals, dietary supplements and food, residue analysis, routine analysis of food and cosmetics, product release and stability tests with HPLC of herbal raw materials and finished herbal products specialist on the development of analytical methods based on HPLC, GC and hyphenated techniques like GC-MS and HPLC-MS. State-appointed and sworn expert of the Chamber of Commerce Nuremberg for the analysis of food and botanical products.

Other activities:

Regular invited speaker and poster presenter in international scientific symposia (Annual Meeting of the Association of Official Analytical Chemists International AOAC Int, Annual International Conference on the Science of Botanicals, ICSB, International Symposium of Chromatography and Related Techniques, Analytica Conference, German Chemical Society, Separation Science Asia....etc.)

Active member of AOAC International (Pool of Experts, member of different expert review panels, general reviewer for the Journal of AOAC International), Active Member of the Executive Committee of AOAC Europe Section, Member of the Division of Analytical Chemistry and the Working Group of Separation Science of the German Chemical Society, Member of the Scientific Advisory Board of the American Herbal Pharmacopoeia (AHP), Associated Member of the American Herbal Products Association AHPA (Member of the Analytical Laboratories, Botanical Raw Materials and Standards Committee)

Anikó M. Sólyom

Work:
245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

CURRICULUM VITAE

HIGHLIGHTS OF QUALIFICATION

- 30+ years of experience in development, validation, troubleshooting and documentation of analytical methods
- 25+ years experience in laboratory management
- Broad based background in instrumental and wet analytical techniques

PROFESSIONAL EXPERIENCE

GAAS Corporation
Tucson, Arizona

Founder, CEO and CSO **1995-present**

- Supervising and conducting the analysis of dietary supplements, botanicals, pharmaceuticals and food products, including raw materials and finished products
- Analytical method development and validation
- Consulting and training

ProlX Pharmaceuticals/Oncothyreon
Tucson, Arizona

Manager of Analytical Services **2007-2008**

- Developed and validated new assay methods according to cGLP regulations to quantify novel cancer drugs in plasma and urine using QQQ LC/MS technique
- Identified metabolites of new cancer drugs in plasma and urine using TOF LC/MS technique
- Calculated pharmacokinetic parameters

Department of Pharmacology and Toxicology/Department of Pharmacology
College of Pharmacy/College of Medicine, University of Arizona
Tucson, Arizona

Director of Analytical Core, Arizona Center for Phytomedicine Research **1999-2006**
Project coordinator for NIEHS N01-ES-45529 (Chemical Disposition in Mammals) **2004-2006**
Associate Research Scientist **2001-2006**
Assistant Research Scientist **1994-1999**
Research Associate **1992-1994**

- Studied natural products
  - developed analytical procedures for the isolation, identification and quantification of the active

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Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

components in natural products (HPLC, HPLC-MS, HPLC-MS-MS)
  - developed bioactivity guided preparative separation methods for complex botanical mixtures
- Studied chemical disposition in mammals
  - developed analytical procedures for the separation, identification and quantification of the metabolites of different xenobiotics from blood, urine, hepatocyte media and microsomal suspension (HPLC, HPLC-MS, HPLC-MS-MS, GC-MS)
  - served as a technical liaison to the Analytical Core and the Synthetic Chemistry Core of the Southwest Environmental Health Sciences Center
  - contributed to the development and publication of reports and manuscripts
- Characterized promising anticancer compounds
  - developed methods for HPLC, HPLC-MS and HPLC-MS-MS to determine qualitative and quantitative composition of the synthesized organic compounds
  - developed methods for and measured Quantitative Structure Activity Relationship (QSAR) of new compounds
  - measured and evaluated MS, HPLC-MS and HPLC-MS-MS UV, VIS and IR spectra
  - measured and calculated pKa an logP
- Managed the analytical laboratory in compliance with GLP, GMP and FDA regulations
  - supervised laboratory personnel (students and employees)
  - planned budget
  - wrote SOP-s
  - maintained the database of analytical data

ANALTRON Applied Research Company
Budapest, Hungary **1989-1992**

Co-Founder and Director of Engineering

- Principal investigator of a photoacoustic (PAS) gas detector development project for trace gas analysis in ambient air
  - developed a new PAS sensor for trace gas detection
  - designed an analytical instrument based on the PAS sensor
- Lead the design and construction of the calibration system for photoacoustic spectroscopy through all its stages, from grant proposal to final report
- Successfully applied for Hungarian OTKA and OMFB grants (similar to NSF and SBIR grants, respectively) to fund the development of the instrument

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Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

Central Research Institute for Physics of Hungarian Academy of Sciences
Budapest, Hungary

Research Scientist, Director of Analytical Laboratory **1986-1991**
Research Associate **1984-1986**
Research Assistant **1981-1984**

- Developed methods characterizing metallic glasses for:
  - atomic absorption spectroscopy (AAS)
  - graphite furnace atomic absorption spectroscopy (GF-AAS)
  - inductively coupled plasma emission (ICP)
  - nuclear magnetic resonance (NMR)
  - electron microscopy
  - X-ray fluorescence spectroscopy (XRF)
  - method optimization based on mathematical statistics
- Applied various chemical and physical techniques for qualitative and quantitative analysis of metallic glasses:
  - quantitative determination of main components
  - qualitative and quantitative determination of impurities
  - statistical analysis of the test results
- Managed the analytical and quality control laboratory supporting metallic glass development
  - supervised laboratory personnel
  - planned budget

OTHER WORK EXPERIENCE

Department of Chemistry, University of Arizona
Tucson, Arizona **1991 – 1992**

Visiting scientist

- Calibrated and improved the trace gas detection system based on photoacoustic spectroscopy developed by ANALTRON Applied Research Company

Laser Photoacoustic Laboratory, Agricultural University of Wageningen
Wageningen, The Netherlands **1990, 1991**

Visiting scientist

- Applied the photoacoustic system that was developed by ANALTRON Applied Research Company in agricultural, environmental and medical fields

Department of Chemistry, University of Oulu
Oulu, Finland **1986**

Visiting scientist

- Developed method for graphite furnace atomic absorption spectrometry (GFAA) to determine arsenic in geological samples

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Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

Helsingin Kauppiaat Oy (HK)
Helsinki, Finland **1981**
Visiting scientist

- Analyzed beef and pork meat products and ready meats in the Quality Control Laboratory of HK, the fifth largest food manufacturer in Europe

EDUCATION

Technical University of Budapest, *Budapest, Hungary* **1981 - 1984**
Doctor of Philosophy of Analytical Chemistry
Dissertation: Application of Optical Spectroscopic Methods for the Analysis of Metallic Glasses

Technical University of Budapest, *Budapest, Hungary* **1979 - 1981**
Master of Sciences of Chemical Engineering
Thesis: Critical Investigation of Atomic Absorption Techniques for Mercury Determination

Technical University of Budapest, *Budapest, Hungary* **1976 - 1979**
Bachelor of Sciences of Chemical Engineering
Major: Organic Chemistry

ADDITIONAL INFORMATION

Publications: 44 professional publications in refereed periodicals and books
1 patent
49 conference posters and 10 conference lectures

Honors:

1981	Predoctoral Fellowship - Helsingin Kauppiaat Oy, Helsinki, Finland
1980	Recipient of the "PHARE" Travel Award
1990-1992	Recipient of the "Szechenyi Istvan" Research Scholarship for investigating photoacoustic effects in gases
2004	Member, Special Emphasis Review Panel – Botanical Research Centers (ZAT1-DB17), NIH-NCCAM/ODS
2001-2005	Voting member - Presidential Task Force on Dietary Supplements, AOAC
2004-2008	Horwitz Advisor, AOAC
2008-	Reviewer for The Journal of AOAC
2014	Member of the Dietary Supplement Subcommittee of ALACC (Analytical Laboratory Accreditation Criteria Committee)
2014, 2015	Voting member of the Stakeholder Panel on Dietary Supplements, AOAC
2014, 2015	Member of various AOAC's Working Groups (Anthocyanins, Ashwagandha, Chondroitin, Cinnamon, Folin-C, Lutein and Turmeric)

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245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

2014, 2015	Member of AOAC's Expert Review Panels (Anthocyanins, Chondroitin, and Folin-C)
2015-	Chair of the AOAC SPDS Turmeric Working Group
2015-	Member of the NIST/NIH DSQAP Advisory Board
2015-	Member of the USP's Non-botanical Dietary Supplements Expert Committee

Professional training, continuing education:

- Official Methods of Analysis Program: Collaborative Study of Chemicals and Methods (AOAC)
- Single Laboratory Validation of Analytical Methods for Dietary Supplement (AOAC)
- Agilent TOF LC/MS Techniques and Operation (Agilent Technologies)
- Agilent 6410 QQQ LC/MS Techniques and Operation (Agilent Technologies)
- Advanced LC/MSD-Trap Application (Agilent Technologies)
- Fundamentals of Mass Spectrometry and Interpretation of Mass Spectra (University of Arizona)
- Drug Metabolism and Disposition (University of Arizona)
- Optimizing Quality Control of Pharmaceuticals and Biopharmaceuticals (American Chemical Society)
- Combinatorial Chemistry I and II (Fahad Al-Obeidi, Selectide Co.)
- Engineering Statistics (University of Arizona)
- Introduction to Probability and Statistics (University of Arizona)
- Nucleic Acids (University of Arizona)

Other training:

- The University Leadership Institute – The Center for Professional Development
- Bloodborne Pathogens
- Protection Study Volunteers in Research
- IACUC Certifications: "Laws and Regulations", "Handling, Restraint and Techniques of Laboratory Rodents", "Introduction to the Animal Hazards Program" and "Zoonotic Diseases of Laboratory Rodents"
- Basic Radiation Protection Course

Memberships: American Chemical Society,
Division of Analytical Chemistry and Chromatography
Southern Arizona Section of ACS
Women's Chemistry Group
AOAC International
Technical Division on Reference Materials
Technical Division for Laboratory Management

Computer skills: LC and LC-MS software (ChemStation, Chrom Manager, MS Manager, MassHunter), ChemSketch, SigmaPlot, SigmaStat, Reference Manager, Microsoft Office (Word, Excel, PowerPoint), Mathlab, InDesign

Languages: Hungarian (native), Russian and Latin

Citizenship: Naturalized citizen

Anikó M. Sólyom

Work:
245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

LIST OF PUBLICATIONS

Peer reviewed publications

J. Q. Gu, **A. M. Sólyom**, V. P. Rodriguez, Y. Wang, S.G. Franzblau, G. Montenegro, B. N. Timmermann:
Dereplication of Pentacyclic Triterpenoids in Plants with Potential Antitubercular Activity by HPLC-PAD-APCI/MS/MS
Submitted to *Phytochemistry*

J.L. Funk, J.A. Frye, J.N. Oyarzo, P.R. Kiela, N. Kuscuoglu, J. Wilson, G. McCaffrey, G. Stafford, G.J. Chen, R.C. Lantz, S.D. Jolad, **A. M. Sólyom**, B.N. Timmermann:
Ancient Herbal Remedy Prevents Arthritis by Blocking Transcription Factor Activation
Submitted to *Journal of Clinical Investigations*

K.L. Prudic, K. Smriti, **A.M. Sólyom,** B.N. Timmermann:
Isolation, Identification and Quantification of Potential Defensive Compounds in the Viceroy Butterfly and its Larval Host Plant, *Carolina willow.*
J. Chem. Ecology, **33**, 1149-1159 (2007)

W.R. Sorensen, D. Sullivan: (Collaborators: S. Baugh, M. Collison, R. Das, A. Erickson, T. Harmon, S. Heathman, D. Ji, B. Khandelwal, A. Kohn, S. Morris, D. Norden, T. Peng, B. Post, E. Powers, K. Reif, G. Schulzki, C. Shevchuk, **A. M. Sólyom**):
Determination of Campesterol, Stigmasterol, and Beta-Sitosterol in Saw Palmetto Raw Materials and Dietary Supplements by Gas Chromatography: Collaborative Study.
J. of AOAC International, **90(3)**, 670-678 (2007)

D. Gray, K. LeVanseler, M. Pan, E. Waysek: (Collaborators: S. Baugh, A. Chandra, R. Meibos, T. Peng, R. Perez, K. Reif, M. Roman, J. Rousch, J. Skamarack, **A. M. Sólyom,** D. Sullivan, K. Young):
Evaluation of a Method to Determine Flavonol Aglycones in *Ginkgo biloba* Dietary Supplement Crude Materials and Finished Products by High –Performance Liquid Chromatography: Collaborative Study.
J. of AOAC International, **90(1)**, 43-53 (2007)

R.K. Kuester, **A. M. Sólyom**, V.P. Rodriguez, I.G. Sipes:
The Effect of Dose, Route, and Repeated Dosing on the Disposition and Kinetics of Tetrabromobisphenol A in Male F-344 Rats
Toxicological Sciences, **96(2)**, 237-45 (2007)

E. Pfeiffer, S.I. Hohle, S.G. Walch, A. Riess, **A. M. Sólyom**, M. Metzler:
Curcuminoids Form Reactive Glucuronides *in vitro*
Journal of Agricultural and Food Chemistry, **55(2)**, 538-544 (2007)

R. C. Lantz, G. J. Chen, M. Sarihan, **A. M. Sólyom**, S. D. Jolad, B. N. Timmermann:
The Effect of Extracts from Ginger Rhizome on Inflammatory Mediator Production
Phytomedicine, **14(2-3)**, 123-128 (2007)

S.I. Hohle, E. Pfeiffer, **A. M. Sólyom**, M. Metzler:
Metabolism of Curcuminoids in Tissue Slices and Subcellular Fractions from Rat Liver
Journal of Agricultural and Food Chemistry, **54(3)**, 756-764 (2006)

J.L. Funk, J.N. Oyarzo, J.A. Beischel, G.J. Chen, R.C. Lantz, S.D. Jolad, **A. M. Sólyom**, B.N. Timmermann:
Turmeric Extracts Containing Curcuminoids Prevent Experimental Rheumatoid Arthritis
Journal of Natural Products, **69(3)**, 351-355 (2006)

J.L. Funk, J.B. Frye, J.N. Oyarzo, N. Kuscuoglu, J. Wilson, G. McCaffrey, G. Stafford, G.J. Chen, R.C. Lantz, S.D. Jolad, **A. M. Sólyom**, P.R. Kiela, B.N. Timmermann:

Anikó M. Sólyom

Work:
245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

Efficacy and Mechanism of Action of Turmeric Supplements in the Treatment of Experimental Arthritis
Arthritis and Rheumatism, **54(11)**, 3452-3464 (2006)

H. Jiang, **A.M. Sólyom, B.N.** Timmermann, D.R. Gang:
Characterization of gingerol-related compounds in ginger rhizome (*Zingiber officinale* Rosc.) by high performance liquid chromatography/electrospray ionization mass spectrometry.
Rapid Communications in Mass Spectrometry, **19**, 2957-2964 (2005)

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Boswellia serrata does not offer protection and is potentially hepatotoxic in mouse models of chemically induced colitis.

Anikó M. Sólyom

Work:
245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

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6- and 7-Substituted 2-[2'-(Dimethylamino)ethyl]-1,2-dihydro-3*H*-dibenz[*de*,*h*]isoquinoline-1,3-diones. Synthesis, Nucleophilic Displacements, Antitumor Activity, and Quantitative Structure-Activity Relationship
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A. M. Sólyom, Gy. Z. Angeli, D. D. Bicanic, M. Lubbers:
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Calibration of A Windowless Photoacoustic Cell for Detection of Trace Gases
Analytical Chemistry, 64, 155-158 (1992)

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A. M. Sólyom, D. D. Bicanic, Gy. Z. Angeli, A. Miklós, M. Lubbers:
Use of an Open Photoacoustic Cell for Some Applications in Agriculture
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Anikó M. Sólyom

Work:
245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

D. D. Bicanic, H. Jalink, M. Chirtoc, H. Sauren, M. Lubbers, J. Quist, E. Gerkema, C. van Asselt, A. Miklós, **A. M. Sólyom**, Gy. Z. Angeli, P. Helander, H. Vargas
Interfacing Photoacoustic and Photothermal Techniques for New Hyphenated Methodologies and Instrumentation Suitable for Agricultural, Environmental and Medical Applications
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A. Sólyom, P. Fodor, S. Kemény:
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Magyar Kémikusok Lapja, 46. 107-114 (1991)

L. Illgen, H. Mühlbach, S. Roth, G. Konczos, J. Takács, **A. Sólyom**:
Zum Einfluss von Verunreinigungen auf die Duktilitat und die Magnetischen Eigenschaften amorpher Bander aus Eisen-Bor-Silizium
Hung. Acad. Sci. Centr. Res. Inst. Phys. KFKI Report KFKI-1990-22/E (1990)

E. Tóth-Kádár, I. Bakonyi, J. Lóránth, **A. Sólyom**, L. Pogány, T. Dankházi, J. Tóth, G. Konczos, P. Fodor and H.H. Liebermann:
Determination of the Phosphorus Content in Ni-P Alloys
Plating and Surface Finishing 77(9) 70-75 (1990.)

E. Tóth-Kádár, I. Bakonyi, **A. Sólyom**, J. Hering, G. Konczos, and F. Pavlyák:
Preparation and Characterization of Electrodeposited Amorphous Ni-P Alloys
Surface and Coating Technology, 31, 31-43 (1987)

I. Bakonyi, L. K. Varga, A. Lovas, E. Tóth-Kádár, **A. Sólyom**:
Magnetization and NMR Study of Amorphous Ni-P Alloys in the Paramagnetic Concentration Range
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A. Lovas, L. F. Kiss, G. Konczos, **A. Sólyom**:
Influence of Amorphous Ribbon Processing on the Magnetic Properties of Heat Treated Wound Cores
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S. Antus, E Baitz-Gács, F. Boros, M. Nógrádi, **A. Sólyom**:
Oxidation of 1,3-Diphenyl-1,3-Propanediones with Thallium(III)-Nitrate in Methanol
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Book chapter

E.Pfeiffer, H. Esch, S. Hohle, **A.M. Sólyom**, B.N. Timmermann, M. Metzler.
In vitro studies on the estrogenic activity and the metabolism of curcumin.
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Anikó M. Sólyom

Work:
245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

Patent

G. J. Chen, R.C. Clark, **A.M. Sólyom**, B.N. Timmermann, S.D. Jolad:
Anti-inflammatory activity of a specific turmeric extract
Patent No.: US 2005123632

Oral presentations at national and international conferences

A. M. Sólyom (invited speaker):
Anthocyanin Working Group of AOAC: Did that bilberry powder come from bilberries, or something else?
Annual Meeting of Pacific Southwest Section of AOAC International
Monterey, CA, February 18-19th, 2015

A. M. Sólyom (invited speaker), E. Pfeiffer, M. Metzler, I.G. Sipes:
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Gy. Z. Angeli, A. M. Sólyom, A. Miklós, D. D. Bicanic:
Dependence of the photoacoustic cell constant on the material choice
Conference Digest of 7th International Topical Meeting on Photoacoustic and Photothermal Phenomena, O III/2. pp. 96-97.
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Bergen, Norway, June 9-14, **1991.**

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Book of Abstracts of XXVII. Colloquium Spectroscopicum Internationale, B-1.7.
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The application of a new analytical method - the photoacoustic spectroscopy - for environmental air analysis (in Hungarian)
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A. Sólyom, P. Fodor, S. Kemény:

Anikó M. Sólyom

Work:
245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

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Csopak, Hungary, October 22-24. **1984.**

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Development of optical spectroscopic methods for the analysis of phosphorus content of metallic glasses (in Hungarian)
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Anikó M. Sólyom

Work:
245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

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A. M. Sólyom, Gy. Z. Angeli, A. Miklós, D. D. Bicanic, M. Lubbers:
Detection of ammonia - CO_2 laser photoacoustic spectroscopy compared to conventional spectrophotometry
Book of Abstracts of XXVII. Colloquium Spectroscopicum Internationale, D-1.5 (1991)

Gy. Z. Angeli, A. M. Sólyom, A. Miklós, D. D. Bicanic:
Calibration of a specially designed windowless photoacoustic cell for low concentration gas analysis
Book of Abstracts of XXVII. Colloquium Spectroscopicum Internationale, B-1.7. (1991)

Gy. Z. Angeli, A. Miklós, A. Sólyom, A. Lörincz:
Photoacoustic gas analyzer instrument for environmental measurements (in Hungarian)
Proceedings of XXXIII. Hungarian Spectroscopic Itinerary Congress, pp. 13-16. (1990)

A. Sólyom, A. Miklós, Gy. Z. Angeli, A. Lörincz:
The application of a new analytical method - the photoacoustic spectroscopy - for environmental air analysis (in Hungarian)
Proceedings of XXXIII. Hungarian Spectroscopic Itinerary Congress, pp. 7-11. (1990)

A. Sólyom, K. Balla-Zámbó:
Development of optical spectroscopic methods for the analysis of phosphorus content of metallic glasses (in Hungarian)
XXVI. Hungarian Spectroscopic Itinerary Congress, pp. 139-145 (1983)

Posters presented at national and international conferences

A.M. Sólyom:
A Single Laboratory Validation Study for the Determination of Curcuminoids in Dietary Supplements and Foods by Rapid Resolution HPLC using PDA Detection.
Presented at the 123rd AOAC International Annual Meeting and Exposition, Philadelphia, Pennsylvania, September 13-16, 2009

A.M. Sólyom, R.K. Kuester, V.P. Rodriguez, L. Jacobs, C.J. Sweet, I.G. Sipes:
Disposition of Tetrabromobisphenol A (TBBPA) in Male Fischer-344 rats.
Presented at the 45th Annual Meeting of the American Society of Toxicology, San Diego, California USA, March 5-9, 2006

Anikó M. Sólyom

Work:
245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

G.A. Knudsen, R.K. Kuester, V.P. Rodriguez, **A.M. Sólyom**, I.G. Sipes:
Disposition and Excretion of Tetrabromobisphenol A bis[2,3-Dibromopropylether] (TBBPA-DBPE) in Male Fischer-344 rats.
Presented at the 45th Annual Meeting of the American Society of Toxicology, San Diego, California USA, March 5-9, 2006

E. Pfeiffer, S.G. Walch, A. Riess, S.I. Hoehle, **A.M. Sólyom**, M. Metzler:
Curcumin Glucuronide Inhibits Cell-free Microtubule Assembly.
Presented at the 45th Annual Meeting of the American Society of Toxicology, San Diego, California, USA, March 5-9, 2006

E. Pfeiffer, A. Riess, S.I. Hoehle, S.G. Walch, **A.M. Sólyom**, M. Metzler:
Curcuminoids from Reactive Glucuronides that Inhibit Cell-free Microtubule Assembly.
Presented at Biological Reactive Intermediates VII, Tucson, Arizona, January 4-7, 2006

Zhou, J.Z., Waszkuc, T., Mohammed, F., Ray, C., Buren, R., Sullivan, D., Jabusch, J., Kou, X., Yang, Q., **Sólyom, A.M**., Wang, J., Peng, T.S., Collison, M., Blumhorst, M., Nagarajan, M., Podhola, B., Li, H., Shevchuk, C., Wang, W., Nguyen, H., Das, R., Orellana, K., Reif., K.:
Determination of glucosamine in raw materials and dietary supplements containing glucosamine sulfate and/or glucosamine hydrochloride by high-performance liquid chromatography with FMOC-Su derivatization: Collaborative study.
Presented at the 229th ACS National Meeting, San Diego, California, March 13-17, 2005

K. L. Prudic, B. N. Timmermann, **A.M. Sólyom**:
Analysis of the Viceroy Butterfly Defensive Compounds using Liquid Chromatography with Ion Trap Mass Spectrometric Detection and its Implications in a Classical Mimicry System
Presented at*119th AOAC International Annual Meeting and Exposition*, Orlando FL, USA, September 11-15, 2005

A.M. Sólyom, G.J. Chen, V.P. Rodriguez, R.C. Lantz, S.D. Jolad, B.N. Timmermann:
Changes in Chemical Composition and *in vitro* Anti-inflammatory Activity of Turmeric Oil during Long Term Storage
Presented at*119th AOAC International Annual Meeting and Exposition*, Orlando FL, USA, September 11-15, 2005

A.M. Sólyom, E. Pfeiffer, S. I. Hoehle, M. Metzler:
LC/MS Analysis of Glucuronides of Curcuminoids and their Reductive Metabolites
Presented at*119th AOAC International Annual Meeting and Exposition*, Orlando FL, USA September 11-15, 2005

S.I. Hoehle, E. Pfeiffer, **A.M. Sólyom,** B.N. Timmermann:
Glucuronidation of Curcuminoids Catalyzed by Multiple Human UDP-glucuronosyltransferases.
Presented at *Europian ISSX Meeting at the Pharmaceutical Science Fair*, Nice, France, June 12-16, 2005

J.L Funk, G Chen, G. McCaffrey, G. Stafford, J. Beischel, J. Wilson, R.C. Lantz, **A.M Sólyom**, S.D. Jolad, BN.Timmermann:
Curcumin-enriched Turmeric Extract Prevents Arthritis in Lewis Rats
Presented at *26th annual Meeting of the American Society of Bone and Mineral Research*, Seattle, WA, October 1-5, 2004,

A.M. Sólyom, V.P. Rodríguez, J.D. Jolad and B.N. Timmermann:
Analysis of Turmeric Extracts Using Liquid Chromatography with Ion Trap Mass Spectrometric Detection.
Presented at*118th AOAC International Annual Meeting and Exposition*, St. Louis, Missouri, September 19-23, 2004

Anikó M. Sólyom

Work:
245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

G.G. Angeli, V.P. Rodríguez, B.N. Timmermann, **A.M. Sólyom**:
Extraction and Analysis of Fresh Ginger Root and Ginger Dietary Supplement.
Presented at *118th AOAC International Annual Meeting and Exposition*, St. Louis, Missouri, September 19-23, 2004

V.P. Rodríguez, C.Sweet, B.N. Timmermann, **A.M. Sólyom**:
Development of an LC/MS/MS Method to Separate and Analyze Curcuminoids, their Metabolites and Degradation Products.
Presented at*118th AOAC International Annual Meeting and Exposition*, St. Louis, Missouri, September 19-23, 2004

K.L. Prudic, **A.M. Sólyom**, J.Q. Gu, B.N. Timmermann:
Defensive Chemicals in the Viceroy Butterfly (Limenitis Archippus) and its Larval Host-Plant, Carolina Willow (Salix Caroliniana)
Presented at *International Congress on Natural Products Research, American Society of Pharmacognosy*, Phoenix AZ, USA. July 31-August 4, 2004,

Amber S. Roberts, V.P. Rodríguez, B.N. Timmermann and **A.M. Sólyom**:
Quantification of the Curcuminoids Content in Bulk Wholesale and Retail Dietary Supplements.
Presented at *Undergraduate Research Posters on the Hill* (organized by The Council on Undergraduate Research), Washington D.C., April 20, 2004,

R.C. Lantz, G.J. Chen, M. Sarihan, **A.M. Sólyom**, S.D. Jolad, and B.N. Timmermann:
Sites of Action of Compounds Isolated from Ginger.
Presented at *Experimental Biology 2004*, Washington DC, April 18, 2004.

A.M. Sólyom, V.P. Rodriguez, and B.N. Timmermann:
Development of a Solid Phase Extraction (SPE) Method for the Analysis of Curcuminoids.
Presented at *117th AOAC International Annual Meeting and Exposition*, Abstract P1025, Atlanta, GA, USA, September 14-18, 2003

A.M. Sólyom, A.S. Roberts, V.P. Rodriguez, B.N. Timmermann:
Quantification of the Curcuminoids Content in Bulk Wholesale and Retail Turmeric Dietary Supplements.
Presented at *117th AOAC International Annual Meeting and Exposition,* Abstract P1026, Atlanta GA, USA, September 14-18, 2003

A.M. Sólyom, V.P. Rodriguez, Shivanand D. Jolad, B.N. Timmermann:
Ginger: What's in the bottle?
Presented at *117th AOAC International Annual Meeting and Exposition*, Abstract P1032, Atlanta GA, USA, September 14-18, 2003

S. Höhle, E. Pfeiffer, **A. M. Sólyom**, B. N. Timmermann, M. Metzler:
In vitro Studies on the Biotransformation of Curcuminoids.
Presented at *8th European ISSX Meeting*, Dijon, France, April 27-May 1, 2003

R.K. Kuester, D. Castro, **A.M. Sólyom**, I. G. Sipes:
Characterization BPA Glucuronidation by Rat and Human Hepatocytes
Presented at *42nd Annual Meeting of the American Society of Toxicology*, Salt Lake City UT,USA, March 09-13, 2003

E. Pfeiffer, S. Höhle, **A. M. Sólyom**, B. N. Timmermann, and M. Metzler:
Stable and unstable glucuronides in curcumin metabolism.
Presented at *42nd Annual Meeting of the American Society of Toxicology*, Salt Lake City UT, USA, March 09-13, 2003

E. Pfeiffer, H.L. Esch, S. Höhle, **A.M. Sólyom**, B.N. Timmermann, M. Metzler:
In vitro studies on the estrogenic activity and the metabolism of curcumin.

Anikó M. Sólyom

Work:
245 S. Plumer Ave., Suite 5
Tucson, AZ 8519-6345
Tel: (520) 975-0411
E-mail: asolyom@gaasanalytical.com

Home :
6925 N. Camino de las Candelas
Tucson, AZ 85718-1023
Tel : (520) 544-9477
E-mail: solyomaniko@gmail.com

Presented at *Symposium of the Deutsche Forschungsgemeinschaft, Senate Commission on Food Safety.* Functional Food: Safety Aspects. Abstract # 11, Karlsruhe, Germany, May 05-07, 2002..

R. C Lantz, G. J. Chen, **A. M. Sólyom**, B. N. Timmermann:
The Effect of Botanical Compounds on Inflammatory Mediator Production.
Presented at *Experimental Biology 02*, New Orleans LA, USA, April 20-24, 2002

A.M. Sólyom, R.C. Lantz, G.J. Chen, and B.N. Timmermann:
Bioactivity Guided Separation of Raw Turmeric *(Curcuma longa).*
Presented at *41st Annual Meeting of the American Society of Toxicology*, Nashville TN, USA, March 17-21, 2002

C.J. Sweet, **A.M. Sólyom**, I.G.Sipes:
Pharmacokinetics and disposition of D&C Red No. 28 in Male Fischer-344 Rats
Presented at *41st Annual Meeting of the American Society of Toxicology*, Nashville TN, USA, March 17-21, 2002

E. Pfeiffer, H. Esch, S. Höhle, M. Metzler, **A.M. Sólyom**, and B.N. Timmermann:
Chemical Stability of Curcuminoids and their Estrogenic Activity in Ishikawa Cells.
Presented at *41st Annual Meeting of the American Society of Toxicology*, Nashville TN, USA, March 17-21, 2002

E. Pfeiffer, S. Höhle, **A.M. Sólyom,** M. Metzler:
Studies on the stability of turmeric constituents.
Presented at *6th Karlsruhe Nutrition Symposium*, abstract P24 abstract book p.65, Karlsruhe, Germany, October 21-23, 2001.

R.K. Kuester, J.J Pritchett, S.M. Fontaine**, A.M. Sólyom**, I.G. Sipes:
Glucuronidation of Bisphenol A in Hepatic Microsomes: Age-Dependent Differences.
Presented at *4ost Annual Meeting of the American Society of Toxicology*, San Francisco CA, USA, March 25-29, 2001

A. M. Sólyom, I.G.Sipes:
The *in vivo* absorption, distribution and excretion of 14C-methyleugenol in male F-344 rats after topical administration
Presented at *4ost Annual Meeting of the American Society of Toxicology*, San Francisco CA, USA, March 25-29, 2001

CURRICULUM VITAE: DARRYL M. SULLIVAN

CURRENT POSITION

Title:	Associate Scientific Director
Department:	Food and Drug Analysis Covance Laboratories Inc. Madison, Wisconsin

EDUCATION

BS Biological Conservation with a minor in Biochemistry, University of Wisconsin-Madison, Madison, Wisconsin, 1975

Additional Training

Six Sigma Green Belt Training. Covance Laboratories, Madison Wisconsin, 2003
GMP Compliance and Regulatory Update, Covance Laboratories, Madison, Wisconsin, 2001
Good Laboratory Practices (GLP) Covance Laboratories, Madison, WI, 2000, 2001, 2002, 2003, 2004
Building Loyalty Through Customer Service, Covance Laboratories, Madison, Wisconsin, 2000
Violence in the Workplace, Covance Laboratories Inc., Madison, Wisconsin, 2000
Total Quality Management System, sponsored by Covance Laboratories Inc., Madison, Wisconsin 1988, 1989, 1990, 1991
Supervisory Management Certificate Program, Management Institute, University of Wisconsin Extension, Madison, Wisconsin, 1985-1986
High Performance Liquid Chromatography Training School, Waters Associates, St. Louis, Missouri, 1979

Additional Course Work

Graduate studies in biochemistry and limnology, University of Wisconsin-Madison, Madison, Wisconsin, 1976

PROFESSIONAL EXPERIENCE

2008 - Present: Associate Scientific Director, Food and Drug Analysis

As the associate scientific director in the Food and Drug Analysis Department, Mr Sullivan is responsible for the overall scientific rigor of all testing programs. Mr. Sullivan brings new test methods, new technologies, and new innovations into the laboratory. He is then responsible for implementing and validating these methods and technologies.
Mr. Sullivan is the primary Covance liason to AOAC International, and other scientific assoaciations.

2000 – 2008: Manager of Business Development, Food and Drug Analysis

As a senior manager in the Food and Dietary Supplement Groups, Mr. Sullivan is responsible for the department's major food and nutraceutical testing programs. His responsibilities include design and

implementation of the testing programs, assuring the quality of the data, and communicating directly with the clients. Mr. Sullivan manages laboratory supervisors, scientists, technicians, and administrative personnel in carrying out these duties.
Mr. Sullivan is held accountable for the total performance of these testing programs. He is responsible for the quality of the data, the timeliness of the testing and the financial performance of the teams. Mr. Sullivan is expected to direct method development programs, problem solving projects, and new testing ventures.
In addition, Ms. Sorenson continues to assist scientific leaders with AOAC Single Laboratory Validation and Collaborative Studies and has led AOAC projects in the past.

CURRICULUM VITAE: DARRYL M. SULLIVAN

PROFESSIONAL EXPERIENCE (Continued)

1990 - 2000: Senior Client Manager, Food Chemistry

As a senior client manager in the Food Sciences Group, Mr. Sullivan provided a wide variety of services to both clients and the laboratory staff as an expert in nutritional, inorganic, and lipid chemistry. He consulted with and advised clients on regulatory issues, proper selection of assays, and understanding analytical results. He utilized his extensive experience in designing programs for a variety of projects, including major nutritional surveys, nutrition labeling programs, stability studies, and major research and development projects, and he assisted clients and laboratory staff with all aspects of these studies. Mr. Sullivan acted as a liaison between the laboratory and the client by providing technical direction and advice; he discussed results and methodology with the scientists and helped clients in their interpretation and understanding of the data. He also assisted the client service representatives by providing technical direction to individuals working directly with accounts.
Mr. Sullivan is very active in AOAC International; he served as a member of the Official Methods Board and chair of one of the Food Methods committees.

1987 - 1990: Technical Manager, Inorganic Analysis

Mr. Sullivan had the same supervisory duties as described under the Staff Scientist/Supervisor position. He also had the additional responsibilities of budget preparation, department cost analysis, and productivity analysis. Mr. Sullivan researched new analytical technologies and often published or presented his findings.

1981 - 1987: Staff Scientist/Supervisor, Inorganic Analysis

Mr. Sullivan managed the Inorganic Department, including supervision of the ICAP and Nonmetals, Atomic Absorption, and Proximate/Lipid Chemistry sections. This involved organizing and evaluating data, and performing or advising others on research of new methods or modifications of existing methods. These sections conducted a wide range of food and feed analyses for trace elements, heavy metals, organic and inorganic salts, proximate composition, and lipids. Much of the work was done as part of quality control or nutritional labeling compliance testing. Mr. Sullivan also supervised the Formulation Quality Control section which performed analytical testing for the Toxicology Department. Mr. Sullivan was instrumental in managing the startup of ion chromatography techniques at Hazleton, as well as in developing applications ofion chromatography to food analyses. He also managed other method development projects including gravimetric methods for total dietary fiber and a heavy metals screen by inductively coupled argon plasma atomic emission spectrophotometry.

1980 - 1981: Scientist II/Section Leader, Nutritional Adjuncts

As a section leader in the proximate and lipid chemistry area, Mr. Sullivan supervised scientists and technicians in the analysis of protein, moisture, ash, fat, fiber, carbohydrates, and calories in foods and feeds. Mr. Sullivan also worked on the analysis of fatty acids, cholesterol, plant sterols, and antioxidants.

CURRICULUM VITAE: DARRYL M. SULLIVAN

PROFESSIONAL EXPERIENCE (Continued)

1979 - 1980: Scientist, Nutritional Adjuncts

Mr. Sullivan worked in the Micro vitamin section where he regularly identified and quantified vitamins and amino acids in proteins, foods, and animal feeds using wet chemical techniques, high performance liquid chromatography, and an amino acid autoanalyzer.

1977 - 1978: Scientist, Pesticide Evaluation

Mr. Sullivan's primary responsibilities were the management and operation of the Drosophila mutagenesis laboratory. This involved leading long-term projects as well as method development and data analysis.

1975 - 1977: Development Engineer, Research Projects Corporation, Madison, Wisconsin

Mr. Sullivan researched and developed air movement and filtration systems for integration with a solar heating program.

PUBLICATIONS

Paske, N., Berry, B., Schmitz, J., Sullivan, D., “Determination of Low-Level Agricultural Residues in Soft Drinks and Sports Drinks by Liquid Chromatography/Tandem Mass Spectrometry: Single-Laboratory Validation” Journal of the AOAC INTERNATIONAL, 90 (2):521-533 (2007)

Paske, N., Berry, B., Schmitz, J., Sullivan, D., “Determination of Low-Level Agricultural Residues in Soft Drinks and Sports Drinks by Gas Chromatography with Mass-Selective Detection: Single-Laboratory Validation” Journal of the AOAC INTERNATIONAL, 90 (2):534-543 (2007)

Sullivan, D. M., Wehrmann, J., Schmitz, J., Crowley, R., and Eberhard, J., "Determination of Ephedra Alkaloids by Liquid Chromatography/Tandem Mass Spectrometry," Journal of the AOAC INTERNATIONAL, 86(3):471-475 (2003).

Lee S.C., Prosky L., Sullivan D.M. and Vincent R., “Evaluating an Analytical Method for Complex Carbohydrate Determinations,” *American Association for Cereal Chemists, Inc.*, *41*:64-70 (1996).

Sullivan, D.M., “Cholesterol” *Analyzing Food for Nutrition Labeling and Hazardous*

Contaminants, (eds.) I. Jeon, W. Ikins, Ch. 4, pp. 77-86, Marcel Dekker Inc., New York, Basel, Hong Kong (1995).

DeVries J.W., Sullivan D.M. and Sungsoo L.C., "Carbohydrate/Dietary Fiber Analysis," *Methods of Analysis for Nutrition Labeling,* (eds.) D. Sullivan and D. Carpenter, Ch. 4, pp. 69-83 (1993).

CURRICULUM VITAE: DARRYL M. SULLIVAN

PUBLICATIONS (Continued)

Sullivan D.M., "Proximate and Mineral Analysis," *Methods of Analysis for Nutrition Labeling,* (eds.) D. Sullivan and D. Carpenter, Ch. 6, pp.105-109 (1993).

Sullivan, D. M., and Walton J.C., "The Needs of the Contract Laboratory in Regard to Reference Material," *Fresenius' Journal of Analytical Chemistry 338*: 580-581 (1990).

Kehoe, D. F. and Sullivan, D. M., "Determination of Gold in Tissue by Graphite Furnace Atomic Absorption Spectrophotometry," Journal of the Association of Official Analytical Chemists, 70(6):1, 153-1, 155 (1988).

Sullivan, D. M., Kehoe, D. F., and Smith, R. L., "Measurement of Trace Levels of Total Aluminum in Foods by Atomic Absorption Spectrophotometry," Journal of the Association of Official Analytical Chemists, 70(1):118-120 (1987).

Smith, R. L. and Sullivan, D. M., "Quantitation of Vegetable Sterols in Dairy Products Using Capillary Gas Chromatography," Journal of the Association of Official Analytical Chemists, 70(5):912-915 (1987).

Adams, M. L., Sullivan, D. M., Smith, R. L., and Richter, E. F., "Evaluation of Direct Saponification Method for Determination of Cholesterol in Meats," Journal of the Association of Official Analytical Chemists, 69(5):844-846 (1986).

Sullivan, D.M., "Methods for Low Level Sodium Analysis: An Overview," Arkansas Processing Crops Review, Vol. XXII (Issue 2), University of Arkansas (April 1985).

Sullivan, D. M. and Smith R. L., "Determination of Sulfites in Foods by Ion Chromatography," Food Technology, 39(7):45-48 (July 1985).

Greger, J. L., Sullivan, D. M., Goetz, W., and Daun, R. J., "Aluminum Levels in Foods Cooked and Stored in Aluminum Pans, Trays, and Foil," Journal of Food Protection, 48(9):772-777 (September 1985).

Sullivan, D. M., "Sulfate by Ion Chromatography," in Sulfur and Sulfur Amino Acids, O. Griffith and W. Jakoby (eds.), Methods in Enzymology, Academic Press, Orlando, Florida (in press).

PRESENTATIONS

Sullivan, D.M., "GLP Compositional Analysis of Biotech-Derived Foods/Crops," IFT Annual Meeting and Food Exposition, Chicago, Illinois, July 2003.

Randall Smith, Darryl M. Sullivan and James Wehrmann, "Implementing LC-MS/MS Analytical Applications in the Contract Laboratory," AOAC International Annual Meeting and Exposition, Atlanta, Georgia, September 2003.

CURRICULUM VITAE: DARRYL M. SULLIVAN

PRESENTATIONS (Continued)

Sullivan, D.M., "Compositional Analysis of Biotech-Derived Foods and Crops," AOAC International Annual Meeting and Exposition, Atlanta, Georgia, September 2003.

John Schmitz, Darryl M. Sullivan and James Wehrmann, "Validation of an LC-MS/MS Method for Quantitation of Ephedrine Alkaloids in Dietary Supplements," AOAC International Annual Meeting and Exposition, Los Angeles, California, September 2002.

Chad Scheuerell, Donald L. Hughes, Darryl M. Sullivan and James Wehrmann, "The Analysis of Acrylamide in Foods Using LC-MS/MS," AOAC International Annual Meeting and Exposition, Los Angeles, California, September 2002.

Sullivan, D.M., AOAC International Official Methods(sm) Program, "Actions of the AOAC Task Force to Develop/Validate Official Methods for Diet Supplement Analysis," IFT Annual Meeting and Food Exposition, Anaheim, California, June 2002.

Sullivan, D.M., "Problems and Pitfalls in Analysis of Foods, Feeds, and Crop Materials for Amino Acids," Pittsburgh Conference, New Orleans, Louisiana, March 2002.

Sullivan, D.M., "AOAC International Proactive Program of Work for Validating Analytical Methods for Dietary Supplements," SupplySide East International Trade Show & Conference, Secaucus, New Jersey, 2001.

Sullivan, D.M., "Low-Level Lactose Determination" Association of Official Analytical Chemists Meeting and Exposition, San Diego, California, 1997.

Sullivan, D.M., "Interlaboratory Collaboration Review, & Acceptance," Standardization and Validation of Methods for Characterizing and Analyzing Dietary Supplements Topical Conference, Baltimore, Maryland, 1996.

Sullivan, D.M., "Use of Reference Materials for Dietary Fiber Analysis in the Q.C. Laboratory," American Association of Cereal Chemists Meeting, Seattle Washington, 1992.

Sullivan, D. M., "Determination of Total Fat in Foods in Compliance with NLEA," American Association of Cereal Chemists Meeting, 1991.

Sullivan, D. M., “Comparison of Methods to Determine Total Fat in Food,” American Association of Cereal Chemists Meeting, Minneapolis, Minnesota, 1990.

Polywacz, J. P. and Sullivan, D. M., "Determination of Total Dietary Fiber in Food," Midwest Association of Official Analytical Chemists Meeting, Fargo, North Dakota, June 1987.

Sullivan, D. M., "Determination of Omega-3 Polyunsaturated Fatty Acids," Fall Association of Official Analytical Chemists Meeting, San Francisco, California, September 1987.

Sullivan, D. M. and Giegerich, J. R., "Determination of Iodine in Foods Using Ion Chromatography," Pittsburgh Conference, Atlantic City, New Jersey, March 1986.

CURRICULUM VITAE: DARRYL M. SULLIVAN

PRESENTATIONS (Continued)

Sullivan, D. M., "Ion Chromatographic Analysis of Foods," Spring Association of Official Analytical Chemists Workshop, Seattle, Washington, April 1986.

Giegerich, J. R. and Sullivan, D. M., "New Methods for Food Analysis Using Ion Chromatography," Midwest Association of Official Analytical Chemists Meeting, Lincoln, Nebraska, June 1986.

Kehoe, D. F. and Sullivan, D. M., "Quantitation of Selenium in Infant Formula Using Hydride Generation Atomic Absorption Spectrophotometry," Fall Association of Official Analytical Chemists Meeting, Scottsdale, Arizona, September 1986.

Sullivan, D. M., "Determination of Iodine in Food Using Ion Chromatography," Fall Association of Official Analytical Chemists Meeting, Scottsdale, Arizona, September 1986.

Sullivan, D. M. and Smith, R. L., "Total Dietary Fiber in Food and Food Ingredients," presented at the Annual Meeting of the American Association of Cereal Chemists, Toronto, Canada, October 1986.

Sullivan, D. M. and Giegerich, J. R., "Analysis of Sulfites and Other Anions in Food by Ion Chromatography," Pittsburgh Conference, New Orleans, Louisiana, February 1985.

Sullivan, D. M. and Smith, R. L., "Comparison of Atomic Absorption and Inductively Coupled Argon Plasma Atomic Emission Spectrometry for the Analysis of Infant Formula," 1st Association of Official Analytical Chemists Conference on Infant Formula, Virginia Beach, Virginia, May 1985.

Smith, R. L. and Sullivan, D. M., "Comparison of Chromatographic and Microbiological Procedures for the Determination of Tryptophan Content in Infant Formula," 1st Association of Official Analytical Chemists Conference on Infant Formula, Virginia Beach, Virginia, May 1985.

Sullivan, D. M., "Ion Chromatographic Determination of Sulfites," Fall Association of Official Analytical Chemists Meeting, Washington, DC, October 1985.

Burkhart, M. O. and Sullivan, D. M., "Determination of Total Dietary Fiber in a Wide Variety of Food Products," Midwest Association of Official Analytical Chemists Meeting, Chicago, Illinois, June 1985.

Sullivan, D. M., "Ion Chromatographic Method for the Determination of Sulfites," Association of Official Analytical Chemists Sulfite Task Force Meeting, Washington, DC, August 1985.

Sullivan, D. M., "Quantitation of Sulfite in Foods Using Ion Chromatography," LabCon Central Meeting, Chicago, Illinois, October 1985.

Sullivan, D. M., "Ion Chromatographic Determination of Sulfites," Fall Association of Official Analytical Chemists Meeting, Washington, DC, October 1985.

Burkhart, M. O. and Sullivan, D. M., "Measurement of Total Dietary Fiber in a Wide Variety of Food Products," Fall Association of Official Analytical Chemists Meeting, Washington, DC, October 1985.

CURRICULUM VITAE: DARRYL M. SULLIVAN

PRESENTATIONS (Continued)

Sullivan, D. M., Giegerich, J. R., and Addison, T. A., "Ion Chromatography: A New Approach to Anion Analysis in Food," Midwest Association of Official Analytical Chemists Meeting, Minneapolis, Minnesota, June 1984.

Sullivan, D. M., Smith, R. L., and Richter, E. F., "Quantitation of Vegetable Sterols in Dairy Products Using Capillary Column Chromatography," Fall Association of Official Analytical Chemists Meeting, Washington, DC, October 1984.

Sullivan, D. M., "Aluminum in Food," Conference on Aluminum Analysis in Biological Materials, University of Virginia, Charlottesville, Virginia, June 1983.

Sullivan, D. M., "Determination of Selenium Levels in Feed After Dry Ashing," Midwest Association of Official Analytical Chemists Meeting, Ames, Iowa, June 1983.

Adams, M. L., Sullivan, D. M., Smith, R. L., and Richter, E. F., "Evaluation of a Direct Saponification Method for the Determination of Cholesterol in Meats," Fall Association of Official Analytical Chemists Meeting, Washington, DC, 1983.

PROFESSIONAL MEMBERSHIPS

Society for Applied Spectroscopy
AOAC INTERNATIONAL
Association of Official Analytical Chemists Sulfite Task Force, 1985-1986
Association of Official Analytical Chemists NLEA Task Force, 1993-1996
AOAC INTERNATIONAL Dietary Supplement Task Force, 2000-
AOAC INTERNATIONAL Dietary Supplement Task Force Chair, 2000-2003
AOAC INTERNATIONAL Official Methods Board Member, 1998-2001
AOAC INTERNATIONAL Official Methods Board Chair, 2001-2004
AOAC INTERNATIONAL Board of Directors, 2004-
Institute of Food Technologists

JIANMING TAO

460 Budding Ridge Road, CT 06410
Phone: 610.996.4173
Email: jtao@spectrixservices.com

PROFESSIONAL PROFILE

Laboratory Director with the experience and hands-on laboratory expertise essential for contributing in analytical chemistry, microbiology, in-vitro toxicology, immunology, molecular biology, and biochemical engineering-related research capacities, and with the knowledge of principles of the Good Laboratory Practice (GLP). Proven track record in product development, from laboratory to manufacturer. Energetic, confident leader with a strong drive for efficiency, simplicity, and excellence. Readily accepts change and new challenges, applying natural abilities in project management, team building, and verbal / written communications.

- *Expertise in:* analytical HPLC and LCMS analysis… GCMS analysis… ICPMS analysis… microbiological examinations… cell / tissue culture… DNA / RNA isolation… immunoprecipitation… northern and western blot… expression vector construction… oligonucleotide primer design… DNA sequencing… DNA transformation and transfection… PCR and quantitative RT-PCR… in vitro cytotoxicity and genotoxicity studies under compliance of GLP…SOP writing…
- *Strong technical and theoretical background in:* DNA damage and repair, cancer biology, cytokine biology, and T-cell immunology, including: in vitro and in vivo transgenic T-cell proliferation, activation, and differentiation assay… adoptive transfer technique… CTL Assay… apoptosis assay… flow cytometry analysis
- *Skilled in rodent animal models, in fungus infection study, T-cell related immune system studies, and skin fibrosing disease studies, specifically:* … lab animal handling… genotyping… phenotyping… small animal dissection surgical skills
- *Biochemical engineering experience in:* laboratorial / industrial scale fermentation, from 0.6 liter to 120 ton of fermenter… online analysis of fermentation procedures
- *Proficient in:* online search and analysis of information and databases for research projects

PROFESSIONAL EXPERIENCE

Spectrix Analytical Services, LLC 2013-present
Senior Microbiologist /Laboratory Director

- Quantitate active ingredients and impurities/contaminants of dietary supplements or pharmaceutical materials using LCMS, GCMS, ICPMS, etc.
- Establish biosafety level 2 Microbiology Laboratory for microbiological examinations on customers' products.
- Obtain the laboratory accreditation (ISO/IEC 17025) for Microbiology Laboratory.

MB Research Laboratories, Spinnerstown, PA 2005-2013
Study Director / Research Scientist

- Conduct alternative in-vitro toxicity/genotoxicity tests for cosmetics and pharmaceutical industrial under compliance of GLP.
- Lead the project of the in-vitro detection for unscheduled DNA synthesis by using flow cytometric technology, which is funded by NCI for SBIR.
- Write SOP for in vitro toxicology studies.

JIANMING TAO
page 2 of 4… jtao@spectrixservices.com

PROFESSIONAL EXPERIENCE

Roswell Park Cancer Institute, Buffalo, NY 2003 – 2005
Research Associate
- Led projects on: (1) the mechanism of T-cell trafficking and developing in murine allergic bronchopulmonary aspergillosis (ABPA) model; (2) the effect of IL-21 on antigen specific naïve CD8+ T cell activation, proliferation, differentiation, effector function, and memory cell formation in a T-cell transferred mouse model.

Case Western Reserve University, Cleveland, OH 2001 – 2003
Research Associate
- Initiated and conducted in-depth study on the cytokine and chemokine relationship in the murine GvHD model of human scleroderma and engineered cell therapy.

Cleveland Clinic Foundation, Cleveland, OH 2000 – 2001
Research Fellow
- Investigated the effects of alternated structure of DNA polymerase beta on human breast, lung, and colorectal cancers.

CIB-CSIC, Madrid, Spain 1994 – 2000
Graduate Research Assistant
- Developed the mutation detection method, PCR single-stranded conformation polymorphism (PCR-SSCP), as a routine tool in laboratory.
- Elucidated the structure-function relationship of intergrin alphaIIb-beta3 by studying molecular-genetic basis of human inherited platelet disease, Glanzmann thrombasthenia, and through comparison of cDNA sequences for species integrins alphaIIb and beta3 with that of human counterparts.

ECUST, Shanghai, China 1989 – 1994
Engineer
- Studied inosine fermentation by an inosine-producing auxotroph of a B.subtilis strain.
- Optimized the fermentation process of penicillin by computer-aided design and control in industrial scale.
- Developed an immobilization method for whole cell of Methanotroph Z201 for converting propylene to propylene oxide.
- Studied the cultivation of B. subtilis DB403 (pNC3) cloned neutral protease gene (nprE).
- Screened and improved the strain of B. subtilis for high-yield inosine.
- Optimized the fermentation process for production of atrial natriuretic polypeptide by a recombinant yeast Y33::YFD71-3.
- Developed high cell density cultivation with high level of expression of recombinant human interferon Gamma by DH5alpha E. coli (pBV220A) harboring target gene.
- Studied and supported the manufacture of RIBE-6 5-litre semi-automatic laboratory fermenter.
- Researched interferon alpha A production by cultivation of E. coli W3110(pEC901) cloning an interferon alphaA gene.

JIANMING TAO
page 3 of 4… jtao@spectrixservices.com

EDUCATION

Ph.D., Molecular Biology, 1999
Genetic and Molecular Basis of Platelet Function
CIB-CSIC (Center of Biological Investigations), Madrid, Spain

B.S., Biochemical Engineering, 1989
Continuous Extraction Fermentation for Ethanol Production by Immobilized S. Cerevisiae
ECUST (East China University of Science and Technology), Shanghai, China

PUBLICATIONS

Tao J., Newhard W., Cerven D.R., and DeGeorge G.L. Assessment of ultraviolet light- and chemical-induced UDS in various cell lines using flow cytometry. Poster, 48th Annual Meeting and ToxExpo™, Baltimore, MD, 2009

Tao J., Kirk C, Pratt L.F., Williams G.M. and DeGeorge G.L. An improved flow cytometry-based unscheduled DNA synthesis (UDS) assay. Poster, 47th Annual Meeting and ToxExpo™, Seattle, WA, 2008.

Kirk C., **Tao J**., Stempo B., Iatropoulos M., Williams G.M., and DeGeorge G.L. A non-animal-based, high-throughput unscheduled DNA synthesis assay for screening of genotoxins (HT-UDS). Poster, 46th Annual Meeting and ToxExpo™, Charlotte, NC, 2007.

Tao J., Segal B.H., Eppolito C., Li Q., Dennis C.G., Youn R., and Shrikant P.A. Aspergillus fumigatus extract differentially regulates antigen-specific CD4+ and CD8+ T cell responses to promote host immunity. J. Leukoc. Biol., 2006 Jun 22 [Epub ahead of print].

Zhang A.Y., Wu C., Zhou L., Ismail S.A., **Tao J.**, McCormick L.L., Cooper K.D., and Gilliam A.C. Transduced monocyte/macrophages targeted to murine skin by UV light. Exp. Dermatol. 15(1):51-57, 2006.

Moroz A., Eppolito C., Li Q., **Tao J.**, Clegg C.H., and Shrikant P.A. IL-21 enhances and sustains CD8+ T cell responses to achieve durable tumor immunity: comparative evaluation of IL-2, IL-15, and IL-21. J Immunol. 173(2):900-909, 2004.

Bhattacharyya N., **Tao J.**, Klein E.A., and Banerjee S. Alterations of transforming growth factor beta receptor II, insulin growth factor receptor II genes in microsatellite unstable prostate carcinomas. Oncol Rep. 11(1):231-236, 2004.

Arias-Salgado E.G., **Tao J.**, Gonzalez-Manchon C., Butta N., Vicente V., Ayuso M.S., and Parrilla R. Nonsense mutation in exon-19 of GPIIb associated with thrombasthenic phenotype. Failure of GPIIb(delta597-1008) to form stable complexes with GPIIIa. Thromb. Haemost. 87(4):684-691, 2002.

Tao J., Arias-Salgado E.G., Gonzalez-Manchon C., Iruin G., Butta N., Ayuso M.S., and Parrilla R. A 1063G-->A mutation in exon 12 of glycoprotein (GP)IIb associated with a thrombasthenic phenotype: mutation analysis of [324E]GPIIb. Br. J. Haematol., 111(3):965-973, 2000.

JIANMING TAO
page 4 of 4... jtao@spectrixservices.com

PUBLICATIONS

Tao J., Arias-Salgado E.G., Gonzalez-Manchon C., Diaz-Cremades J., Ayuso M.S., and Parrilla R. A novel (288delC) mutation in exon 2 of GPIIb associated with type I Glanzmann's thrombasthenia. Br. J. Haematol., 111(1):96-103, 2000.

Tao, J., and Parrilla, R. cDNA sequences for GPIIb and GPIIIa of species. GI: 5733733 (dog GPIIb), GI: 5805336 (pig GPIIb), GI: 5805340 (rabbit GPIIb), GI: 5733735 (dog GPIIIa), GI: 5805338 (pig GPIIIa), and GI: 5805342 (rabbit GPIIIa). Published in GenBank, 1999.

Ferrer, M., **Tao, J.**, Iruin, G., Sanchez-Ayuso, M., Gonzalez-Rodriguez, J., Parrilla, R., and Gonzalez-Manchon, C. Truncation of glycoprotein (GP) IIIa (del616-762) prevents complex formation with GPIIb: Novel mutation in exon 11 of GPIIIa associated with thrombasthenia. Blood, 92(12):4712-4720, 1998.

Ibarreta, D., **Tao, J.**, Parrilla, R., and Ayuso, M.S. Mutation analysis of chromosome 19 calmodulin (CALM3) gene in Alzheimer's disease patients. Neurosci. Lett., 299:157-160, 1997.

Ferrer, M., **Tao, J.**, Menaya, J., Gonzalez-Manchon, C., Fernandez, M., Alvarez, M.V., Garcia-Munoz, M., Ayuso, M.S., and Parrilla, R. A novel point mutation in the GPIIIa subunit of the integrin alphaIIbbeta3 associated to Glanzmann's thrombasthenia. In Advances in Gene Technology. Therapeutic Strategies in Molecular Medicine. Ahmad F, etc. Eds. (Oxford: Oxford University Press), 1996.

Ye, Q., Zhang, S.L., Lu, S.C., **Tao, J.M.**, and Yu, J.T. Interferon gamma production in *E. coli* DH5alpha (pBV220). Better Living Through Innovative Biochemical Engineering (Proceedings of the 3rd Asia-Pacific Biochemical Engineering Conference), pp. 140, Singapore, 1994.

Lu, S.C., **Tao, J.M.**, Qiu, W.R., and Yu, J.T. Propylene oxide production from propylene by immobilized whole cell of methanotroph Z201 (in Chinese). Huadong Ligong Daxue Xuebao (Journal of ECUST), 20(1):21-26, 1994.

Ye, Q., **Tao, J.M.**, Zhang H., Zhang S.L., Cai, H.B., Bao, W.G., and Li Y.Y. Human alpha atrial natriuretic peptide fermentation by using a genetically engineered yeast strain (in Chinese). Shengwu Gongcheng Xuebao (Chinese Journal of Biotechnology), 10(4):312-317, 1994.

Ye, Q., **Tao, J.M.**, Zhang, S.L., and Yu, J.T. Production of human atrial natriuretic peptide by a recombinant yeast strain. Better Living Through Innovative Biochemical Engineering (Proceedings of the 3rd Asia-Pacific Biochemical Engineering Conference), pp. 143, Singapore, 1994.

Tao, J.M., Ye, Q., Qi, L.H., and Zhang, S.L. Human alpha atrial natriuretic peptide production using a genetically engineered yeast strain (in Chinese). Proceedings of the 5th National Symposium on Biotechnology and Bioengineering, pp. 125, Beijing, 1993.

Ye, Q., Kang, F.X., Lu, S.C., **Tao, J.M.**, Zhang, S.L., and Yu, J.T. Continuous and high cell density cultivation of *E. coli* W3110 (pEC901) harboring human interferon alpha A gene. Biochemical Engineering for 2001 (Proceedings of Asia-Pacific Biochemical Engineering Conference '92), pp. 221, Yokohama, 1992.

CURRICULUM VITAE

Personal Details

Name: Marina Graciela
Surname: Torres Rodriguez
Date of Birth: 16th December 1964
Address: Avenida Estanislao López 4862/701
Zip Code: 11400
Phone: 598 2 619-26-48 - 598 99 373 101
City: Montevideo
Country: Uruguay

Organization

Laboratorio Tecnológico del Uruguay-Technological Laboratory of Uruguay (LATU)
Chromatography and Mass Spectrometry Department-Department of Method Development
Address: Avenida Italia 6201
Zip Code: 11500
Montevideo-Uruguay
Phone: 598 2 601-37-24
Fax: 598 2 601-85-54
e-mail: mtorres@latu.org.uy
www.latu.org.uy

Education Level

- 1989 Bachelor Degree in Chemistry (Faculty of Chemistry. Universidad de la República Oriental del Uruguay- State University)
- 1991 Pharmaceutical Chemist Degree (Faculty of Chemistry. Universidad de la República Oriental del Uruguay- State University)
- 1995 Postgraduate Studies in Analytical Chemistry: Chromatography (Faculty of Chemistry. Virginia Polytechnic Institute and State University- USA)
- 2000 Quality Manager (ÖVQ- Austrian Association for Quality Assurance)
- 2003 Environmental Systems Manager (ÖVQ- Austrian Association for Quality Assurance)
- 2006 Quality Auditor (ÖVQ- Austrian Association for Quality Assurance)
- 2009 Postgraduate Certificate in Dairy Technology and Dairy Products (Faculty of Engineering and Technologies-Universidad Católica del Uruguay)

Work Experience

- **April 1992 to present:** Laboratorio Tecnológico del Uruguay (Technological Laboratory of Uruguay-LATU)

    1) Chromatography and Mass Spectrometry Department-Department of Analytical Method Development

- Senior Analyst:
  - ✓ Responsible for method development, validation and accreditation of new analytical methods in food and environmental samples
  - ✓ In charge of Nutrients and Pesticide Residues analysis laboratory
- Responsible for Department Quality System

2) Quality Coordination Division: supporting LATU´s Quality System as internal auditor in ISO 9001 and ISO 17025

- **August 2008 to present:** Organismo Uruguayo de Acreditación (Uruguayan Accreditation Service-OUA) working as ISO 17025 Auditor

- **June- October 1991:** Squibb Laboratories, scholarship for training in Pharmaceutical Industry

- **September 1987- September 1992:** Organic Department Faculty of Chemistry. Universidad de la República Oriental del Uruguay- State University
  - In charge of laboratory practices
  - Organic synthesis

Professional Achievements

- Committees Participation:
  - Sub coordinator of Uruguayan Technical Subcommittee of Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)
  - Member of ISO/TC34/WG14 - "Vitamins, Carotenoids and other Nutrients" Coordinator of the National Standardization Body sub-committee
  - Member of Uruguayan Surveillance Plan for Pesticide Residues
  - AOAC International´s participation:
    - ✓ Member of AOAC since September 2006
    - ✓ Member of Latin America and Caribbean Section since 2008
    - ✓ Past member of Committee E (Food and Food Nutrition 2006-2010)
    - ✓ Food Nutrition Pool of Expert since 2010
    - ✓ 2010-2013 participation in different Method Centric Committees
    - ✓ Member of SPIFAN Stakeholder Panel in Infant Formula and Adult Nutritionals
      - Member of Whey Casein Ratio Expert Review Panel
    - ✓ Member of Pesticides in Tea Expert Review Panel
    - ✓ Membership Committee member
    - ✓ Editorial Board member
    - ✓ Reviewer for Journal of AOAC
- Author and coauthor of articles for journals
- Speaker at analytical science congress and symposiums
- Author and coauthors of posters for congress and symposiums

- Thesis tutor for undergraduate students (Faculty of Chemistry and Faculty of Engineering-Universidad de la República Oriental del Uruguay- State University)

Skills

- Skilled in method development
- Skilled in sample preparation and chromatographic analysis
- Languages:
  - Spanish as mother language
  - English: advanced level
  - German: first official international certificate as a foreign language

Dan-Hui Dorothy Yang, Ph.D.

Contact Info: Email: dorothy_yang@agilent.com; Tel: (408) 553 7091 (O); (408) 368 1405 (C)

Objective: Expert Review Panel for AOAC

Education:

Degree:	University	Year
B.Sc. (Chemistry)	Peking University, P.R. China	1988
Ph.D. (Chemistry)	Université Libre de Bruxelles, Belgium	1992

Relevant Experience:

Aug. 2000 – Present: Senior Scientist, Agilent Technologies, Inc.

Mass Spectrometers and Reagent Kits Related Experience: 2006-Present

- Food safety and environmental market applications on Agilent triple quadrupole and time of flight (QTOF) Mass Spectrometry – designed applications tests and executed plan; conducted internal and external trainings/webinars. Focused on multi-residue pesticides screening in foods, estrogens analysis in milk, pesticides/pharmaceutical and personal care product detection in surface water.
- Supported sales team on new product launch, customer education and conducted "show and tell" demos to customers.
- Mentored junior team members on application test planning and applied market application test management.
- Validated Agilent reagent kits for food safety market: trouble shooting on veterinary drug kits, new method development for challenging compounds, and proposing changes for customers.
- Worked with genomic reagent team (former Stratagene) to develop single quadrupole Mass Spectrometer clinical application using MassCode technology – PCR bioreagent validation, mass tags selection, assay protocol development and software testing.
- Developed an automated HPLC – single quadrupole MS method for PCR amplicon purification and detection.
- Developed methods on blood vitamin D, testosterone, thyroid hormones, dihydroxy vitamin D testing using low-end and high-end triple quadrupole mass spectrometer.

HDL 2b (High Density Lipoprotein 2b) Development and 510K Filing: 2005 - 2009

- Developed HDL subfractionation assay on microfluidic electrophoresis platform – reagents development including polymer matrix selection for electrophoresis, buffers and florescent dyes developments.
- Set QC specifications for all reagents components and transfer the process to manufacturer.
- Conducted design verification and design validation for both reagents and software.
- Supervised multi-sites validation and clinical trials in compliance with quality system requirement.
- Submitted Agilent first IVD 510K to US FDA and was responsible for technical write-ups.

Protein Detections and Microarrays: 2000 - 2005

- Designed and prepared surfaces for protein immobilization in an array format.
- Improved protein printing process to generate high quality protein microarrays.
- Applied antibody microarrays on atherosclerosis, insulin resistance and liver cancer biomarker discovery and early diagnosis.
- Evaluated proximity ligation technology for ultra-sensitive protein detection based on aptamers and antibodies.

June 1998 – July 2000 Senior Scientist and Chemistry Lead, LjL Biosystems, Sunnyvale, California (acquired by Molecular Devices, Inc. in 2000)

- Designed and synthesized new long lifetime fluorescent labels for energy-transfer and polarization applications for pharmaceutical entities screening.
- Labelled protein, peptide and small molecules (GTP, cAMP, cGMP etc) with reactive fluorophores and developed preliminary testing to demonstrate the assay feasibility.
- Supervised external collaborations related to synthetic fluorophore chemistry and two associates.

Jan 1994 – May 1998 Research Associate, Department of Chemistry, Univ. of Connecticut

- Synthesized benzyl ethers, sulfur-containing cyclic and acyclic compounds, organic phosphates and their photosensitized deprotection
- Photosensitized debromination of 2'-deoxy-8-bromoguanosine and its application in oligonucleotide
- Managed lab of 6 graduate students and 3-4 undergraduate students.

July 1992-July 1993 Postdoctoral Research Fellow, Institute of Organic Chemistry, Universität Bern, Switzerland.

- Multi-step synthesis of bipyridine derivatives as signal transducer and biosensor.
- Synthesis of organometallic compounds and study mechanisms on reductive cleavage

Jan 1989-May 1992 Graduate Research Assistant
Université Libre de Bruxelles, Brussels, Belgium; **Graduated with highest honor**

- Application of high intensity ultrasound for heterogeneous organic reaction system
- Studies of the influence of experimental parameters on sonochemical organic reactions
- Synthesis of organometallic compound intermediates

Oct 1991-Jan 1992 Exchange Researcher, Department of Chemical Development, Continental Pharma INC, Searle European Development Center, Belgium.

- The influence of ultrasound on bromination of substituted toluene with NBS
- Synthesis of drug intermediates

Aug 1990-Dec 1990 Exchange Researcher, Université Joseph Fourier, Grenoble, France.

- The influence of ultrasound on lithium-modified Barbier reaction of carboxylic acids and lithium carboxylates.

Patent Applications:

20 patents (15 with Agilent). Available upon request.

Publications:

10 peer reviewed papers, 5 after joining Agilent . Available upon request.
8 published appnotes on food safety and enviromental applications using triple quadrupole and time of flight high resolution mass spectrometry (being first author on 6 appnotes).

Conference Presentations:

>45 application related presentations in the area of food safety, environment testing, and clinical research: ASMS, NEMC, EPRW, RAFA, IMSC, Montreux, AACC, MSACL, training, workshops, roadshows, etc.

Scientific Society Service:

Worked as a reviewer for American Chemical Society (ACS) journals on demand basis.

Jinchuan Yang Ph. D.

47 Saddle Hill Road
Hopkinton, MA 01748
Phone: (508) 435-5394 (H)
Phone: (508) 482-2107 (O)
Email: Yang36j@yahoo.com

EMPLOYMENT

- **Waters Corporation,** Milford, MA.
  Business Development Manager (July, 2009 - Present)
  - Responsible for the business development for the new generation of supercritical fluid chromatography (Ultra-Performance Convergence Chromatography) in food and environmental markets.
  - Focus on the business development in the food quality control market segment.
  - Business development for the Open-architecture UPLC system for water analysis.

  Sr. Applications Chemist (May, 2002 – June, 2009)
  - Develop characterization techniques for chemicals using high performance liquid chromatography (including SEC with viscosity and light scattering detection).
  - Cooperate with engineers to develop and validate new instrument and software designs for modern HPLC instrumentation.
  - Support and train Waters Technical Specialists and sales personals to support the world wide marketing operation.

EDUCATION

- **University of Alabama at Birmingham,** Birmingham, AL. (Jan. 1997 – May 2002)
- Ph.D. in **Polymer Science**. Dec. 2001. Research Advisor: Dr. Jimmy W. Mays
- **East China University of Science and Technology,** Shanghai, China. (Sept. 1992 – July 1995)
- M.S. in **Polymer Science**. July 1995. Research Advisor: Prof. Zhongde Xu.
- **Shanghai Jiao Tong University,** Shanghai, China. (Sept. 1988 – July 1992)
- B.S. in **Polymer Materials**. July 1992

PUBLICATIONS

1) Qi Chen, Jingshun Zhang, Xing Ke, Shiyun Lai, Baohua Tao, Jinchuan Yang, Weimin Mo, and Yiping Ren, "Quantification of bovine beta-casein allergen in baked foodstuffs based on ultra-performance liquid chromatography with tandem mass spectrometry", Food Additives & Contaminants: Part A, 2015 32(1): 25-34
2) Jinchuan Yang, Rich DeMuro, and Joe Romano, "Analysis of flavonoids in juices with the ACQUITY QDa detector", Waters Application Note, Waters Corporation, Milford, MA, 2014, Art. No. 720004985EN
3) Jinchuan Yang, "Rapid separation of vitamin K1 isomers and vitamin K2 in dietary supplements using UltraPerformance Convergence Chromatography with a C18 column", Waters Technology Brief, Waters Corporation, Milford, MA, 2014, Art. No. 720004937EN.
4) Rui Chen, Jinchuan Yang, and John McCauley, "A single-injectin UPC2 method for fast and simultaneous separation of nine fat-soluble vitamins", Waters Technology Brief, Waters Corporation, Milford, MA, 2013, Art. No. 720004551EN.
5) Mehdi Ashraf-Khorassani, Larry T. Taylor,1 Jinchuan Yang, and Giorgis Isaac, " Fast Separation of Triacylglycerols in Oils using UltraPerformance Convergence Chromatography (UPC2)", Waters Application Note, Waters Corporation, Milford, MA, 2014, Art. No. 720004871EN.
6) Jinchuan Yang, "Determination of Brominated Vegetable Oil in Soft Drinks by UPC2/MS", Waters Application Note, Waters Corporation, Milford, MA, 2014, Art. No. 720005079EN.
7) Jinchuan Yang, " Simultaneous Determination of Vitamins A and E in Infant Formula by ACQUITY UPC2 with PDA Detection", Waters Technology Brief, Waters Corporation, Milford, MA, 2013, Art. No. 720004538EN.
8) Dimple Shah, Jinchuan Yang, Gordon Fujimoto, Lauren Mullin, and Jennifer Burgess, " Rapid Detection of Pesticide Residues in Fruit Juice Without Sample Extraction Using UPLC-MS/MS", Waters Application Note, Waters Corporation, Milford, MA, 2012, Art. No. 720004403EN.

9) Yiping Ren, Jinchuan Yang, "Determination of Common Beta-Agonist Residues in Meat Products by UPLC-MS/MS", Waters Application Note, Waters Corporation, Milford, MA, 2012, Art. No. 720004388EN.
10) Jinchuan Yang, Ken Rosnack, Joesph Romano, "Q-Tof MS and Residue Analysis", Waters Application Note, Waters Corporation, Milford, MA, 2011, Art. No. 720004100EN.
11) Jinchuan Yang and Alice J. Di Gioia, " Rapid Analysis Of Antioxidants In Synthetic Lubricants", Waters Application Note, Waters Corporation, Milford, MA, 2009, Art. No. 720003221EN.
12) Dimple D. Shah, Jinchuan Yang, Mark Benvenuti, Peter J. Lee, and Alice J. Di Gioia, " Monitoring Waterborne Wood Preservatives", Waters Application Note, Waters Corporation, Milford, MA, 2008, Art. No. 720002906EN.
13) Jinchuan Yang and Alice J. Di Gioia, " Fast Analysis FOR Fe rmentation E thanol with the Breeze 2 HP LC System", Waters Application Note, Waters Corporation, Milford, MA, 2008, Art. No. 720002884EN.
14) Jinchuan Yang and Alice J. Di Gioia, "HPLC determination of free acrylic acid and monomers in polyacrylates", Waters Application Note, Waters Corporation, Milford, MA, 2006, Art. No. 720001909EN.
15) Jinchuan Yang and Giorgis Isaac, "Characterization of triacylclycerols in edible oils using the ACQUITY UPC2 system and mass spectrometry", Waters Technology Brief, Waters Corporation, Milford, MA, 2013, Art. No. 720004809EN.
16) Marian Twohig, Dana Krueger, Antonietta Gledhill, Jinchuan Yang, Jennifer Burgess, Super fruit juice authenticity, Focus on Food Analysis-Supplement to AgroFood Industry Hi-tech September/October 2011 vol 22 n 5, page 23-26
17) Qi Chen, Jingshun Zhang, Xing Ke, Shiyun Lai, Baohua Tao, Jinchuan Yang, Weimin Mo, Yiping Ren, "Quantification of bovine beta-casein allergen in baked foodstuffs based on ultra-performance liquid chromatography with tandem mass spectrometry", Food additives & Contaminants Part A, 2014
18) Jinchuan Yang and Alice J. Di Gioia, “Quantification of Homopolymer in a Copolymer Product: Comparison of HPLC with ELSD and UV Detection” Waters Application Note, Waters Corporation, Milford, MA, 2006, Art. No. 720001560EN
19) Jinchuan Yang, Peter J. Lee, and Alice Di Gioia. “Fast HPLC analysis for fermentation ethanol processes” Waters Application Note, Waters Corporation, Milford, MA, 2006, Art. No. 720001896EN
20) Peter J. Lee, Jinchuan Yang, and Alice J. Di Gioia. “Acquity UPLC with ELS and MS detection: Polyetheramines” Waters Application Note, Waters Corporation, Milford, MA, 2006, Art. No. 720001751EN
21) Toomey, R; Mays, J; Yang, JC; Tirrell, M. “Postadsorption rearrangements of block copolymer micelles at the solid/liquid interface” Macromolecules, 2006, 39(6), 2262-2267
22) Li, F; Balastre, M; Schorr, P; Argillier, JF; Yang, JC; Mays, JW; Tirrell, M. “Differences between tethered polyelectrolyte chains on bare mica and hydrophobically modified mica” Langmuir, 2006, 22(9), 4084-4091
23) Jinchuan Yang and Alice J. Di Gioia. “Analysis of Starch Using the Alliance GPCV2000 System” Waters Application Note, Waters Corporation, Milford, MA, 2005, Art. No. 720001379EN
24) Nielson R.; Alden, P.; Yang, J. ”High-speed gel permeation chromatography” AMERICAN LABORATORY, 2004, 36(3), 34
25) Jinchuan Yang. “Surfactant Analysis Using The 2420 Evaporative Light Scattering Detector” Waters Application Note, Waters Corporation, Milford, MA, 2004, Art. No. 720001000EN
26) Yang, Jin Chuan; Mays, Jimmy W. “Synthesis and Characterization of Neutral/Ionic Block Copolymers of Various Architectures” Macromolecules , 2002 , Volume: 35 , Number: 9 , Page: 3433-3438
27) Yang, Jin Chuan; Jablonsky, Michael J. ; Mays, Jimmy W. “NMR and FT-IR studies of sulfonated styrene-based homopolymers and copolymers” Polymer , 2002 , Volume: 43 , Number: 19 , Page: 5125-5132
28) Yang, Jinchuan; Nonidez, William K. ; Mays, Jimmy W. “MALDI/TOF/MS as a method for characterizing micelle-forming polymers: a MALDI/TOF/MS study of amphiphilic diblock copolymers based on sulfonated polystyrene” *Int. J. Polym. Anal. Charact.* , 2001 , Volume: 6 , Number: 6 , Page: 547-563
29) Zhongde Xu, Jinchuan Yang and Tianzi Huang. “The steric stabilization of colloidal dispersions, polymer brush on nano-particle surface”, *Polymers and Organic Solids,* Lianghe Shi and Daoben Zhu Ed. Science Press, Beijing, 1997,54
30) Balastre, Marc; Li, Feng; Schorr, Phillip; Yang, Jinchuan; Mays, Jimmy W. ; Tirrell, Matthew V. “A Study of Polyelectrolyte Brushes Formed from Adsorption of Amphiphilic Diblock Copolymers Using the Surface Forces Apparatus” *Macromolecules* , 2002 , Volume: 35 , Number: 25 , Page: 9480-9486
31) Dubreuil, F.; Romet-Lemonne, G.; Guenoun, P.; Yang, J.; Mays, J. W. ; Daillant, J. “Structure and buckling of charged diblock copolymer films at liquid interfaces” Adv. Colloid Interface Sci. , 2001 , Volume: 94 , Number: 1-3 , Page: 151-165
32) Muller, F.; Fontaine, P. ; Delsanti, M.; Belloni, L.; Yang, J. ; Chen, Y. J. ; Mays, J. W.; Lesieur, P.; Tirrell, M.; Guenoun, P. “Counterion distribution in a spherical charged sparse brush” Eur. Phys. J. E 2001 , Volume: 6 , Number: 2 , Page: 109-115
33) Muller, F.; Delsanti, M.; Auvray, L.; Yang, J.; Chen, Y. J. ; Mays, J. W. ; Deme, B.; Tirrell, M.; Guenoun, P. “Ordering of urchin-like charged copolymer micelles: electrostatic, packing and polyelectrolyte correlations” Eur. Phys. J. E , 2000 , Volume: 3 , Number: 1 , Page: 45-53

34) Youk, Ji Ho; Park, Mi-Kyoung; Locklin, Jason; Advincula, Rigoberto; Yang, Jinchuan; Mays, Jimmy "Preparation of Aggregation Stable Gold Nanoparticles Using Star-Block Copolymers" Langmuir , 2002 , Volume: 18 , Number: 7 , Page: 2455-2458
35) Saint-Jalmes, A.; Sonin, A. A.; Delsanti, M.; Guenoun, P.; Yang, J. ; Mays, J. W.; Langevin, D. "Disjoining Pressures and Ordering in Thin Liquid Films Containing Charged Diblock Copolymers Adsorbed at the Interfaces" Langmuir , 2002 , Volume: 18 , Number: 6 , Page: 2103-2110
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C. V. for Kurt A. Young

Kurt A. Young, Ph.D.
Senior Principal Scientist
GNC/Nutra Manufacturing
1050 Woodruff Rd.
Greenville, SC 29607
Work: (864) 987-3522
Cell: (864) 293-0428
kurt.young@nutramfg.com
kurt.young@att.net

Education

- B.A. in Chemistry, Barrington College, Barrington, RI
- M.S. in Pharmacognosy (Aug. 1985) and Ph.D. (Dec. 1992) in Pharmaceutical Sciences (Pharmacognosy), University of Rhode Island College of Pharmacy. Research on bioactive compounds from marine and freshwater microalgae. Postdoctoral Research Fellow (1993-94).

Work Experience

- Senior (Principal) Scientist (1996-present): Nutra Manufacturing, Greenville, SC (formerly General Nutrition Products). Oversee analytical method development to support product label claims and quality control testing. Evaluate specifications and testing requirements for raw materials and finished products. Scientific liaison between manufacturing quality group and corporate management.
- National Research Council Research Associate (1995-96): NOAA National Oceanographic Service Laboratory, Charleston, SC. Research on seafood toxins. LC/MS analysis and bioassay development.
- Organic Chemist/Technical Director (1988-1991): EnviroServices, Inc., North Kingstown & Providence, RI. Contract environmental testing laboratory work.

General Experience

- Over 30 years experience in chromatographic analysis, method development/ validation, instrument setup and troubleshooting. Experienced in HPLC & UHPLC, LC/MS, GC, GC/MS, CE, ion-chromatography, GPC, TLC.
- Natural product isolation and structure determination. NMR, MS, IR spectroscopy. Bioassay-guided fractionation of natural product extracts.

Affiliations/Professional Service

- Adjunct Assistant Professor, Department of Food, Nutrition & Packaging Sciences, Clemson University, Clemson, SC.
- Member NIST DSQAP Advisory Board
- Served on AOAC Expert Review Panels for Omega 3-Fatty Acids, Cranberry and Milk Thistle Method Evaluations

- Member ACS, AOAC, American Society of Pharmacognosy (ASP)

Publications & Presentations

- Young, K.and Katzenberger, D., Analysis of Amino Acids in Dietary Supplements Using Waters AccQ-Tag™ Ultra Derivatization on UPLC®/UHPLC Systems With Sub-2µm and Core-Shell Particle Columns. Poster Presentation, Waters Corporation Natural Products and Dietary Supplements Technology Summit, North Bethesda, MD, April 28-29, 2015.
- Young, K. and Hall, A., Use of Solid Core Particle HPLC Columns for Dietary Supplement Analyses. Poster Presentation, 125th AOAC Annual Meeting, New Orleans, LA, Sept. 18-21, 2011.
- Young, K., Hall, A. and Katzenberger, D., Determination of Amino Acids and Glucosamine in Dietary Supplements Using HPLC with Evaporative Light Scattering Detection (ELSD). Poster Presentation, 122nd AOAC Annual Meeting, Dallas, TX, Sept. 21-24, 2008.
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YANJUN ZHANG
6152 Topeka Dr
Tarzana, CA 91335
310-985-2798
Yjzhang66@yahoo.com

EDUCATION:
B.S., Pharmaceutical Science, Hebei Medical University, China, 1985.
M.S., Medicinal Chemistry, Shenyang Pharmaceutical University, China, 1991.
Ph.D., Medicinal Chemistry, Chinese Academy of Medical Sciences & Peking Union Medical College, China. 1999.

PROFESSIONAL EXPERIENCE:

Principal Scientist, Herbalife International. From March 2014-present.
Directing analytical approach for botanical ingredients and natural products. Setting the strategic direction for the natural products program and develop plans, policies to ensure success. Define project objectives, requirements, and timelines. Identify, develop, and foster good working relationships with external departments and support initiatives required to continually enhance natural product testing program worldwide.

Director, Mark Hughes Cellular and Molecular Nutrition Laboratory**,** UCLA Center for Human Nutrition. From July 01, 2007-present. Manage Mark Hughes Cellular and Molecular laboratory including launch new research projects; maintain the ongoing research projects related to botanical research.

- Launch UCLA-Herbalife Botanical Evaluation Program in 2007, established 25 identification and quantitatively analysis methods for identification, evaluation and quality control of key botanical ingredient for Herbalife products.
- Launch tea-chemical comprehensive project in 2008, including establish the analytical methods for tea catechin, tea amino acid, tea purine alkaloids content, established the optimized condition for the extraction of tea, and to obtain the best tea extracts for Herbalife products.
- Launch the investigation of supplementation of tea-on weight gain project in 2009, using small animal MRI to monitor the impact of green tea, oolong and black tea extract on the weight gain of small animals feeding with high fat and high carbohydrate food.
- Establish the method for identification of cocoa powder in Herbalife Nutritional Shake Mix to avoid the tax from Mexico
- Analysis of tea catechins, amino acid, and purine alkaloids contents, establish botanical Evaluation Program in 2007, established 25 identification and quantitatively analysis methods for identification, evaluation and quality control of key botanical ingredient for Herbalife products.
- Direct UCLA-Herbalife Botanical Evaluation Program lunched 2008, established 10 methods for evaluation of key raw botanical ingredients in Herbalife products.

- Direct UCLA-Herbalife Botanical Evaluation Program lunched 2009, established 6 methods for evaluation of key raw botanical ingredients in Herbalife products.
- Establish a novel analytical method

Consultant, Herbalife International, From May 2009-present.

- Botanical Identification Program –Phase I, Direct Herbalife Botanical Identification Program launched in 2009, and established 90 botanical identification methods for all Herbalife botanical raw ingredients used for production of US dietary supplements.
- Botanical Identification Program-Phase II: Direct Herbalife Botanical Identification Program, phase II, established 63 botanical identification methods for all Herbalife botanical raw ingredients used worldwide.
- Herbalife tea: Launch tea-chemical project in 2008, including establish the analytical methods for tea catechin, tea amino acid, tea purine alkaloids content, established the optimized condition for the extraction of tea, and to obtain the best tea extracts for botanical dietary supplements.

Assistant researcher, UCLA Center for Human Nutrition, UCLA, From December 2004 to July 1st, 2006 –present
Staff Research Associate, UCLA Center for Human Nutrition, UCLA, From December 2004 to June 30, 2006.
Research Associate, Michigan State University, From January 2001 to November 2004.
Consultant for Traditional Chinese medicine R&D, Kedi Pharmaceutical Co. Ltd. China, From January 1993 to June 2000.
Project manager, Kedi Pharmaceutical Co. Ltd. China, From January 2000 to June 2000.
Visiting scholar, Muséum National d'Histoire Naturelle, CNRS, Paris, France. From October 1999 to January 2000, and From July 2000 to January 2001.
Associate professor, Institute of Chinese Materia Medica, Chengde Medical College, From July 1991 to August 1999.
Assistant professor, Institute of Chinese Materia Medica, Chengde Medical College, From July 1985 to August 1988.

PROFESSIONAL ACTIVITIES:

Professional Memberships:
Member of American Chemical Society, USA.
Member of American Society of Pharmacognosy, USA.

Review of Journals:
Bioorganic and Medicinal Letters
Botanical Bulletin China
Food and Chemical Toxicology
International Journal of Food Science and Nutrition
Journal of Agricultural and Food Chemistry
Journal of Chromatography A

Journal of Chromatography B
Journal of Functional Food
Journal of Natural Products
Journal of the Science of Food and Agriculture
Natural Product Communication
Nutrition and Cancer
Phytotherapy Research
Rapid Communication in Mass Spectrometry
The Journal of Alternative and Complementary Medicine
Tetrahedron

PUBLICATION/BIBLIOGRAPHY:

RESEARCH PAPERS (PEER REVIEWED)

A. RESEARCH PAPERS - PEER REVIEWED

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2. **Yanjun Zhang**, Guangxiong Zhou, Ruoyun Chen, Dequan Yu. Styryllactones from the rhizomes of *Goniothalamus griffithii*. *J. Asian Nat. Prod. Research* **1999**, *1*, 189-197.
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8. Bolleddula Jayaprakasam, **Yanjun Zhang**, Navindra P. Seeram, Muraleedharan G. Nair Growth inhibition of human tumor cell lines by withanolides from *Withania somnifera* leaves. *Life Sciences* **2003**, *74*, 125-134.
9. Navindra P. Seeram, **Yanjun Zhang** and Muraleedharan G. Nair Inhibition of proliferation of human cancer cells and cyclooxygenase enzymes by anthocyanidins and catechins. *Nutrition and Cancer* **2003**, *46*, 106-110.
10. **Yanjun Zhang**, Bolleddula Jayaprakasam, Navindra P. Seeram, Lawrence K. Olson, David DeWitt and Muraleedharan G. Nair. Insulin secretion and

cyclooxygenase enzyme inhibition of *Cabernet Sauvignon* grape skin compounds. *J. Agric. Food Chem*. **2004**, *52*, 228-233.

11. **Yanjun Zhang**, Robert H. Cichewicz and Muraleedharan G. Nair. Lipid peroxidation inhibitory compounds from daylily (*Hemerocallis fulva*) leaves. *Life Sciences* **2004**, *75* (6), 753-763.
12. **Yanjun Zhang**, David L. DeWitt, Sorimuthu Murugesan and Muraleedharan G. Nair Novel lipid peroxidation and cyclooxygenase enzyme inhibitory tannins from *Picrorhiza kurroa* seeds. *Chemistry and Biodiversity* **2004**, *1* (3), 426-441.
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38. Navindra P. Seeram, **Yanjun Zhang**, Rodney McKeever, Susanne M. Henning, Ru-po Lee, Marc A. Suchard, Zhaoping Li, Steve Chen, Gail Thames, Alona Zerlin, Martha Nguyen, David Wang, Mark Dreher, David Heber. Pomegranate Juice and Extracts Provide Similar Levels of Plasma and Urinary Ellagitannin Metabolites in Human Subjects. *J. Med Food* **2008**, 11(2), 390-394.
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Growing Areas *J. Agric. Food Chem*. 2009, 57(21), 10408-10413.
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52. Adams, Lynn S.; **Zhang, Yanjun**; Seeram, Navindra P.; Heber, David; Chen, Shiuan Pomegranate ellagitannin-derived compounds exhibit antiproliferative and antiaromatase activity in breast cancer cells in vitro Cancer Prev. Res. 2010, 3(1), 108-113.
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55. Mulabagal, Vanisree; Ngouajio, Mathieu; Nair, Ajay; **Zhang, Yanjun**; Gottumukkala, Aditya L.; Nair, Muraleedharan G. In vitro evaluation of red and green lettuce (Lactuca sativa) for functional food properties Food Chem., 2010, 118(2), 300-306.
56. Hong, Mee Young; Henning, Susanne; Moro, Aune; Seeram, Navindra P.; **Zhang, Yanjun**; Heber, David, Chinese red yeast rice inhibition of prostate tumor growth in SCID mice, Cancer Prev Res 2011, 4(4), 608-615.
57. Henning, Susanne M.; **Zhang, Yanjun**; Seeram, Navindra P.; Lee, Ru-Po; Wang, Piwen; Bowerman, Susan; Heber, David, Antioxidant capacity and phytochemical content of herbs and spices in dry, fresh and blended herb paste form. Int. J. Food Sci. Nutr. 2011, 62(3), 219-225.
58. Stephen J. Freedland, Michael Carducci, Nils Kroeger, Alan Partin, Jian-yu Rao, Yusheng Jin, Susan Kerkoutian, Hong Wu, Yunfeng Li, Patricia Creel, Kelly Mundy, Robin Gurganus, Helen Fedor, Serina A. King, **Yanjun Zhang**, David Heber, and Allan J. Pantuck, Double-Blind, Randomized, Neoadjuvant Study of the Tissue Effects of POMx Pills in Men with Prostate Cancer Before Radical Prostatectomy, Cancer prevention research (2013) volume: 6 issue: 10 page:

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RESEARCH PAPERS (NON-PEER REVIEWED)

D. RESEARCH PAPERS - NON-PEER REVIEWED

1. **Yanjun Zhang,** Shaowen Kang. Design a new preparative TLC device. *Zhong cao yao* 1986, 7, 662.
2. **Yanjun Zhang**, Shaowen Kang. The measurement of total flavonoids in the leaves of *Scutellaria Baicalensis*. *Journal of Chengde Medical College*, 1987 (4), 552-554.
3. Jin Li, Hesong Yang, **Yanjun Zhang.** Body-dependent effect of 91041 and 91046 and their acute toxicity *Bulletin of New Drug Research Foundation* 1994, 4, 131-134.
4. Jin Li, Hesong Yang, **Yanjun Zhang**, Analgesic effects of 91041 and 91046 (active constituents from *Papaver nudicaule*) *Bulletin of New Drug Research Foundation* 1994, 4, 135-138.
5. **Yanjun Zhang**, Xian Li, Lijun Wu. Studies of the constituents of the stem bark of Japanese yew (*Taxus cuspidata*). *Zhongcaoyao* 1996, 27 (4), 200-202.
6. **Yanjun Zhang**, Yongfang Yu, Shaowen Kang. TLC-scan analysis of alkaloids in the herb of *Papaver nudicaule. J. Chengde Med. College* 1996, 13 (1), 15-18.
7. Xiaoyan Gao, **Yanjun Zhang**, Shaowen Kang and Yongfang Yu. Dynamic analysis of 91-041 content in the alkaloidal extract from aerial part of *Papaver nudicaule* L. *J. Chengde Medical College*, 1996, 13 (2), 103-105.
8. Cuizhe Liu, **Yanjun Zhang**, Yongfang Yu and Shaowen Kang. Studies on chemical constituents of stem and leaves of *Scutellaria baicalensis* Georgi. *J. Chengde Medical College*, 1996, 13 (2), 106-107.

9. **Yanjun Zhang**, Xiaofen Wei. Isolation and identification of (±) catechins from the dried stem bark of *Taxus cuspidata* Sieb et Zucc. *J. Chengde Medical College*, 1996, 13 (3), 187-189.
10. Siping Chen, **Yanjun Zhang**, Xiaoyan Gao and Yanbin Meng. Structure determination of chemical constituents of *Albizzia julibrissin* Durazz *J. Chengde Medical College*, 1996, 13 (4), 266-267.
11. **Yanjun Zhang**, Shaowen Kang, Wen Yu and Yanbin Meng. Isolation and purification of minor alkaloids from *Papaver nudicaule* L. *J. Chengde Medical College*, 1997, 14 (1), 6-7.
12. **Yanjun Zhang**, Yongfang Yu, Shaowen Kang. Studies on the chemical constituents of capsule of *Papaver nudicaule*. *Zhongcaoyao* 1997, 28 (1), 7-10.
13. **Yanjun Zhang**, Haifeng Pan, Siping Chen, Yanbin Meng, Shaowen Kang. Studies on the minor alkaloids from the capsule of *Papaver nudicaule*. *Zhongguo Zhongyao Zazhi* 1997, 22 (9), 550-551.
14. Haifeng Pan, Siping Chen, Cuizhe Liu, **Yanjun Zhang**. Studies on the modification isolation procedure of alkaloidal extract from Papaver nudicaule L. *J. Chengde Medical College*, 1997, 14 (2), 88-89.
15. **Yanjun Zhang**, Man Kong, Ruoyun Chen, Dequan Yu. New alkaloids from the rhizomes of *Goniothalamus Griffithii*. *Chinese Chem. Lett.* 1998, 9 (11), 1029-1032.
16. **Yanjun Zhang**, Jin Li, Shaowen Kang, Man Kong, Zhiyi He. Chemical constituents of the capsule of *Papaver nudicaule.* *Zhongcaoyao* 1998, 29 (5), 296-298.
17. Hong Chen, Longen Zhou, **Yanjun Zhang**, Dequan Yu. Synthesis of (+)-8-O-cinnamyl-p-chlorogoniotriol and its analogues. *Chinese Chem. Lett.* 1999, 10 (6), 449-452.
18. Guangxiong Zhou, **Yanjun Zhang,** Danming Peng, De Quan Yu, Yunfang Chen. Pterolactone, a new norsesquiterpene lactone from *Pterocarya stenoptera*. *J. Chinese Pharm. Sci.* 1999, 8 (1), 11-14.
19. Guangxiong Zhou, Ruoyun Chen, **Yanjun Zhang**, Dequan Yu. Calamistrin E, the first annonaceous acetogenin with double bond in aliphatic chain from genus *Uvaria*. *Chinese Chem. Lett.* 2000, **11** (4), 341-342.

BOOK CHAPTERS

1. Seeram, Navindra P.; **Zhang, Yanjun**; Reed, Jess D.; Krueger, Christian G.; Vaya, Jakob. *Pomegranate phytochemicals.* Medicinal and Aromatic Plants--Industrial Profiles 2006, 43 (Pomegranates), 3-29.
2. Seeram, Navindra P.; **Zhang, Yanjun**; Heber, David. *Commercialization of pomegranates: fresh fruit, beverages, and botanical extracts.* Medicinal and Aromatic Plants--Industrial Profiles 2006, 43 (Pomegranates), 187-196.
3. Navindra Seeram, **Yanjun Zhang**, Susan Bowerman and David Heber Phytochemicals and health aspects of pistachios (*Pistacia vera* L.), In Tree Nuts, Composition, Phytochemicals and Health Effects, CRC Press **2009**, pp295-304.

Joseph Zhou CV

Email: josephzhou@sunshinevillehp.com, Cell: (630) 618-7888

Summary:

- 21 years US dietary supplement industry experience: technical management, products development, QA/QC, food safety including adulteration, contamination and toxic compounds verification, GMP, analytical methods development, etc. Dealt with all kinds of dietary supplement products;
- Have been actively participating in many AOAC dietary supplement programs since 2000.
- Some Accomplishments:
  - Special Recognition: AOAC 2005 Study Director of the Year;
  - Developed the AOAC official method of glucosamine (originated at NOW Foods). AOAC SLV Coordinator and Study Director for the glucosamine method. Organized 12 analytical labs for the collaborative study of the glucosamine method;
  - Developed the current AOAC chondroitin method (jointly developed the method at NOW Foods with David Ji of Anaheim Analytical Laboratory). One of the AOAC SLV coordinators for the chondroitin method (with David Ji and Mark Roman).
  - Developed the current AOAC MSM method (originated at NOW Foods). Performed the SLV study of the method and then handed over the project to Make Roman.
  - AOAC ERP members: Ginkgo, CoQ10, turmeric and yohimbe, etc.;
  - Wrote the current USP (USP 33 – NF 28, 2009) monograph for Arginine and Arginine products;
  - Adjunct professor of Pharmacognosy, College of Pharmacy, University of Illinois at Chicago.

Employment History

1. Sunshineville Health Products, Inc. Kearneysville, WV 2009 – Present
   - President and Technical Director
2. NOW Foods, Bloomingdale, IL 1999 – 2008
   - Director of Lab Methods and Technical Support
   - Director of Quality Control
3. Nature's Sunshine Products, Inc., Provo, UT 1995 – 1999
   - R&D manager

Education:

Ph.D.	Physical Chemistry	University of Illinois at Chicago	1993
B.S.	Chemical Engineering	East China Institute of Technology	1982

Postdoctoral Training: College of Pharmacy, University of Michigan, Ann Arbor 1994 – 1995

Yang Zhou, Ph.D.

3801 SW 4th ST, Des Moines, IA 50315
Phone:(515)450-7007 (cell)
Email: yangzhous@hotmail.com

QUALIFICATION

- Serves as Stakeholder of Strategic Food Analytical Methods of AOAC International and SPSFAM Heavy Metals Working Group
- Developed Vitamin D LC-MSMS method for Eurofins (ENAC) and oversees its performance
- Participated AOAC SPIFAN Vitamin D MLT
- Membership of AOAC International, American Society for Nutrition(ASN) and Society of Experimental Biology and Medicine (SEBM).

EDUCATION

Ph.D., Biophysics(2007) Iowa State University, Ames IA, USA
B.S., Biochemistry(1998) Wuhan University, Wuhan, China

PROFESSIONAL EXPERIENCE

Scientist, Eurofins Scientific Inc., Des Moines, IA 2011-Present

- Lead method development and validation for vitamins, enzymes, authenticity department.
- Responsible for draft SOPs, reports, method investigations.
- Oversee and investigate method performance
- Work with chief scientific officer, department managers and quality manager and client toprovide technique assurance
- Developed and validated methods for various enzymes including Amylase, Xylanase, Phytase, Glucanse, Cellulase, Bromelain, Nattokinase, Lipase, Lactase etc.
- Developed and validated methods for various vitamins includingvitamin A, D, E, K, Folic acid, B1,B3, B5, B6, B12, Biotin, Inositol, Choline etc..
- Developed and validated method for various analytesincluding Elastin, Collagen, organic acid, Acteic acid etc.

Postdoctoral Research Associate, Iowa State University in collaboration withUnilever R&D, Vlaardingen, The Netherlands.2008-2011

- Role as investigator and analytical expert forhuman clinical projects, provides quality control and technical support for analytical data.
- Develop bioassays for clinical samples, prepare SOPs for analytical methods, analyze experimental samples and direct laboratory procedures
- Discovered the quantitative effects of various factors on nutrition absorption.

Research Intern, DuPont Pioneer Inc.,Johnston, IA 2007-2008

- Screened for novel genes with roles in yield enhancement and drought resistance in maize and soybean, comprehensively characterized the effect of genes on traits in corn and soybean

Research Associate,Wuhan University, China 1998–2001

- Investigator and project coordinator responsible for collaboration with Tongji Medical School and Wuhan Medical Inc.: Facilitated project studying the physiological effects of pyrroloquinoline quinine (PQQ) at non-clinic and pre-clinic stage.

COMMITTEESERVICE

- Nutritional Sciences Council at Iowa State University 2010- 2011
- Stakeholder Panel on Strategic Food Analytical Methods 2013-Now
- AOAC International SPSFAM Heavy Metals Working Group2013-Now

SELECTED PRESENTATION/PUBLICATION

- **Y. Zhou**, G. Poole, K. Karsjens, J. Jordan, E. Jobgen. Challenges associated with determining protein content in potato products. 129th AOAC Annual meeting & Exposition. Los Angeles, CA, Sept. 2015.
- R. Jahromi, H. Pratt, **Y. Zhou**, L. Reimann, D. Hammond. Recent developments to detect lemon juice adulteration. 129th AOAC Annual meeting & Exposition. Los Angeles, CA, Sept. 2015.
- White, W.S. **Zhou, Y**. Agustiana, A. Quadt, F. Dixon, P. Flendrig, L. Soybean Oil in Salad Dressing and Bioavailability of Fat-soluble Micronutrients in Salads: a Dose-Response Study. The 17th International Symposium on Carotenoids. Salt Lake City, UT, July, 2014.
- **Y. Zhou**, T. Newman, M Johnson, E Jobgen. Detection of choline in food and feed matrices by HPLC-Fluorescence through chemical derivatization. 3rd International Vitamin Conference. Washington DC, May 2014
- Y. Zhang, **Y. Zhou**, L. Flendrig, M. Gribnau, W. White. Effects of lecithin in salad dressing on the plasma appearance of fat-soluble micronutrients consumed in salads: contributions of chylomicrons and large VLDL. *FASEB J. April 2014; vol. 28 no. 1 Supplement 645.16.*
- Zhang, Y., **Zhou, Y.**, Flendrig, L., Gribnau, M., White, W.S. Effects of lecithin/oil ratio in salad dressing on the bioavailability of fat soluble micronutrients in salad vegetables. *FASEB J. 2012;26:640.9.*
- Flendrig, L., **Zhou, Y.**, Quadt, F., Mulder, T., Schuurbiers, E., White, W.S. Effects of phosphatidyl choline liposomes on the relative bioavailability of fat soluble micronutrients in salad vegetables. *FASEB J. 2012;26:31.4.*
- **Zhou, Y.,** Agustiana, A., Flendrig, L.M., Quadt, F., White, W.S. The dose-response effects of the amount of oil in salad dressing on the bioavailability of carotenoids and fat-soluble vitamins in salad vegetables. *FASEB J. 2010 24:539.15.*
- Liu, W., **Zhou, Y**., Sanchez, T., Ceballos, H., White, W.S. The vitamin A equivalence of the β-carotene in β-carotene-biofortified cassava porridges ingested by women. *FASEB J.2010 24:92.7.*

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MEMORANDUM

Date: June 22, 2016

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: Item IIIb. Recommendations for Final Action – ERP for SPIFAN Nutrient Methods

On March 16, 2016, the AOAC ERP for SPIFAN Nutrient Methods met during the AOAC Mid-Year Meeting. During their meeting, the ERPchaired by Darryl Sullivan, recommended AOAC 2012.22 for Final Action status. In May and June 2016, the method author provided AOAC with a final draft of the method. This method author's final draft was sent out to the Expert Review Panel with a ballot and 2/3 of the ERP returned the ballot recommending the method. The checklist and supporting information are included. Don Gilliland served as the OMB liaison during this meeting.

Recommendations: For OMB to discuss review the ERP's recommendation and render a decision on Final Action status of AOAC 2012.22.

Enclosures: ERP Summary and Checklist and Supporting Information.

ERP SUMMARY FOR FIRST TO FINAL ACTION METHOD RECOMMENDATION

AOAC 2012.22	Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula

GUIDANCE FOR AOAC ERPS - APPENDIX G[1]	Considered?	Comments/Reference if applicable
Method Applicability	Yes	ERP satisfied with applicability omparability to SMPR. See ERP reports
ERP First Action to Final Action recommendations & improvements implemented/addressed	Yes	ERP comments during March 2015. Comments addressed with additional work. No additional comments during review for Final Action in March 2016.
Draft Final Action method reviewed by ERP	Yes	June 2016; See draft of method
Safety Concerns	Yes	All issues resolved
Reference Materials	Yes	NIST SRM 1849a; SPIFAN matrices
Single Laboratory Validation	Yes	Giménez et al., J. AOAC Int. **96**, 1065(2013); ERP report for August 17, 2013.
Reproducibility/Uncertainty and Probability of Detection	Yes	Reviewed in March 2015, and March 2016 by ERP; See ERP reports.
Comparison to SMPR (SMPR criteria met?)	Yes	Reviewed in September 2012, March 2015, and March 2016
Feedback from Users of Method	Yes	Addressed, no additional feedback submitted

DOCUMENTATION	Available?	Comments
Safety Evaluation	Yes	Completed during ERP meeting
Reference Materials	Yes	NIST SRM 1849a; SPIFAN Matrices
SLV or PTM	Yes	Not published, but ERP reviewed report, submitted for ERP review July 2013
Approved Validation Protocols	Yes	Used SMPR; OMA Appendix D; SPIFAN Resource Pages; Assistance from ERP chair, working group chair.
Statistics Review	Yes	Completed during ERP meeting
Method Published in OMA	Yes	AOAC 2012.22
Method Performance vs SMPR criteria	Yes	AOAC SMPR 2012.012 – SMPR for Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula
Feedback Information	Yes	Discussed during ERP meeting
Additional Recognition(s)	No	
ERP Reports	Yes	September 2012, August 2013, March 2015, March 2016
Manuscript(s) Published in JAOAC	Yes	Giménez et al., J. AOAC Int. **96**, 1065(2013)
ERP Method Recommendation (Final Action/Repeal/Continuation)	**Yes**	**ERP report from March 2016 – Final Action Recommendation; See draft of method**

[1] *Official Methods of Analysis of AOAC INTERNATIONAL*, Appendix G: Procedures and Guidelines for the Use of AOAC Voluntary Consensus Standards to Evaluate Characteristics of a Method of Analysis, p.3 "*First Action to Final Action Methods: Guidance for AOAC Expert Review Panels.*"

AOAC SMPR 2012.012

Standard Method Performance Requirements for Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula

Intended Use: Global dispute resolution method

1 Applicability

Determination of vitamin C in all forms of infant, adult, or pediatric formula (powders, ready-to-feed liquids, and liquid concentrates). For the purpose of this SMPR, vitamin C is defined as the sum of L-ascorbic acid or its salts, and de-hydro ascorbic acid.

2 Analytical Technique

Any analytical technique that meets the following method performance requirements is acceptable.

3 Definitions

Adult/pediatric formula.—Nutritionally complete, specially formulated food, consumed in liquid form, which may constitute the sole source of nourishment made from combination of milk, soy, rice, whey, hydrolyzed protein, hydrolyzed lactose, starch, and amino acids, with and without intact protein.

Infant formula.—Breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding, made from combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Limit of detection (LOD).—The minimum concentration or mass of analyte that can be detected in a given matrix with no greater than 5% false-positive risk and 5% false-negative risk.

Limit of quantitation (LOQ).—The minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Repeatability.—Variation arising when all efforts are made to keep conditions constant by using the same instrument and operator, and repeating during a short time period.

Reproducibility.—The standard deviation or relative standard deviation calculated from among-laboratory data, expressed as reproducibility relative standard deviation or % reproducibility relative standard deviation.

Recovery.—The fraction or percentage of spiked analyte that is recovered when the test sample is analyzed using the entire method.

Table 1. Method performance requirements[a,b]

Analytical range	1.0–250 mg/100 g	
Limit of detection (LOD)	0.3 mg	
Limit of quantitation (LOQ)	1.0 mg	
Repeatability (RSD_r)	1.0 mg	≤10%
	10 mg	≤5%
	75 mg	
	200 mg	
Recovery	90 to 110% of mean spiked recovery over the range of the assay	
Reproducibility (RSD_R)	1.0 mg	≤15%
	10 mg	≤10%
	75 mg	
	200 mg	

[a] Concentrations apply to: (*1*) "ready-to-feed" liquids "as is"; (*2*) reconstituted powders (25 g into 200 g water); and (*3*) liquid concentrates diluted 1:1 by weight.

[b] For all concentrations vitamin C will be expressed as mg/100 g reconstituted liquids.

4 Method Performance Requirements

See Table 1.

5 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blank check samples, and check standards at the lowest point and midrange point of the analytical range.

6 Reference Material(s)

NIST Standard Reference Material® (SRM) 1849a Infant/Adult Nutritional Formula, or equivalent. The SRM is milk-based, hybrid infant/adult nutritional powder prepared by a manufacturer of infant formula. The certified NIST value for SRM 1849a is 784 ± 65 mg/kg as ascorbic acid.

7 Validation Guidance

Recommended level of validation: *Official Methods of Analysis*℠.

8 Maximum Time-to-Result

No maximum time.

Approved by the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) on September 29, 2012. Final Version Date: September 29, 2012.

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AOAC INTERNATIONAL

STAKEHOLDER PANEL INFANT FORMULA AND ADULT NUTRITION (SPIFAN)

Report of the Expert Review Panel

Date: Tuesday, October 2, 2012

Location: Hilton DC/Rockville Hotel & Executive Conference Center

Expert Review Panel Member Attendees:

Darryl Sullivan, Chair, *Covance Laboratories*
John Austad, *Covance Laboratories*
Sneh Bhandari, *Silliker Laboratories*
Chris Blake, *Nestlé*
Scott Christiansen, *Perrigo Nutritionals*
Jonathan DeVries, *Medallion Labs/Gen. Mills*
Brendon Gill, *Fonterra*
Don Gilliland, *Abbott Nutrition*
Min Huang, *Aegis Corp.*
Guifeng Jiang, *Thermo Fisher Scientific*
Estela Kneeteman, *INTI*
Erik Konings, *Nestlé*
Adrienne McMahon, *Pfizer Nutrition*
Shay Phillips, *Mead-Johnson Nutritional*
Guenther Raffler, *Danone*
Kate Rimmer, *NIST*
Karen Schimpf, *Abbott Nutrition*
David Woollard, *NZ Lab Services*
Jinchuan Yang, *Waters Corp.*

AOAC Staff including:

Delia Boyd
E. James Bradford
Scott Coates
Anita Mishra

I. WELCOME & INTRODUCTIONS

The Chair initiated the meeting with introductions. The Chair reviewed the purpose and expected outcome of the Expert Review Panel (ERP) session.

II. REVIEW OF AOAC VOLUNTEER CONFLICT OF INTEREST AND ANTITRUST POLICIES

Sullivan explained to all participants that the AOAC policies and procedures will be followed during the meeting.

III. ERP REVIEW, DETERMINATION AND VOTE ON METHODS PRESENTED

Official First Action: for each method, the ERP will consider additional information submitted. Methods that fulfill the requirements will be granted First Action *Official Methods*^{SM} status. Candidate Dispute Resolution Methods: for each method, the ERP will consider additional information submitted and discuss the rationale(s) for the dispute. The ERP will also down-select and render a decision on a candidate dispute resolution method.

METHODS FOR CONSIDERATION

Methods for Vitamin A

- VitA-01 *Nestlé*
- VitA-09 *General Mills*
- VitA-16 *Abbott Nutrition*
- VitA-17 *Pfizer Nutrition*

Methods for Vitamin D

- VitD-01 *Covance*
- VitD-14 *Fonterra*
- VitD-15 *DSM*
- VitD-16 *Abbott Nutrition*

Methods for Vitamin B_{12}

- VitB_{12}-03 *Nestlé*
- VitB_{12}-12 *Abbott Nutrition*

Methods for Folate

- Fol-15 *Medallion Labs*
- Fol-20 *Univ. of New South Wales*

Methods for Nucleotides

- Nuc-02 *Kinjo Gakin Univ. (Nestlé)*
- Nuc-13 *Thermo Fisher Scientific*

Methods for Vitamin E

- VitE-17 *Silliker*
- VitE-18 *Abbott Nutrition*
- VitE-19 *Pfizer Nutrition*

Methods for Choline

- Chol-03 *Nestlé*
- Chol-06 *Abbott Nutrition*
- Chol-07 *Thermo Fisher Scientific*

Methods for Iodine

- Iod-01 *Abbott Nutrition*
- Iod-02 *Covance*

Methods for Inositol

- Inos-39 *Covance*

Methods for Pantothenic Acid

- Panto-01 *Nestlé*

Methods for Carnitine

- Carn-01 *Abbott Nutrition*

Methods for Vitamin C

- VitC-02 *Abbott Nutrition*
- VitC-03 *Nestlé*

Methods for Fatty Acids

- FA-01 *ISO*

SPIFAN Expert Review Panel Report
October 2, 2012
Final

Method	Method Title	Comments	Reviewer(s)	Recommendation
VitA-01	*2011.07 - Vitamins A Infant Formula and Adult/Pediatric Nutritional Formula by UPLC-UV or FLD. Submitted by Nestlé*		Don Gilliland	Withdrawn by author
VitA-09	*2011.15 - Determination of Vitamins A (retinol) and E (alpha-tocopherol) in Infant Formula and Adult/Pediatric Nutritional Formula by liquid chromatography. Submitted by General Mills*	▪ No further study will be done ▪ No SPIFAN matrices	Sneh Bhandari Guifeng Jiang	No action taken by ERP
VitA-16	*Vitamin A & E Single Laboratory Validation 2011.08. Submitted by Abbott Nutrition*	▪ Editorial comments o Micrograms not IU ▪ Stability issues with reconstitution ▪ Dry blended	Scott Christiansen Jinchuan Yang	Recommend for First Action *Official Methods*^{SM} status
VitA-17	*Simultaneous Determination of Vitamins A, E and Beta Carotene/Mixed Carotenoids in Infant Formula by Normal Phase HPLC. Submitted by Pfizer Nutrition*	▪ Provide addition on SPIFAN matrices ▪ Explain why the accuracy is at fall out ▪ Analysis of retinol	Erik Konings Guifeng Jiang	Recommend for First Action *Official Methods*^{SM} status
Method	**Method Title**	**Comments**	**Reviewer(s)**	**Recommendation**
VitD-01	*2011.11 - AOAC SPIFAN Single Laboratory Validation for Vitamin D Analysis in Infant Formula and Adult Nutritionals and Addendum No. 1a. Submitted by Covance Laboratories*	▪ No data on vitamin D_2	Brendon Gill Sneh Bhandari	Recommend for Candidate Dispute Resolution method
VitD-14	*A rapid analytical method for cholecalciferol (vitamin D3) in fortified infant formula, milk and milk powder using Diels–Alder derivatisation and liquid chromatography–tandem mass spectrometric detection. Submitted by Fonterra*	▪ Need additional data o Require D_2 data	Sneh Bhandari John Austad	No Decision
VitD-15	*Quantification of vitamin D3 in feed, food, and pharmaceuticals employing high performance liquid chromatography-tandem mass spectrometry. Submitted by DSM*	▪ Only measures D_3	Estela Kneeteman Brendon Gill	No Decision
VitD-16	*Simultaneous Determination of Vitamin D3 and D2 by ESI LC-MS/MS. Submitted by Abbott Nutrition*	▪ Clarify precision on adult nutrition ▪ D_3 recovery to be clarified ▪ Present the data ▪ Include blanks as well as SRM	Jeanne Rader Guenther Raffler	Recommend for First Action *Official Methods*^{SM} status

Method	Method Title	Comments	Reviewer(s)	Recommendation
$VitB_{12}$-03	*2011.08 - Determination of Vitamin B_{12} in Infant Formula and Adult/Pediatric Nutritional Formula by Optical Biosensor Protein-Binding Assay. Submitted by Nestlé*		Scott Christiansen Estela Kneeteman	Received new information from author
$VitB_{12}$-12	*2011.10 - Determination of Vitamin B_{12} in Infant Formula and Adult/Pediatric Nutritional Formula by HPLC. Submitted by Abbott Nutrition*		Jon DeVries Shay Phillips	Received new information from author
Method	**Method Title**	**Comments**	**Reviewer(s)**	**Recommendation**
Fol-15	*2011.06 - Determination of Total Folates in Infant Formula and Adult Nutritionals byTrienzyme Extraction and UPLC-MS/MS Quantitation2011.06. Submitted by General Mills*	▪ No additional work will be done ▪ No SPIFAN matrices data	Adrienne McMahon Min Huang	No action taken by ERP
Fol-20	*A validated method to determine folic acid and 5-methyl THF in adult/infant nutritional formulae using ultra performance liquid chromatography-tandem mass spectrometry. Submitted by UNSW*	▪ Meets SMPR requirement ▪ Clarify not just for whey, but other matrices	Kathy Sharpless/Kate Rimmer Adrienne McMahon	No action taken by ERP
Method	**Method Title**	**Comments**	**Reviewer(s)**	**Recommendation**
Nuc-02	*AOAC 2011.21. Submitted by Kinjo Gakin Univ. (Nestlé)*		Adrienne McMahon Min Huang	No further action taken by ERP
Nuc-13	*Simultaneous Determination of Nutritional Nucleotides and Nucleosides by Ultrahigh Performance Liquid Chromatography with UV Detection. Submitted by Thermo Fisher Scientific*	▪ Chromatography ▪ Reference materials reported in all types of infant formula	Sneh Bhandari Estela Kneeteman	No action taken by ERP

Method	Method Title	Comments	Reviewer(s)	Recommendation
VitE-17	*Vitamin E (tocopherols) in Food Samples by HPLC. Submitted by Silliker Labs*	▪ Needs additional data	Adrienne McMahon Guenther Raffler	No further action taken by ERP
VitE-18	*Simultaneous Determination of 13-Cis and All-Trans Vitamin A Palmitate, Vitamin A Acetate, Alpha Vitamin E Acetate, and Alpha Tocopherol by HPLC and Column Switching. Submitted by Abbott Nutrition*	▪ Needs SRM 1849a – reference material	Scott Christiansen Jinchuan Yang	Recommend for First Action *Official Methods*^{SM} status
VitE-19	*Simultaneous Determination of Vitamin A, E and Beta Carotene/Mixed Carotenoids in Infant Formula by Normal Phase HPLC. Submitted by Pfizer Nutrition*	▪ Encapsulation	Erik Konings Kathy Sharpless/Kate Rimmer	Recommend for First Action *Official Methods*^{SM} status
Method	**Method Title**	**Comments**	**Reviewer(s)**	**Recommendation**
Chol-03	*Single Laboratory Validation – Choline by UPLC-MS/MS Method for discussion by Working Group SPIFAN. Submitted by Nestlé*	▪ Percentage of phosphor choline ▪ Update in SMPR	David Woollard Guifeng Jiang	Recommend for First Action *Official Methods*^{SM} status
Chol-06	*Method Development for Determination of Total and Free Choline in Nutritional Products by LC-MS/MS. Submitted by Abbott Nutrition*	▪ Compatible with carnitine (need to see the data) ▪ Present as choline ion	Min Huang Shay Phillips	Recommend for First Action *Official Methods*^{SM} status
Chol-07	*Determination of Choline In Infant Formula and Adult Nutritionals by Ion Chromatography and Suppressed Conductivity. Submitted by Thermo Fisher Scientific*	▪ Want to see recovery ▪ Sensitivity below the SMPR	David Woollard Shay Phillips	Recommend for First Action *Official Methods*^{SM} status
Method	**Method Title**	**Comments**	**Reviewer(s)**	**Recommendation**
Iod-01	*Determination of Total Iodine in Infant Formula and Nutritional Products by Inductively Coupled Plasma/Mass Spectrometry: Single Laboratory Validation. Submitted by Abbott Nutrition*		Min Huang Bill Mindak	Recommend for First Action *Official Methods*^{SM} status

Iod-02	*Determination of Total Iodine in Foods and Dietary Supplements Using Inductively Coupled Plasma–Mass Spectrometry. Submitted by Covance*	▪ No calculation formula ▪ Use different forms of iodine	Erik Konings Guenther Raffler	Recommend for First Action *Official Methods*[SM] status
Method	**Method Title**	**Comments**	**Reviewer(s)**	**Recommendation**
Inos-39	*Analysis of Free and Total myo-Inositol in Foods, Feeds, and Infant Formula by HPAEC-PAD Including a Novel Total Extraction Using Microwave-Assisted Acid Hydrolysis and Enzymatic Treatment. Submitted by Covance Lab*	▪ Modify sample procedure ▪ Soy base product is excluded ▪ Resolve the phytate issue	Brendon Gill Karen Schimpf	Recommend for First Action *Official Methods*[SM] status
Method	**Method Title**	**Comments**	**Reviewer(s)**	**Recommendation**
Panto-01	*Pantothenic Acid (Vitamin B5) in Fortified Foods: Comparison of a Novel Ultra-Performance Liquid Chromatography-Tandem Mass Spectrometry Method and a Microbiological Assay (AOAC Official Method*[SM] *992.07). Submitted by Nestlé*	▪ Reference is to 1846	John Austad Jeanne Rader	Recommend for First Action *Official Methods*[SM] status
Method	**Method Title**	**Comments**	**Reviewer(s)**	**Recommendation**
Carn-01	*Single-Laboratory Validation of a Liquid Chromatographic/Tandem Mass Spectrometric Method for the Determination of Free and Total Carnitine in Infant Formula and Raw Ingredients. Submitted by Abbott Nutrition*	▪ Total used instead of free ▪ Need data on reference material	John Austad Brendon Gill	Recommend for First Action *Official Methods*[SM] status
Method	**Method Title**	**Comments**	**Reviewer(s)**	**Recommendation**
VitC-02	*Determination of Vitamin C by HPLC with UV Detection. Submitted by Abbott Nutrition*	▪ SLV data on SPIFAN matrices ▪ documentation on separation of Isoascorbic	John Austad Brendon Gill	Recommend for First Action *Official Methods*[SM] status
VitC-03	*Single Laboratory Validation – Vitamin C by UPLC-UV method for discussion by Working Group SPIFAN. Submitted by Nestlé*	▪ Establish criteria for the separation of Isoascorbic and ascorbic ▪ SLV data on SPIFAN matrices ▪ Column lifecycle ▪ System suitability ▪ Resolution criteria needs to be set	Guifeng Jiang Jeanne Rader	Recommend for First Action *Official Methods*[SM] status

SPIFAN Expert Review Panel Report
October 2, 2012
Final

Method	Method Title	Comments	Reviewer(s)	Recommendation
FA-01	*Milk Products and infant formulae — Determination of Labelled Fatty Acids content - Capillary gas chromatographic method. Submitted by ISO*	▪ Should show extraction ▪ Note: clarify in the method that it will not work on	Jon DeVries Karen Schimpf	Recommend for First Action *Official Methods*^{SM} status

AOAC Official Method 2012.22
Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula
Ultra-Performance Liquid Chromatography (UPLC®) with Ultraviolet Detection
First Action 2012

[Applicable to the determination of vitamin C (L-ascorbic acid) in infant formula and adult/pediatric nutritional formula by ultra-performance LC (UPLC®)-UV.]

Caution: Refer to Material Safety Data Sheets prior to use of chemicals. Use appropriate personal protective equipment when performing testing.

A. Principle

Ascorbic acid is extracted from the sample using trichloroacetic acid (TCA) in the presence of Tris[2-carboxyethyl]phosphine (TCEP) as a reducing agent. Ascorbic acid is then determined by UPLC-UV at 265 nm. Separation takes place on a C_{18} column with sodium acetate (pH 5.4) as the eluent, combined with TCEP and decylamine as an ion-pairing agent.

B. Apparatus

(**a**) *Balances*.—With readability of 0.1 mg and 0.01 g.

(**b**) *pH meter*.—Metrohm 691 (Herisau, Switzerland), or equivalent.

(**c**) *LC column*.—Waters (Milford, MA) Acquity UPLC ethylene bridged hybrid (BEH) C_{18} column, 1.75 µm, 2.1 × 100 mm, or equivalent.

(**d**) *UPLC system*.—Waters Acquity UPLC system equipped with a Waters Acquity UPLC photodiode array detector, or equivalent.

C. Reagents and Standards

(**a**) *Acetonitrile*.—HPLC grade (Merck, Geneva, Switzerland, or equivalent).

(**b**) *Ascorbic acid*.—Fluka (Buchs, Switzerland), or equivalent.

(**c**) *Decylamine*.—Fluka, or equivalent.

(**d**) *Phosphoric acid*.—85% (Merck, or equivalent).

(**e**) *Purified water*.—Millipore (Le Mont-sur-Lausanne, Switzerland), or equivalent.

(**f**) *Sodium acetate trihydrate*.—Merck, or equivalent.

(**g**) *TCA*.—Merck, or equivalent.

(**h**) *TCEP*.—Fluka, or equivalent.

D. Preparation of Solutions

(**a**) *Sodium acetate solution (pH 5.4)*.—

34.0 g Sodium acetate trihydrate × 1 mol/136.08 g
= 0.25 mol sodium acetate trihydrate into 500 mL
= 0.5 mol/L = 500 mmol/L

(**b**) *TCA (15%)*.—Into a 500 mL volumetric flask, weigh 75.0 g TCA, dissolve, and make up to volume with water.

(**c**) *TCEP (250 µg/mL)*.—Into a 500 mL volumetric flask, weigh 125 mg TCEP-HCl, dissolve, and make up to volume with water.

(**d**) *Mobile phase for UPLC*.—Into a 250 mL flask, mix 0.4 g decylamine, 2.5 mL acetonitrile, 25 mL sodium acetate solution 500 mmol/L (pH 5.4), and 205 mL water. Add 10 mg TCEP. No making up to volume is preferred.

E. Preparation of Standards

(*Note*: Vitamin C is sensitive to light and oxygen. Conduct operations under subdued light, or use amber glassware. Keep all solutions away from direct light.)

(**a**) *Ascorbic acid stock solution (500 µg/mL)*.—Into a 25 mL amber glass volumetric flask, weigh 12.5 mg ascorbic acid. Dissolve and make up to volume with TCEP solution. This solution can be kept for 3 months if stored at 4°C away from light.

(**b**) *Ascorbic acid intermediate standard solution (50 µg/mL)*.—Into a 10 mL amber glass volumetric flask, pipet 1 mL stock solution. Make up to volume with TCEP solution. This solution can be used for 1 month if stored at 4°C away from light.

(**c**) *Ascorbic acid calibration standard solutions (0.5, 1.0, 2.0, 3.0, 5.0, 7.5, and 10.0 µg/mL)*.—Into 10 mL amber glass volumetric flasks, pipet 0.1, 0.2, 0.4, 0.6, 1.0, 1.5, and 2.0 mL intermediate standard solution. Make up to volume with mobile phase to prepare the respective concentrations given above.

F. Preparation of Samples

(**a**) *Reconstitution of powder samples*.—

(*1*) Weigh 25 g powder into a brown glass 250 mL beaker. Add 10 mg TCEP.

(*2*) Add 200 g warm water (40°C) and mix well until complete dissolution. Make sure there are no lumps.

(**b**) *Extraction*.—

(*1*) Weigh 2 g liquid or reconstituted sample into a 10 mL amber glass volumetric flask.

(*2*) Add 4 mL TCEP solution and 2 mL TCA 15%.

(*3*) Bring up to volume with water.

(*4*) Filter solution through folded grade 597½ or greater filter paper (Schleicher & Schuell, Dassel, Germany).

(*5*) Transfer 1 mL filtrate into a 10 mL amber glass volumetric flask containing 1 mL acetate solution (pH 5.4). Bring up to volume with mobile phase.

(*6*) Filter about 2 mL through a 0.22 µm membrane into an HPLC vial.

G. Analysis

(**a**) *Chromatographic conditions*.—

(*1*) *Injection volume*.—5 µL.

(*2*) *Autosampler temperature*.—10°C.

(*3*) *Column temperature*.—25°C.

(*4*) *Flow rate*.—0.35 mL/min.

(*5*) *Run time*.—4.0 min.

(*6*) *Mobile phase for UPLC*.—Sodium acetate (50 mmol/L, pH 5.4), decylamine (1.6 g/L), acetonitrile (1%), and TCEP (40 mg/L).

Note: At the end of each analytical series, rinse the column with acetonitrile–water (1 + 1, v/v) for 10 min at 0.4 mL/min.

(**b**) *System suitability test*.—Equilibrate the chromatographic system for ≥0.5 h. Inject a working standard solution at least six times and check peak retention times and responses (peak height or area). Inject working standard solutions on a regular basis within a series of analyses.

(**c**) *Calibration*.—Make single injections of working standard solutions at least at the beginning and the end of each analytical series. Establish the calibration curve (seven points) by plotting peak response (height or area) versus ascorbic acid concentration. Perform linear regression. Calculate the slope (S) and intercept (I) of the calibration curve.

(**d**) *Analysis*.—Make single injections of sample solutions.

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(**e**) *Identification*.—Identify the ascorbic acid peak in the chromatograms of the sample solutions by comparison with the retention time and UV spectrum of the corresponding peak in the standard solution.

H. Calculations

Calculate the concentration of vitamin C, in mg ascorbic acid/100 g expressed in product "as is" for RTF (ready-to-feed) products or as "reconstituted powder" for powder samples, as follows:

$$C = \frac{(A - I) \times V_1 \times V_3 \times 100}{S \times m \times V_2 \times 1000}$$

where A = response (height or area) of the ascorbic acid peak obtained for the sample solution, m = weight of the test portion in g (2.0 g), V_1 = volume of the test solution (volume used to dissolve the test portion) in mL (10 mL), V_2 = volume used in the sample dilution (1.0 mL), and V_3 = volume of the final sample dilution (10 mL).

Note: If results expressed in powder sample are needed, use the reconstitution rate to calculate (c × 225/25).

References: *J. AOAC Int*. **96**, 1065(2013)
DOI: 10.5740/jaoacint.13-141

AOAC SMPR 2012.012
J. AOAC Int. **96**, 491(2013)
DOI: 10.5740/jaoac.int.SMPR2012.012

*Corrected November 2013 [to correct concentrations of mobile phase in **D(a)**, **D(d)**, and **G(a)**(6)]*

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INFANT FORMULA AND ADULT NUTRITIONALS

Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula by Ultra-Performance Liquid Chromatography with Ultraviolet Detection: First Action 2012.22

ESTHER CAMPOS-GIMÉNEZ, PATRIC FONTANNAZ, KARINE REDEUIL, and TAMARA KILINC
Nestlé Research Center, Nestec Ltd, Department of Quality Assurance, Vers-Chez-les-Blanc, 1000 Lausanne 26, Switzerland
DAWN DOWELL
AOAC INTERNATIONAL, 481 North Frederick Ave, Gaithersburg, MD 20877-7089

During the AOAC Annual Meeting held in Las Vegas, NV from September 30 to October 3, 2012, the Stakeholder Panel on Infant Formula and Adult Nutritionals convened to review single-laboratory validation data submitted for the method, Vitamin C in Adult/Pediatric Formula by Ultra-Performance Liquid Chromatography with Ultraviolet Detection. This method is a modified version of the method "HPLC-UV Determination of Total Vitamin C in a Wide Range of Fortified Food Products" previously published in *Food Chem.,* 94, 626–631 (2006). The SLV data from the modified method were reviewed and compared to the standard method performance requirements (SMPR 2012.012), and it was concluded that the method meets the requirements. The method was approved as AOAC Official First Action. The method is based on the acidic extraction of ascorbic acid in the presence of Tris[2-carboxyethyl] phosphine (TCEP) as a reducing agent. Separation was achieved on a C_{18} column with a sodium acetate eluent (pH 5.4) combined with TCEP and decylamine as an ion-pairing agent. Accuracy rates were between 90 and 100%. Repeatability RSD (RSD_r) ranged from 1.4 to 2.5%, and intermediate reproducibility RSD (RSD_{iR}) ranged from 1.3 to 7.5%.

Vitamin C, L-ascorbic acid, is a water-soluble vitamin that plays an important role in oxidative stress reactions and takes part in a number of metabolic functions (1). This makes its incorporation into the human diet essential; its deficiency results in scurvy. It is found naturally in fresh fruits and green vegetables and is largely used in food fortification to compensate for losses during industrial processes. The method described here, a modified version of a previously published method (2), has been evaluated and determined to meet the Standard Method Performance Requirements (SMPRs; 3) for the determination of vitamin C in infant formula and adult/pediatric nutritional formula.

Submitted for publication April 22, 2013.
The method was approved by the Expert Review Panel on Infant Formula and Adult Nutritionals as First Action.
The AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) invites method users to provide feedback on the First Action methods. Feedback from method users will help verify that the methods are fit for purpose and are critical to gaining global recognition and acceptance of the methods. Comments can be sent directly to the corresponding author or methodfeedback@aoac.org.
Corresponding author's e-mail: esther.campos-gimenez@rdls.nestle.com
DOI: 10.5740/jaoacint.13-141

AOAC Official Method 2012.22
Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula
Ultra-Performance Liquid Chromatography with Ultraviolet Detection
First Action 2012

[Applicable to the determination of vitamin C (L-ascorbic acid) in infant formula and adult/pediatric nutritional formula by ultra-performance LC (UPLC®)-UV.]

Caution: Refer to Material Safety Data Sheets prior to use of chemicals. Use appropriate personal protective equipment when performing testing.

A. Principle

Ascorbic acid is extracted from the sample using trichloroacetic acid (TCA) in the presence of Tris[2-carboxyethyl]phosphine (TCEP) as a reducing agent. Ascorbic acid is then determined by UPLC®-UV at 265 nm. Separation takes place on a C_{18} column with sodium acetate (pH 5.4) as the eluent, combined with TCEP and decylamine as an ion-pairing agent.

B. Apparatus

(**a**) *Balances.*—With readability of 0.1 mg and 0.01 g.

(**b**) *pH meter.*—Metrohm 691 (Herisau, Switzerland) or equivalent.

(**c**) *LC column.*—Waters (Milford, MA) Acquity UPLC® ethylene bridged hybrid (BEH) C_{18} column, 1.75 µm, 2.1 × 100 mm or equivalent.

(**d**) *UPLC® system.*—Waters Acquity UPLC® system equipped with a Waters Acquity UPLC® photodiode array detector or equivalent.

C. Reagents and Standards

(**a**) *Acetonitrile.*—HPLC grade, Merck (Geneva, Switzerland) or equivalent.

(**b**) *Ascorbic acid.*—Fluka (Buchs, Switzerland) or equivalent.

(**c**) *Decylamine.*—Fluka or equivalent.

(**d**) *Phosphoric acid.*—85%, Merck or equivalent.

Table 1. Precision results

	Level	RSD_r, %	RSR_{ir}, %
SRM 1849a infant/adult nutritional formula	8.4	1.7	7.5
Infant elemental powder, mg/100 g	36.8	1.7	1.3
Infant formula powder, milk-based, mg/100 g	11.8	1.4	1.4
Infant formula powder, soy-based, mg/100 g	10.6	1.4	2.0
Adult nutritional RTF, high-fat, mg/100 g	39.3	2.5	5.3

(**e**) *Purified water.*—Millipore (Le Mont-sur-Lausanne, Switzerland) or equivalent.

(**f**) *Sodium acetate trihydrate.*—Merck or equivalent.

(**g**) *TCA.*—Merck or equivalent.

(**h**) *TCEP.*—Fluka or equivalent.

D. Preparation of Solutions

(**a**) *Sodium acetate solution (pH 5.4).*—Into a 500 mL volumetric flask, weigh 34.0 g sodium acetate trihydrate, add about 400 mL water, and dissolve completely. Adjust pH to 5.4 with phosphoric acid 85%, and make up to volume with water.

(**b**) *TCA (15%).*—Into a 500 mL volumetric flask, weigh 75.0 g TCA, dissolve, and make up to volume with water.

(**c**) *TCEP (250 µg/mL).*—Into a 500 mL volumetric flask, weigh 125 mg TCEP-HCl, dissolve, and make up to volume with water.

(**d**) *Mobile phase for UPLC®.*—Into a 250 mL flask, mix 0.4 g decylamine, 2.5 mL acetonitrile, 25 mL sodium acetate solution (pH 5.4), and 205 mL water. Adjust pH to 5.4 with phosphoric acid 85%. Add 10 mg TCEP.

E. Preparation of Standards

Note: Vitamin C is sensitive to light and oxygen; conduct operations under subdued light or use amber glassware. Keep all solutions away from direct light.

(**a**) *Ascorbic acid stock solution (500 µg/mL).*—Into a 25 mL amber glass volumetric flask, weigh 12.5 mg ascorbic acid. Dissolve and make up to volume with TCEP solution. This solution can be kept for 3 months if stored at 4°C away from light.

(**b**) *Ascorbic acid intermediate standard solution (50 µg/mL).*—Into a 10 mL amber glass volumetric flask, pipet 1 mL stock solution. Make up to volume with TCEP solution. This solution can be used for 1 month if stored at 4°C away from light.

(**c**) *Ascorbic acid calibration standard solutions (0.5, 1.0, 2.0, 3.0, 5.0, 7.5, and 10.0 µg/mL).*—Into 10 mL amber glass volumetric flasks, pipet 0.1, 0.2, 0.4, 0.6, 1.0, 1.5, and 2.0 mL of intermediate standard solution. Make up to volume with mobile phase to prepare the respective concentrations given above.

F. Preparation of Samples

(**a**) *Reconstitution of powder samples.*—

(*1*) Weigh 25 g powder into a brown glass 250 mL beaker. Add 10 mg TCEP.

(*2*) Add 200 g warm water (40°C) and mix well until complete dissolution. Make sure there are no lumps.

(**b**) *Extraction.*—

(*1*) Weigh 2 g liquid or reconstituted sample into a 10 mL amber glass volumetric flask.

(*2*) Add 4 mL TCEP solution and 2 mL TCA 15%.

(*3*) Bring up to volume with water.

(*4*) Filter solution through folded grade 597½ or greater filter paper (Schleicher & Schuell, Dassel, Germany).

(*5*) Transfer 1 mL filtrate into a 10 mL amber glass volumetric flask containing 1 mL acetate solution (pH 5.4). Bring up to volume with mobile phase.

(*6*) Filter about 2 mL through a 0.22 µm membrane into an HPLC vial.

G. Analysis

(**a**) *Chromatographic conditions.*—

(*1*) *Injection volume.*—5 µL.

(*2*) *Autosampler temperature.*—10°C.

(*3*) *Column temperature.*—25°C.

(*4*) *Flow rate.*—0.35 mL/min.

(*5*) *Run time.*—4.0 min.

(*6*) *Mobile phase.*—Sodium acetate (25 mmol/L, pH 5.4), decylamine (1.6 g), acetonitrile (1%), and TCEP (50 mg/L).

Note: At the end of each analytical series, rinse the column with acetonitrile–water (1 + 1, v/v) for 10 min at 0.4 mL/min.

(**b**) *System suitability test.*—Equilibrate the chromatographic system for ≥0.5 h. Inject a working standard solution at least six times and check peak retention times and responses (peak height or area). Inject working standard solutions on a regular basis within a series of analyses.

(**c**) *Calibration.*—Make single injections of working standard solutions at least at the beginning and the end of each analytical series. Establish the calibration curve (seven points) by plotting peak response (height or area) versus ascorbic acid concentration. Perform linear regression. Calculate the slope (S) and intercept (I) of the calibration curve.

(**d**) *Analysis.*—Make single injections of sample solutions.

(**e**) *Identification.*—Identify the ascorbic acid peak in the chromatograms of the sample solutions by comparison with the retention time and UV spectrum of the corresponding peak in the standard solution.

H. Calculations

Calculate the concentration of vitamin C in mg ascorbic acid/100 g expressed in product "as is" for RTF (ready-to-feed)

Table 2. Spike recovery results

		+50%		+100%	
	Native level, mg/100 g	Average, %	RSD, %	Average, %	RSD, %
Infant elemental powder	36.8	101	7.2	95	5.8
Infant formula powder, milk-based	11.8	94	4.7	91	5.0
Infant formula powder, soy-based	10.6	96	11.6	91	5.6
Adult nutritional RTF, high-fat	39.3	95	14.5	100	3.9

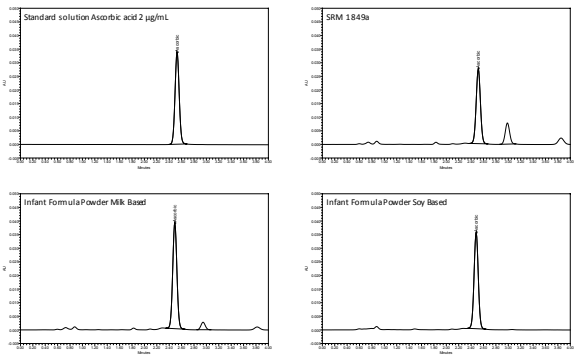

Figure 1. Example chromatograms of infant formula powders/certified reference material.

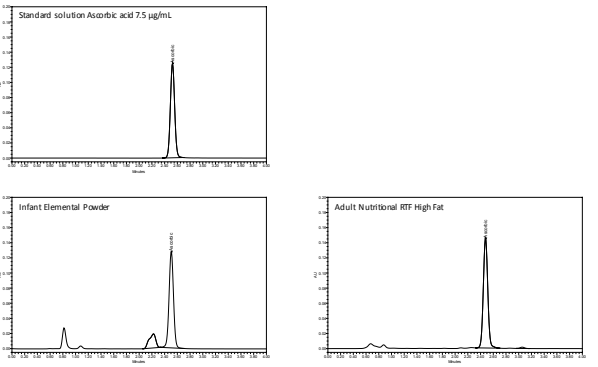

Figure 2. Example chromatograms of nutritional products.

products or as "reconstituted powder" for powder samples, as follows:

$$C = \frac{(A - I) \times V_1 \times V_3 \times 100}{S \times m \times V_2 \times 1000}$$

where A = response (height or area) of the ascorbic acid peak obtained for the sample solution, m = weight of the test portion in g (2.0 g), V_1 = volume of the test solution (volume used to dissolve the test portion) in mL (10 mL), V_2 = volume used in the sample dilution (1.0 mL), and V_3= volume of the final sample dilution (10 mL).

Note: If results expressed in powder sample are needed, use the reconstitution rate to calculate (c × 225/25).

Results

The results from the single-laboratory validation in a selected set of matrixes presented here show the method is suitable for the determination of vitamin C in infant formula and adult/pediatric nutritional formula. Accuracy rates were 90–100%. Duplicate analyses on 7 days showed RSD of repeatability (RSD_r) ranged from 1.4 to 2.5%, and intermediate precision RSD (RSD_{iR}) from 1.3 to 7.5% (Table 1). The linearity was demonstrated by $R^2 > 0.999$ and calibration error lower than 5% in the range of 0.5–10 µg/mL, which corresponds to a quantification range of 2.5–50 mg/100 g (expressed for reconstituted product). Standard Reference Material SRM 1849a (infant/adult nutritional formula) was analyzed in duplicate over 7 days; the overall mean was found to be 8.39 mg/100 g, with an SD of the mean of duplicates of 0.10 mg/100 g, which was statistically not different from the reference value (7.84 ± 0.65 mg/100 g). The average recovery from spiked samples (duplicate analysis, 3 days) at 50 and 100% of target levels ranged from 94 to 101% with an RSD of 4.7–14.5%, and from 94 to 100% with an RSD of 3.9–5.8%, respectively (Table 2). These results validate the modified method for determining vitamin C in infant formula and adult/pediatric nutritional formula. Figures 1 and 2 show example chromatograms.

References

(1) Türkez, H., & Aydin, E. (2012) *Toxicol. Ind. Health* **28**, 684–654

(2) Fontannaz, P., Kilinc, T., & Heudi, O. (2006) *Food Chem.* **94**, 626–631. http://dx.doi.org/10.1016/j.foodchem.2005.02.012

(3) AOAC SMPR 2012.012 (2013) *J. AOAC Int.* **96**, 491. http://dx.doi.org/10.5740/jaoac.int.SMPR2012.012

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Lausanne

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QS PROJECT REPORT

RDLS-RD130018

Single Laboratory Validation – AOAC First Action Method 2012.22 Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula by UPLC-UV

By: E. Campos-Gimenez
T. Kilinc, NRC/QS

Date of Issue: February 14, 2013

Secretary Ref: cre/ldi

Department Head visa:

Detailed Report

Table of Contents

Introduction 2
Methodology and Trials 3
Materials and Methods 3
Validation Protocol 5
Results 6
Single Laboratory Validation 6
Conclusions and next steps 9
References 10
Attachments 11

Introduction

Project background

Infant formula industry has defined a strong need to modernize and harmonize analytical standards to verify compliance of infant/adult nutritionals. It is important that these standards are accepted and applied worldwide to ensure fare trade, benefit inter-market supply and dispute resolution.

The objective of this project is to establish international consensus methods for infant formula and adult nutritionals. This will benefit inter-market supply and dispute resolution. AOAC, mandated by the Infant Formula Council, can provide the scientific tools to accomplish this by offering a forum to bring together all stakeholders and reach consensus on the requirements of these future standards.

Under this context, a new path to achieve AOAC Official Method status was approved in 2011[(1)]. According to this alternative path, methods proposed and reviewed within dedicated AOAC Working Groups can be granted Official First Action status by vetted Expert Review Panels (ERP). The methods remain First Action for a period of about 2 years. During this time, information on method performance generated through the use of the method is monitored. The performance of the method is then reviewed by the ERPs to determine whether Final Action should be recommended to the Official Methods Board. As an intermediate stage to achieve final AOAC Official Methods of Analysis, First Action Method Status was approved in October, 2012

Vitamin C method status

Based on the data presented in a previous publication and on a Single Laboratory Validation study on a selection of matrices previously reported[(2,3)], the method “Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula by UPLC-UV” proposed by Nestlé was granted First Action status and designated AOAC Method 2012.22[(4)] on October 2012. The method corresponds to LI-00.651 “Vitamin C by HPLC-UV”, with adaptation on sample preparation to decrease amount of chemicals, optimize protein precipitation and increase speed.

Next steps included completion of SLV data following SPIFAN guidelines (Attachment 1) on a complete set of SPIFAN matrices (Attachment 2). The data generated will be reviewed by the ERP in March 2013.

The work presented herein summarizes the full Single Laboratory Validation on SPIFAN matrices.

Methodology and Trials

Materials and Methods

Samples

A SPIFAN Single Laboratory Validation Material Test Kit was used (Attachment 2). The kit is aimed to represent the whole range of products in the scope of the project (Infant Formulas and Adult Nutritionals made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch and amino acids, with and without intact protein). It is composed of 6 non fortified (placebo) products and 12 fortified products. Furthermore, it includes a Certified Reference Material (SRM 1849a) with certified value for vitamin C.

Analytical method: AOAC 2012.22

Sample reconstitution

Powder samples were reconstituted by dissolving 25 g of powder sample in 200 g warm water (40 °C). The SRM was reconstituted by dissolving 10 g of powder in 90 g warm water (40 °C). Ten (10) mg of TCEP (Tris(2-carboxyethyl)-phosphine hydrochloride) were added to the samples before reconstitution to prevent oxidation.

Extraction

Two (2) grams of reconstituted or RTF sample were weighed into a 10 mL amber-glass volumetric flask. 4 mL of TCEP solution (250 µg/mL) and 2 mL trichloroacetic acid (TCA) solution (15 %) added before making up to volume with water. After filtration through paper filter, 1 mL of filtrate was transferred to a 10 mL amber-glass volumetric flask containing 1 mL acetate solution (pH 5.4) and made up to volume with water.

Standard solutions

Stock standard solution (500 µg/mL) was diluted in mobile phase to obtain a 50 µg/mL intermediate solution. Into 10 mL amber-glass volumetric flasks, aliquots of the intermediate solution were pipette and made up to volume with mobile phase to yield working standard solutions. (0.5, 1.0, 2.0, 3.0, 5.0, 7.5 and 10.0 µg/mL).

Liquid chromatography

Five (5) µL of final extract were injected onto a UPLC system (Waters Acquity©) equipped with a Waters Acquity UPLC BEH C18, 1.75 µm; 2.1 x 100 mm column. Mobile phase was: sodium acetate, 25 mmol/L, pH 5.4, 1.6 g decylamine, 1 % acetonitrile, 50 mg/L TCEP. Flow rate was 0.35 mL/min, with a run time of 4.0 minutes.
The column was rinsed after each analytical series with 50 % acetonitrile in water for 10 min at 0.4 mL/min.

Continued on next page

Materials and Methods, Continued

Results reporting

All results were reported in mg ascorbic acid/100 g expressed in product "as is" for RTF (ready-to-feed) products, or as "reconstituted powder" for powder samples. Results were compared with Standard Method Performance Requirements (SMPR) (Attachment 3).

Statistical analysis/ calculations

- **Standard deviation of repeatability (S_r) and Standard deviation of intermediate reproducibility (S_{iR})** were calculated from duplicate analysis on 7 different days using classic statistics:

$$S_r = \sqrt{\frac{\sum_{i=1}^{n}(x_{i1}-x_{i2})^2}{2n}} \qquad S_{iR} = \sqrt{SD^2(b) + \frac{1}{2}SD^2(r)}$$

Where:
- n is the number of duplicate determinations (6)
- x_{i1} and x_{i2} are the two single results with i going from 1 to n
- SD(b) is the standard deviation between the means of duplicates
- SD(r) is the standard deviation of repeatability

- **Recovery rates (%)** were calculated as:

$$\text{Recovery (\%)} = \frac{C_{spiked} - C_{native}}{C_{added}} \times 100$$

Where:
- C_{spiked} is the concentration measured in the spiked sample
- C_{native} is the concentration measured in the non fortified sample (overall mean of unspiked samples)
- C_{added} is the concentration of analyte added

Validation Protocol

SLV Guidelines	SPIFAN SLV recommended guidelines were followed (Attachment 1).
System suitability	Replicate (6) injections of a working standard solution (1 µg/mL) were performed before each analytical series. Relative standard deviation of retention time and response was calculated.
Specificity	The five placebo samples supplied with the SPIFAN test material kit were analyzed.
Linearity/ Calibration Fit	Three independent stock solutions of ascorbic acid were prepared at a concentration 500 µg/mL. Working solutions at nine levels covering the range 0.1-10 µg/mL were prepared by diluting the stock solutions and injected for linearity demonstration. Seven levels (0.5-10 µg/mL) were used for daily calibration.
LOD/LOQ	Ten independent analysis of a non fortified sample (Infant Formula RTF Milk Based) spiked with low concentrations of ascorbic acid were used for determination of LOD/LOQ.
Precision studies	All samples in the kit were used for precision studies. They were analyzed in duplicate on 7 different days by 2 analysts. Fresh reagents and working standards were prepared each day.
Accuracy (trueness)	• ***Reference material***: SRM 1849a was analyzed in duplicate on 6 different days by 2 analysts. Overall mean was calculated and compared to certified value (78.4 ± 6.5 mg/100 g). • ***Spike recovery***: The five placebo samples were spiked at 2 levels (50 % and 100 % of target value). Spiked and non spiked samples were analyzed in duplicate on 3 different days by 2 different analysts.
Reference sample	An internal reference sample from Nestlé Proficiency Testing was used as control sample in each series of analysis.

Results

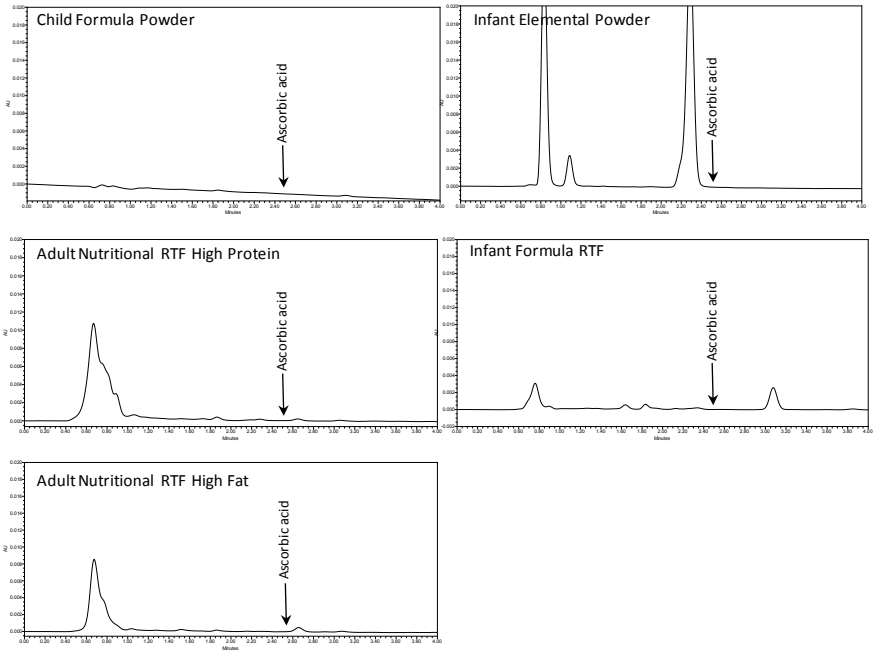
Single Laboratory Validation

System suitability test

Relative standard deviation of retention time and response between the six standard injections were below 1 % for all analytical series.

Specificity

All the placebo samples were free from chromatographic interferences.



Linearity/ Calibration Fit

Calibration curves were plotted and linearity demonstrated by R^2 > 0.9999 and calibration errors well below 5 % for all levels used in daily operation (0.5-10 µg/mL) (Figure 2). This corresponds to 2.5–50 mg/100 g in reconstituted samples. Although linearity up to 500 mg/100 g has been proven (data not shown), we recommend diluting the samples if they contain more than 50 mg/100 g.

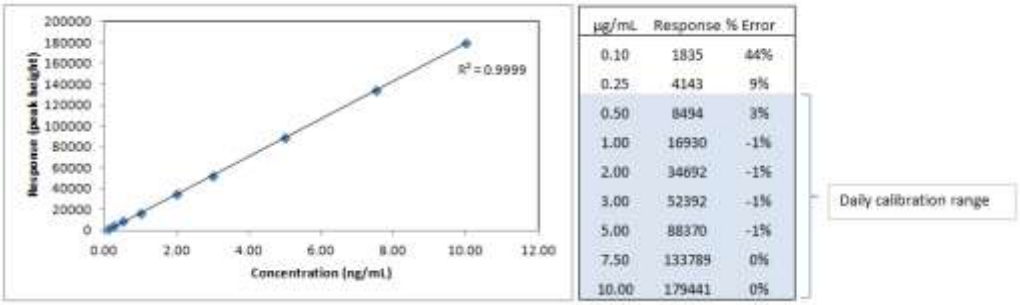


Figure 2: linearity range/calibration fit.

Continued on next page

Single Laboratory Validation, Continued

LoD/LoQ

Results from 10 independent analysis of a placebo sample spiked at low concentrations are given below:

Infant Formula RTF, milk based	Average (mg/100 g)	RSD	Accuracy
Spike level 2.5 mg/100 g	2.47	1 %	99 %
Spike level 1.25 mg/100 g	1.29	1 %	103 %
Spike level 0.5 mg/100 g	0.65	3 %	130 %

Although the precision at 0.5 mg/100 g was still acceptable, the accuracy did not meet the performance requirements. Thus, the quantification limit was set at 1.25 mg/100 g.

Precision studies

Results of precision studies are shown below.

Requirements (SMPR)		≤ 5 %	
	Mean (mg/100 g)	RSD_r (%)	RSD_{iR} (%)
SRM 1849a	7.0	2.0	4.4
Adult Nutritional Powder Milk Protein Based	5.9	1.0	3.9
Infant Formula Powder Part Hyd Milk Based	13.4	0.9	5.5
Infant Formula Powder Part Hyd Soy Based	19.1	0.9	2.6
Adult Nutritional Powder Low Fat	13.5	1.3	3.1
Child Formula Powder	4.8	0.5	1.0
Infant Elemental Powder	36.8	1.7	1.3
Infant Formula Powder Milk Based	11.8	1.4	1.4
Infant Formula Powder Soy Based	10.6	1.4	2.0
Infant Formula RTF Milk Based	8.0	0.7	4.8
Adult Nutritional RTF High Protein	29.9	0.8	4.2
Adult Nutritional RTF High Fat	39.3	2.5	5.3

RSD_r is the relative standard deviation of repeatability
RSD_{iR} is the relative standard deviation of intermediate reproducibility

Continued on next page

Single Laboratory Validation, Continued

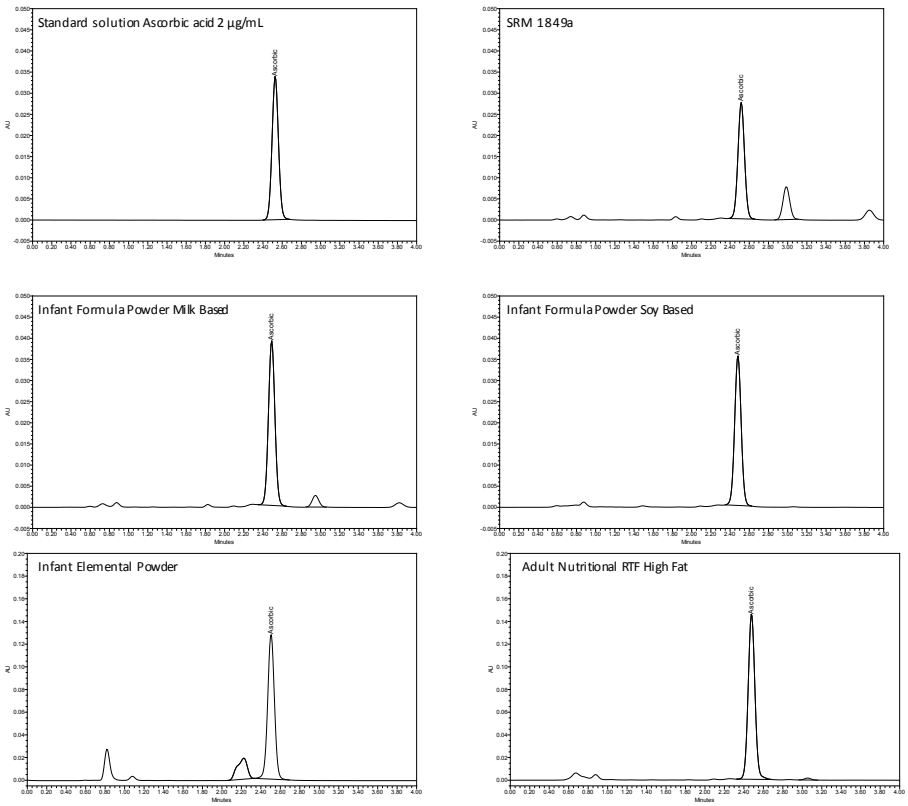
Accuracy studies

- ***Reference material***: The overall mean of duplicate analysis of the certified reference material SRM 1849a on 6 different days by 2 analysts was 70.3 mg/100 g, with a SD (standard deviation of the mean of duplicates) of 2.9 mg/100 g, which is not statistically different from the certified value (78.4 ± 6.5 g/100 g).

- ***Spike recovery:*** Results of spiking experiments are shown below. All recovery rates complied with requirements (90-110 %).

	Target	+50 % of target		+ 100 % of target	
Non fortified products		**Avg**	**RSD**	**Avg**	**RSD**
Child Formula Powder	4.4	111 %	0.9 %	98 %	1.8 %
Infant Elemental Powder	40	93 %	0.9 %	94 %	1.1 %
Adult Nutritional RTF High Prot	30	97 %	2.4 %	93 %	2.0 %
Adult nutritional RTF High Fat	35	98 %	1.1 %	95 %	2.3 %
Infant Formula RTF Milk Based	10	99 %	0.6 %	97 %	1.4 %

Example chromatograms



Conclusions and next steps

Conclusions

Method performance characteristics met Standard Method Performance Requirements (SMPR AOAC 2012.012) for all the matrices in the scope of the project. Accuracy of the method was proven by analysis of a Certified Reference Material (SRM 1849a), as well as by recovery rates within 90-110 %. The precision of the method showed Relative Standard Deviation of repeatability SDr ≤ 2.5, and Relative Standard Deviation of intermediate reproducibility SDiR ≤ 5.5 %.

The results prove that the method is a good candidate for further validation by Multi Laboratory Testing in order to grant Final Action status.

Next steps

Next step is to report SLV data to AOAC for revision by the ERP and publication of the method in the J. AOAC Int.

If the method is accepted to pursue further validation, a Multi Laboratory Testing will take place. E. Campos Giménez will be Study Director.

References

1. Sullivan, D. (2012) “Infant Formula and Adult/Pediatric Nutritional Methods Approved First Action Using the AOAC voluntary Consensus Standards Process”, *J. AOAC Int*., 95, No 2, 287-297

2. Fontannaz, P.; Kilinc, T.; Heudi, O. (2006) “HPLC-UV determination of total vitamin C in a wide range of fortified food products”, *Food Chemistry.* 94, 626-631

3. R&D Report RDLS-RD120054 Single Laboratory Validation – Vitamin C by UPLC-UV method for discussion by Working Group SPIFAN. E. Campos Giménez, T. Kilinc. June, 27th 2012

4. *Inside Laboratory Management*, November/December 2012, 43-48

Attachments

Attachment 1: SPIFAN Single Laboratory Validation Guidelines
Attachment 2: SPIFAN Single Laboratory Validation Test Materials Kit
Attachment 3: AOAC SMPR 2012.012 Vitamin C
Attachment 4: Complete set of raw data

AOAC INTERNATIONAL

RECOMMENDED GUIDELINES FOR SPIFAN SINGLE LABORATORY VALIDATION (SLV)

I. GENERAL

A. All methods for a given nutrient or nutrient group will be subjected to a common SLV protocol utilizing the available SPIFAN matrices.

B. SLV protocols may vary somewhat BETWEEN nutrients, depending on the specific demands associated with each.

C. Study directors (SDs) for each nutrient or nutrient group will agree on final details of the required SLV protocol.

D. Suitability criteria indicating method/system performance is acceptable will be generated during SLV.

II. LINEARITY/CALIBRATION FIT

A. Minimum of 6 levels[i] that span the desired working range.

B. Relative error of back-calculated concentrations determined within the desired working range.[ii]

C. Minimum of 3 independent experiments.[iii]

III. LOD/LOQ

A. 10 independent analyses of blank or blank spiked at low level[iv] (if there is no detectable blank signal):

LOD = Blank Mean +3 Standard Deviations
LOQ = Blank Mean + 10 Standard Deviations[v]

IV. SPECIFICITY

A. No explicit proposals for evaluating specificity have been suggested.

B. Because useful strategies for doing this vary from analyte to analyte, study directors for each nutrient will agree on acceptable practice.

C. An adequate evaluation of specificity may have already been done for some methods, in which case it would not have to be repeated.

V. PRECISION

A. All samples selected for precision studies will be analyzed in duplicate on each of 6 days using multiple analysts and instruments as practical for the different days. Fresh reagents and working standards will be used each day. Reports will include information of number of analysts, instruments, etc.

B. Precision data using SRM 1849a should be included for ALL methods. For each nutrient or nutrient group, precision data shall be collected using an appropriate variety of SPIFAN matrices that

contain the nutrient or nutrient group (as agreed upon by the SDs). The number of matrices may vary between nutrients.

C. Estimate within-day (repeatability), day-to-day, and overall (intermediate precision) for each sample type. Estimates pooled across sample types may also be useful.

VI. ACCURACY (TRUENESS)

A. Analysis of SRM 1849a

1. Comparison to SRM values may not always be applicable because nutrient definitions are not aligned. SDs will agree on whether this should be part of the accuracy assessment.

B. Spike Recovery

1. Recovery will be determined from an appropriate sampling of SPIFAN matrices. Either Unfortified (preferably) and/or fully fortified products may be used.
2. Each selected matrix will be spiked at 2 levels. Recommended spike levels are 50 and 150% of typical target; or 50 and 100% overspikes. SDs will agree on levels used.
3. Spiked and unspiked samples will be analyzed in duplicate on each of 3 days.
4. The overall mean of unspiked samples will be used for computing recoveries.
5. Matrices used for estimating recoveries may or may not coincide with one or more of those selected for precision studies. If there is overlap, then a single 2x6 replication of the unspiked matrix covers both requirements for that sample type.

C. Comparison to Reference Methods

1. This is not required as matter of routine, because the additional effort and lack of appropriate reference methods.
2. SDs may choose to collect reference method comparison data.

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[i] Levels to be agreed upon by SDs.
[ii] No specific criterion in SMPR. Recommend calibration errors to be <5%.
[iii] Independently prepared standards, if feasible.
[iv] To be agreed upon by SDs.
[v] Concentration of blank to be <10% of the estimated LOQ.

AOAC INTERNATIONAL

SPIFAN Single Laboratory Validation Test Materials Kit

I. Contents of Single Laboratory Validation (SLV) Test Materials Kit:

A. Placebo Products

1. Child Formula Powder, 1 - 250 g container
2. Infant Elemental Powder, 1 - 250 g container
3. Adult Nutritional RTF, High Protein, 1 - 250 g container
4. Adult Nutritional RTF, High Fat, 1 - 250 g container
5. Infant Formula RTF, Milk Based, 12 - 60 g container

Placebo products can be used to establish method specificity and to complete repeatability and recovery experiments at levels specified in SMPR. For most methods there is enough placebo product to complete precision (duplicate analyses on six days) and/or recovery (duplicate analyses on three days) experiments. There is enough placebo powder to make at least 9 reconstitutions by diluting 25 grams of powder to 225 grams with water and enough placebo liquid to prepare at least 8 samples if the sample size is 25 grams or less.

B. Fortified Products

1. SRM 1849a, 6 – 10 g pouches
2. Adult Nutritional Powder Milk Protein Based, 2 – 400 g containers
3. Infant Formula Powder Partially Hydrolyzed Milk Based, 2 – 360 g containers
4. Infant Formula Powder Partially Hydrolyzed Soy Based, 2- 360 g containers
5. Adult Nutritional Powder Low Fat, 2 – 250 g containers
6. Child Formula Powder, 2 – 250 g containers
7. Infant Elemental Powder, 2 – 250 g containers
8. Infant Formula Powder Milk Based, 2 – 360 g containers
9. Infant Formula Powder Soy Based, 2 – 730 g containers
10. Infant Formula RTF Milk Based, 12 – 60 g containers
11. Adult Nutritional RTF High Protein, 3 – 250 g containers
12. Adult Nutritional RTF High Fat, 3 – 250 g containers

Fortified products will be used to complete repeatability and recovery experiments and may be used to establish method specificity. For all methods there should be enough fortified product to complete precision (duplicate analyses on six days) and/or recovery (duplicate analyses on three days) experiments. There is enough fortified powder to make at least 9 reconstitutions by diluting 25 grams of powder to 225 grams with water and enough placebo liquid to prepare at least 24 samples if the sample size is 25 grams or less.

II. Instructions for SLV Test Materials Kit:

A. Store products in a cool dry place, protected from light.

B. For all nutrient groups except vitamin C, samples can be taken from opened liquid product containers for up to 1 week after the containers are opened if the product is flushed with nitrogen

and stored refrigerated in sealed containers. For vitamin C new containers of fortified liquid should be opened each day, but for placebo liquids, samples can be taken from opened liquid product containers for up to 1 week after the containers are opened if the product is flushed with nitrogen and stored refrigerated in sealed containers.

C. For all nutrient groups, samples can be taken from opened powder product containers for up to 2 weeks after the containers are opened if the product is flushed with nitrogen and stored frozen in sealed containers.

D. Per the SMPR's, all powder products except SRM 1849 should be reconstituted by dissolving 25 grams of powder in 200 grams of water. SRM 1849 can be reconstituted by dissolving 10 grams of powder in 90 grams of water or SRM 1849 powder can be weighed directly.

E. Do not throw away any unopened product containers. Store these in a cool dry place, protected from light.

AOAC SMPR 2012.012

Standard Method Performance Requirements for Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula

Intended Use: Global dispute resolution method

1 Applicability

Determination of vitamin C in all forms of infant, adult, or pediatric formula (powders, ready-to-feed liquids, and liquid concentrates). For the purpose of this SMPR, vitamin C is defined as the sum of L-ascorbic acid or its salts, and de-hydro ascorbic acid.

2 Analytical Technique

Any analytical technique that meets the following method performance requirements is acceptable.

3 Definitions

Adult/pediatric formula.—Nutritionally complete, specially formulated food, consumed in liquid form, which may constitute the sole source of nourishment made from combination of milk, soy, rice, whey, hydrolyzed protein, hydrolyzed lactose, starch, and amino acids, with and without intact protein.

Infant formula.—Breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding, made from combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Limit of detection (LOD).—The minimum concentration or mass of analyte that can be detected in a given matrix with no greater than 5% false-positive risk and 5% false-negative risk.

Limit of quantitation (LOQ).—The minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Repeatability.—Variation arising when all efforts are made to keep conditions constant by using the same instrument and operator, and repeating during a short time period.

Reproducibility.—The standard deviation or relative standard deviation calculated from among-laboratory data, expressed as reproducibility relative standard deviation or % reproducibility relative standard deviation.

Recovery.—The fraction or percentage of spiked analyte that is recovered when the test sample is analyzed using the entire method.

Table 1. Method performance requirements[a,b]

Analytical range	1.0–250 mg/100 g	
Limit of detection (LOD)	0.3 mg	
Limit of quantitation (LOQ)	1.0 mg	
Repeatability (RSD_r)	1.0 mg	≤10%
	10 mg	≤5%
	75 mg	
	200 mg	
Recovery	90 to 110% of mean spiked recovery over the range of the assay	
Reproducibility (RSD_R)	1.0 mg	≤15%
	10 mg	≤10%
	75 mg	
	200 mg	

[a] Concentrations apply to: (*1*) "ready-to-feed" liquids "as is"; (*2*) reconstituted powders (25 g into 200 g water); and (*3*) liquid concentrates diluted 1:1 by weight.

[b] For all concentrations vitamin C will be expressed as mg/100 g reconstituted liquids.

4 Method Performance Requirements

See Table 1.

5 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blank check samples, and check standards at the lowest point and midrange point of the analytical range.

6 Reference Material(s)

NIST Standard Reference Material® (SRM) 1849a Infant/Adult Nutritional Formula, or equivalent. The SRM is milk-based, hybrid infant/adult nutritional powder prepared by a manufacturer of infant formula. The certified NIST value for SRM 1849a is 784 ± 65 mg/kg as ascorbic acid.

7 Validation Guidance

Recommended level of validation: *Official Methods of Analysis*℠.

8 Maximum Time-to-Result

No maximum time.

Approved by the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) on September 29, 2012. Final Version Date: September 29, 2012.

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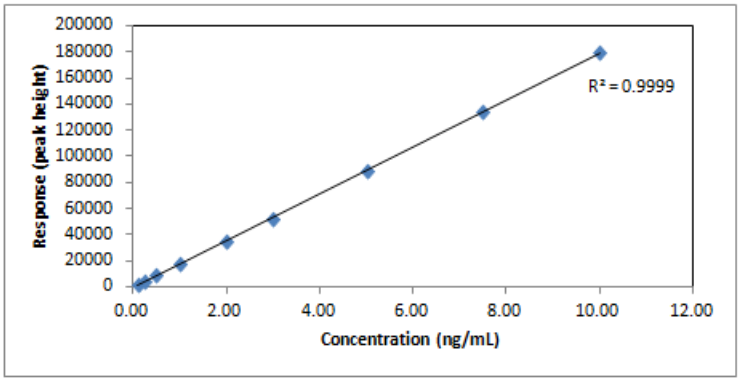
II. Linearity /Calibration Fit

9 levels from 0.1 to 10 µg/mL (corresponding to 0.5-50 mg/100 g of ascorbic acid in reconstituted product) were prepared from stock solution



µg/mL	Response	% Error
0.10	1835	44%
0.25	4143	9%
0.50	8494	3%
1.00	16930	-1%
2.00	34692	-1%
3.00	52392	-1%
5.00	88370	-1%
7.50	133789	0%
10.00	179441	0%

Daily calibration range

III. LOD/LOQ

10 Independent analysis of a blank sample (Infant Formula RTF Milk Based) spiked with different amount of standard

	Spike level 2.5 mg/100 g										Average	SD	CV	Accuracy
Infant Formula RTF,milk based (non fortified)	2.48	2.44	2.45	2.45	2.47	2.48	2.51	2.49	2.48	2.49	2.47	0.0217	1%	99%

	Spike level 1.25 mg/100 g										Average	SD	CV	Accuracy
Infant Formula RTF,milk based (non fortified)	1.288	1.291	1.304	1.279	1.298	1.273	1.296	1.296	1.311	1.3	1.29	0.0113	0.9%	103%

	Spike level 0.5 mg/100 g										Average	SD	CV	Accuracy
Infant Formula RTF,milk based (non fortified)	0.621	0.661	0.676	0.622	0.655	0.651	0.656	0.656	0.636	0.643	0.65	0.0174	2.7%	130%

III. PRECISION

The samples were analyzed in duplicate on each of six days using two analysts.
Fresh reagents and working standards were prepared each day by each one of the analysts.

RESULTS EXPRESSED IN PRODUCT AS IS	Day 1		Day 2		Day 3		Day 4		Day 5		Day 6		Day 7	
SRM 1849a (Reference value; 126.8 ± 12.8 mg/100 g, in choline hydroxide)	68.4	67.9	68.1	69.7	72.3	72.0	73.1	73.7	71.6	71.5	67.9	63.5		
7.Adult Nutritional Powder Milk Protein Based	52.2	52.8	51.9	50.9	51.4	51.1	55.0	55.2	52.3	51.7	56.2	54.7	55.8	55.8
8.Infant Formula Powder Partially Hydrolyzed Milk Based	112.0	113.1	112.8	116.5	115.4	116.3	125.2	125.2	124.6	125.0	123.1	124.1	130.3	129.3
9.Infant Formula Powder Partially Hydrolyzed Soy Based	165.7	169.4	167.3	164.6	167.9	168.7	175.1	174.6	174.2	172.8	172.8	172.2	177.2	178.8
10.Adult Nutritional Powder Low Fat	119.7	116.8	119.3	122.2	119.3	122.2	123.3	123.5	117.0	115.6	122.5	120.4	127.7	127.0
11.Child Formula Powder	42.8	43.3	43.1	43.4	43.1	43.4	43.7	43.6	42.6	42.2	43.6	43.3	43.1	43.4
12.Infant Elemental Powder	327.9	329.8	328.9	335.0	338.3	326.0	327.0	332.3	333.4	331.4	340.7	326.5	329.0	333.8
13.Infant Formula Powder Milk Based	105.6	105.5	105.6	105.2	107.1	107.3	107.5	108.7	107.3	107.1	105.9	108.5	108.1	103.5
14.Infant Formula Powder Soy Based	96.4	96.0	94.3	94.0	97.0	97.2	95.8	96.9	96.3	93.0	96.3	98.0	91.3	94.5
15.Infant Formula RTF Milk Based	8.3	8.2	12.2	12.1	11.1	11.1	8.3	8.2	7.7	7.7	8.3	8.3	7.5	7.4
16.Adult Nutritional RTF High Protein	30.8	30.3	31.5	31.6	30.9	30.7	30.8	30.3	29.3	29.0	29.1	28.6	28.1	28.1
17.Adult Nutritional RTF High Fat	39.3	40.3	37.2	35.4	41.1	38.8			38.8	39.2	41.6	41.6		

RESULTS EXPRESSED IN PRODUCT AS RECONSTITUTED	Day 1		Day 2		Day 3		Day 4		Day 5		Day 6		Day 7		Average mean of duplicates	Sr	CVr	SiR	CViR
SRM 1849a	6.8	6.8	6.8	7.0	7.2	7.2	7.3	7.4	7.2	7.2	6.8	6.4			7.0	0.137	2.0%	0.305	4.4%
7.Adult Nutritional Powder Milk Protein Based	5.8	5.9	5.8	5.7	5.7	5.7	6.1	6.1	5.8	5.7	6.2	6.1	6.2	6.2	5.9	0.060	1.0%	0.227	3.9%
8.Infant Formula Powder Partially Hydrolyzed Milk Based	12.4	12.6	12.5	12.9	12.8	12.9	13.9	13.9	13.8	13.9	13.7	13.8	14.5	14.4	13.4	0.126	0.9%	0.729	5.5%
9.Infant Formula Powder Partially Hydrolyzed Soy Based	18.4	18.8	18.6	18.3	18.7	18.7	19.5	19.4	19.4	19.2	19.2	19.1	19.7	19.9	19.1	0.154	0.8%	0.499	2.6%
10.Adult Nutritional Powder Low Fat	13.3	13.0	13.3	13.6	13.3	13.6	13.7	13.7	13.0	12.8	13.6	13.4	14.2	14.1	13.5	0.168	1.3%	0.413	3.1%
11.Child Formula Powder	4.8	4.8	4.8	4.8	4.8	4.8	4.9	4.8	4.7	4.7	4.8	4.8	4.8	4.8	4.8	0.026	0.5%	0.048	1.0%
12.Infant Elemental Powder	36.4	36.6	36.5	37.2	37.6	36.2	36.3	36.9	37.0	36.8	37.9	36.3	36.6	37.1	36.8	0.631	1.7%	0.483	1.3%
13.Infant Formula Powder Milk Based	11.7	11.7	11.7	11.7	11.9	11.9	11.9	12.1	11.9	11.9	11.8	12.1	12.0	11.5	11.8	0.162	1.4%	0.162	1.4%
14.Infant Formula Powder Soy Based	10.7	10.7	10.5	10.4	10.8	10.8	10.6	10.8	10.7	10.3	10.7	10.9	10.1	10.5	10.6	0.150	1.4%	0.209	2.0%
15.Infant Formula RTF Milk Based	8.3	8.2					8.3	8.2	7.7	7.7	8.3	8.3	7.5	7.4	8.0	0.055	0.7%	0.391	4.8%
16.Adult Nutritional RTF High Protein	30.8	30.3	31.5	31.6	30.9	30.7	30.8	30.3	29.3	29.0	29.1	28.6	28.1	28.1	29.9	0.252	0.8%	1.256	4.2%
17.Adult Nutritional RTF High Fat	39.3	40.3	37.2	35.4	41.1	38.8			38.8	39.2	41.6	41.6			39.3	0.983	2.5%	2.067	5.3%

IV. ACCURACY (TRUENESS)

A. Analysis of SRM 1849a Infant/Adult Nutritional Formula

SRM 1849a was analyzed in duplicate on 6 different days as independent experiments. Overall mean was calculated and compared to reference value

		Day 1		Day 2		Day 3		Day 4		Day 5		Day 6			Overall mean
SRM 1849a (Reference value 78.4 ± 6.5 mg/100 g)	Analysis date Dec 2012	68.4	67.9	68.1	69.7	72.3	72.0	73.1	73.7	71.6	71.5	67.9	63.5		70.0
SRM 1849a (Reference value 78.4 ± 6.5 mg/100 g)	Analysis date May 2013	83.9	85.1	82.4	82.1	85.3	84.1	83.5	86.7	85.1	81.5	83.7	84.5	82.9	83.3	84.0

Recovery analysis conclusion

	Robust	Classical
Median / Mean of results	70.250	70.000
Standard Deviation	3.995	2.895
Recovery	89.6%	89.3%
SD(Recovery)	0.043	0.040
t test	2.442	2.681
p value	0.059	0.044
SD(Rec)corrected	0.043	0.067
RSD(Rec)corrected	4.8%	7.5%

Conclusion The recovery is NOT different from 100% (at 95% confidence interval).

B. SPIKE RECOVERY

Recovery was determined in a selected sampling of fortified products and non fortified products.
Each selected matrix was spiked at 2 levels. Spiked samples were analyzed in duplicate on each of 3 days by 2 different analysts, as independent experiments.
The overall mean of unspiked samples was used to compute recoveries. Recovery rates were calculated as:
All results expressed in mg/100 g

$$\text{Recovery}(\%) = \frac{C_{\text{spiked sample}} - C_{\text{non-spiked sample}}}{C_{\text{added}}}$$

		Day 1				Day 2				Day 3				Average Recovery				
	(mg/100 g)	As is		as RTF*		Recovery rates		(mg/100 g)	As is		as RTF*		Recovery rates	(mg/100 g)	As is		as RTF*		Recovery rates	Day 1	Day 2	Day 3	Overall	RSD
1.Child Formula Powder (non fortified)		0.0	0.0	0.0	0.0				0.0	0.0	0.0	0.0			0.0	0.0	0.0	0.0						
1.Child Formula Powder (fortified 50 %)	20	22.4	22.4	2.5	2.5	112%	112%	20	22.0	22.0	2.4	2.4	110%	110%	11	22.2	22.4	2.5	2.5	111%	112%	112%	110%	112%	111%	0.9%
1.Child Formula Powder (fortified 100 %)	40	38.7	38.5	4.3	4.3	97%	96%	40	39.0	39.7	4.3	4.4	98%	99%	22	39.8	40.3	4.4	4.5	100%	101%	97%	98%	100%	98%	1.8%

*Reconstitution rate : 25 g + 225 g water

		Day 1				Day 2				Day 3				Average Recovery				
	(mg/100 g)	As is		as RTF*		Recovery rates		(mg/100 g)	As is		as RTF*		Recovery rates	(mg/100 g)	As is		as RTF*		Recovery rates	Day 1	Day 2	Day 3	Overall	RSD
2.Infant Elemental Powder (non fortified)		0.0	0.0	0.0	0.0				0.0	0.0	0.0	0.0			0.0	0.0								
2.Infant Elemental Powder (fortified 50 %)	180	165.4	165.7	18.4	18.4	92%	92%	180	169.6	167.8	18.8	18.6	94%	93%	180	167.4	166.7	18.6	18.5	93%	93%	92%	94%	93%	93%	0.9%
2.Infant Elemental Powder (fortified 100 %)	360	333.6	336.3	37.7	37.4	94%	93%	360	342.3	344.0	38.0	38.2	95%	96%	360	336.8	335.1	37.4	37.2	94%	93%	94%	95%	93%	94%	1.1%

*Reconstitution rate : 25 g + 225 g water

		Day 1				Day 2				Day 3				Average Recovery				
	(mg/100 g)	As is		as RTF*		Recovery rates		(mg/100 g)	As is		as RTF*		Recovery rates	(mg/100 g)	As is		as RTF*		Recovery rates	Day 1	Day 2	Day 3	Overall	RSD
3. Adult Nutritional RTF High Protein (non fortified)		0.0	0.0						0.0	0.0					0.0	0.0								
3. Adult Nutritional RTF High Protein (fortified 50 %)	15	14.2	14.0			95%	93%	15	14.6	14.8			97%	99%	15	14.5	14.9			97%	99%	94%	96%	96%	97%	2.4%
3. Adult Nutritional RTF High Protein (fortified 100 %)	30	27.3	27.1			91%	90%	30	28.2	28.0			94%	93%	30	28.3	28.2			94%	94%	91%	94%	94%	93%	2.0%

*Reconstitution rate : 25 g + 225 g water

	Added (mg/100 g)	Day 1				Day 2				Day 3				Average Recovery				
		As is		as RTF*		Recovery rates		Added (mg/100 g)	As is		as RTF*		Recovery rates	Added (mg/100 g)	As is		as RTF*		Recovery rates	Day 1	Day 2	Day 3	Overall	RSD
4. Adult Nutritional RTF High Fat (non fortified)		0.0	0.0						0.0	0.0					0.0	0.0								
4. Adult Nutritional RTF High Fat (fortified 50 %)	18	16.9	16.9			97%	97%	18	17.0	17.5			97%	100%	18	17.0	17.3			97%	99%	97%	99%	98%	98%	1.1%
4. Adult Nutritional RTF High Fat (fortified 100 %)	35	32.4	33.5			93%	96%	35	34.0	34.5			97%	99%	35	32.3	32.8			94%	94%	94%	96%	94%	95%	2.3%

*Reconstitution rate : 25 g + 225 g water

	Added (mg/100 g)	Day 1				Day 2				Day 3				Average Recovery				
		As is		as RTF*		Recovery rates		Added (mg/100 g)	As is		as RTF*		Recovery rates	Added (mg/100 g)	As is		as RTF*		Recovery rates	Day 1	Day 2	Day 3	Overall	RSD
5. Infant Formula RTF,milk based (non fortified)		0.0	0.0						0.0	0.0					0.0	0.0								
5. Infant Formula RTF,milk based (fortified 50 %)	5	4.9	5.0			98%	100%	5	5.0	5.0			100%	100%	5	4.9	5.0			98%	100%	99%	100%	99%	99%	0.6%
5. Infant Formula RTF,milk based (fortified 100 %)	10	9.5	9.6			95%	96%	10	9.8	9.8			98%	98%	10	9.6	9.6			96%	96%	96%	98%	96%	97%	1.4%

*Reconstitution rate : 25 g + 225 g water

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

MEETING HELD AT

Palmer House Hilton
Chicago, IL

Tuesday, August 27, 2013

REPORT OF THE EXPERT REVIEW PANEL (ERP) PROCEEDINGS

Expert Review Panel Member Attendees:

Darryl Sullivan, Chair, *Covance Laboratories*
John Austad, *Covance Laboratories*
Sneh Bhandari, *Silliker Laboratories*
Esther Campos-Giménez/Adrienne McMahon, *Nestlé/Wyeth*
Scott Christiansen, *Perrigo Nutritionals*
Jonathan DeVries, *Medallion Labs/Gen. Mills*
Don Gilliland/Karen Schimpf, *Abbott Nutrition*
Min Huang, *Aegis Corp.*
Harvey Indyk/Brendon Gill, *Fonterra*
Estela Kneeteman, *INTI*
Bill Mindak, *FDA*
Shay Phillips, *Mead-Johnson Nutritional*
Melissa Phillips/Kate Rimmer, *NIST*
Jinchuan Yang, *Waters Corp.*

Expert Review Panel Members Not in Attendance:

Jeanne Rader, *FDA*
Günther Raffler, *Danone*

AOAC Staff including:

Delia Boyd
E. James Bradford
Scott Coates
Dawn Frazier
Deborah McKenzie
Alicia Meiklejohn
Anita Mishra

I. WELCOME/INTRODUCTIONS

Darryl Sullivan (Covance), Chair of the Stakeholder Panel on Infant Formula and Adult Nutrition, introduced and welcomed the participants to Expert Review Panel (ERP) meeting of the SPIFAN project. The ERP members in attendance and participants were introduced.

II. DOWN SELECTION PROCESS & REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP)

The Expert Review Panel (ERP) discussed the methods and selected a single method for multi-lab testing (MLT) through the SPIFAN process. The following is the result of the discussions and vote.

1) Vitamin C

a. OMA# 2012.21 (VitC-02) & OMA# 2012.22 (VitC-03)
b. **Score**: 757 points (OMA# 2012.21) / 826 points (OMA# 2012.22)

2) Choline

a. OMA# 2012.18 (Chol-03) & OMA# 2012.20 (Chol-07)
b. **Score**: 852 points (OMA# 2012.18) / 869 points (OMA# 2012.20)

3) Iodine

a. OMA# 2012.14 (Iod-01) & OMA#2012.15 (Iod-02)
b. **Score**: 838 points (OMA# 2012.14) / 877 points (OMA# 2012.15)

4) Pantothenic Acid

a. OMA# 2012.16 (Panto-01) - **Moved to MLT**

5) Carnitine

a. OMA# 2012.17 (Carn-01) - **Method Withdrawn**

1. Move to advance the selected method for reproducibility study

Method	Method Title	Reviewer(s)	Score	Vote	Comments
VitC-02	*2012.21 - Determination of Vitamin C by HPLC with UV Detection*	Brendon Gill John Austad	757		➢ No measurable bias against the SRM ➢ Met all SMPR requirements ➢ SRM results; average was higher ➢ Which option was used for data collection?
VitC-03	*2012.22 - HPLC-UV Determination of Total Vitamin C in a Wide Range of Fortified Food Products*	Jon DeVries Harvey Indyk	826	Yes- 11/ No-0 /Abstain-2	
Chol-03	*2012.18 - Simultaneous Determination of Free Carnitine and Total Choline by Liquid Chromatography/Mass Spectrometry in Infant Formula and Health-Care Products: Single-Laboratory Validation*	John Austad Sneh Bhandari	852		➢ Within RSD requirements ➢ Meets SMPR
Chol-06	*2012.19 - Method Development for Determination of Total and Free Choline in Nutritional Products by LC–MS/MS*	Method withdrawn			
Chol-07	*2012.20 - Determination of Choline in Powdered Infant Formula*	Scott Christiansen Shay Phillips	869	Yes- 12/ No-0 /Abstain-2	➢ Repeatability o Pretty rugged ➢ Meets SMPR ➢ Instruction o When predicted life time ➢ Use of guard column should be part of system suitability
Iod-01	*2012.14 - Determination of Total Iodine in Infant Formula and Nutritional Products by Inductively Coupled Plasma/Mass Spectrometry: Single Laboratory Validation*	Bill Mindak Min Huang	838		➢ Well written method ➢ Difference in the sample prep ➢ digestion
Iod-02	*2012.15 - Method of Analysis for the Determination of Total Iodine in Foods and Dietary Supplements Using Inductively Coupled Plasma-Mass Spectrometry*	Esther Campos-Giménez Min Huang	877	Yes- 12/ No-0 /Abstain-2	➢ May require additional detail ➢ Decide on one (1) digestion technique only ➢ See data on both through MLT
Panto-01	*2012.16 - Pantothenic Acid (Vitamin B5) in Fortified Foods: Comparison of a Novel Ultra-Performance Liquid Chromatography-Tandem Mass Spectrometry Method and a Microbiological Assay (AOAC*	John Austad Don Gilliland		Yes- 13/ No-0 /Abstain-1	➢ Units were wrong o Units in grams should be milligrams ➢ Address high fat issue ➢ Use free pantothenic acid according to NIST ➢ Define what the prep looks

	Official MethodSM 992.07)				like o No option (one or the other)
Carn-01	*2012.17 - Single-Laboratory Validation of a Liquid Chromatographic/Tandem Mass Spectrometric Method for the Determination of Free and Total Carnitine in Infant Formula and Raw Ingredients*	Method withdrawn			

III. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FIRST ACTION *OFFICIAL METHOD*SM STATUS

The Expert Review Panel (ERP) members Primary and Secondary Reviewers provided updates on their assigned method(s) and rendered a decision on First Action *Official Method* status. The ERP collectively discussed the method(s) and selected a single method to move forward through the SPIFAN process.

1. Folate

a. Fol-20

b. Fol-21

2. Move to advance the selected method for First Action *Official Method*SM Status

Method	Method Title	Reviewer(s)	ERP Vote	Reviewer's Comments
Fol-20	*A validated method to determine folic acid and 5-methyl THF in adult/infant nutritional formulae using ultra performance liquid chromatography-tandem mass spectrometry*	Adrienne McMahon Melissa Phillips/Kate Rimmer	Yes- 3/ No-5/Abstain-2	➢ Recovery didn't meet the SMPR ➢ Extraction o Difference in the totals ➢ Values in the SRM is high
ERP RECOMMENDATIONS FOR FOL-20: ➢ More data on SPIFAN suite o Choose between heat treatment or o Tri-enzyme ➢ Check calculations *Will not move to MLT at this time **Study director proposes to have additional data within one month				
Fol-21	*Single-Laboratory Validation - Free Folates in Infant Formula and Adult/ Pediatric Nutritional Formula by UHPLC-UV*	Min Huang Shay Phillips	Yes- 10/ No-1/Abstain-1 **Second vote:** Yes- 10/ No-0 /Abstain-2	➢ Meets SMPR ➢ Sample prep ➢ Standard purity
ERP RECOMMENDATIONS FOR FOL-21: ➢ Check methodology (concentration of calibration standard) ➢ Use spectro-photometric combined with HPLC (recommend both) ➢ MS/MS not UV ➢ Tri-enzyme Caveat ➢ Measurement of poly-glutamate				

IV. UPDATE ON MULTI-LABORATORY TESTING SCHEDULE

Robert Rankin (International Formula Council) provided an update on the Multi-Laboratory Testing schedule.

V. UPDATE ON VITAMIN A & E

Adrienne McMahon of Wyeth Nutrition (formerly Pfizer) provided an update on the Vitamin A & E method slated to move to multi-lab testing.

Method	Method Title	Original Reviewer(s)	Vote	Recommendation
VitA-17 **VitE-19**	*2012.10 - Simultaneous Determination of Vitamins A, E and Beta Carotene/Mixed Carotenoids in Infant Formula by Normal Phase HPLC. Submitted by Pfizer Nutrition.*	Erik Konings Kathy Sharpless/ Kate Rimmer	Yes- 12/ No-0 /Abstain-1	➢ Move to MLT

VI. REVIEW ACTIONS FROM PREVIOUS MEETINGS

Darryl Sullivan & Anita Mishra reviewed previous actions/items from past meetings.

Nestlé Research Centre
Lausanne

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R&D REPORT

RDLS-RD150006

Multi Laboratory Test – AOAC First Action Method 2012.22 Ascorbic Acid (Vitamin C) in Infant Formula and Adult/Pediatric Nutritionals.

By E. Campos Giménez (NRC, Lausanne)

R&D REPORT

Detailed Report

Table of Contents

STUDY DESCRIPTION 3
Study Information 3
Materials, Method and Laboratories 5
Forms 6
INSTRUCTIONS TO PARTICIPANTS 7
Part 1: Method set up and qualification of participants 7
Part 2: Multi-Laboratory Test Participation 8
RESULTS 9
Part 1. Method set up and qualification of participants 9
Part 2. Multi Laboratory Test 10
CONCLUSIONS 12
ANNEXES 13
List of Annexes 13
Annex A: List of Materials 14
Annex B: Method 15
Annex C: List of participants 19
Annex D: Cover letters to participants 21
Annex E: Receipt Forms 23
Annex F: Reporting templates 25
Annex G: Raw data practice samples 27
Annex H: Raw data MLT samples 28
Annex I: Graphical representation of data 29

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STUDY DESCRIPTION

Study Information

Study Title	Vitamin C (ascorbic acid) in Infant Formula and Adult/Pediatric Nutritional Formula by UHPLC-UV, AOAC First Action 2012.22: Multi-Laboratory Study.
Study Objective	The objective of the study was to validate the current method (AOAC First Action 2012.22) by determining its precision figures (repeatability and reproducibility) through a multi-laboratory testing (MLT). This is mandatory to finalize the work in progress and go forward to obtain Final Action status.
Study Director	Esther Campos Giménez Nestlé Research Center PO Box 44 CH-1000 Lausanne 26 Switzerland Phone (direct): +41 21 785 94 29 Fax: +41 21 785 85 53 E-mail: esther.campos-gimenez@rdls.nestle.com
Study Monitor	Liaison with SPIFAN/AOAC (Official Methods Board): Sneh Bandhari
Study Description	The study was divided in two parts: method set up and qualification of participants (part 1) and multi-laboratory test participation (part 2). **Part 1: method set up and qualification of participants** Each participating laboratory was asked to analyze two practice samples using the method provided in the protocol and report the results to the Study Director within the required timelines (6 weeks after receipt). Results within a range of expected levels qualified the laboratory for the second part of the study. **Part 2: Multi-Laboratory Test participation** Each qualified laboratory received twenty samples to be analyzed using the method provided in the protocol. The laboratory was asked to analyze them on two different days. Each sample was be assigned to either day 1 or day 2. The results were submitted to the Study Director for evaluation within the required timelines (6 weeks after receipt).

Continued on next page

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Study Information, Continued

Statistical evaluation

After data collection, outliers were detected using Cochran and Grubbs tests. The number and coded identity of statistical outlier laboratories are included in this report.

Average ascorbic acid concentrations, standard deviations of repeatability (S_r) and relative standard deviations of repeatability (RSD_r) were estimated from blind duplicates in MLT samples. The duplicates were assigned to be analyzed on the same day.

Standard deviations of reproducibility (S_R), relative standard deviations of reproducibility (RSD_R), and HORRAT values (RSD_R/predicted RSD_R) were also estimated.

Details on statistical analysis can be found in the “Appendix D: Guidelines for Collaborative Study Procedures To Validate Characteristics of a Method of Analysis” of the Official Methods of Analysis of AOAC INTERNATIONAL, 18th Edition (2005).

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Materials, Method and Laboratories

Matrices

The study took place using SPIFAN matrices, which represent most of the products in the scope of the project (Infant Formula and Adult Nutritionals made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch and aminoacids, with and without intact protein). All samples were codified.

The complete list of samples can be found in Annex A.

Homogeneity Tests

Homogeneity tests were performed by analyzing several compounds (i.e. calcium, manganese, zinc, pyridoxine and tocopheryl acetate). The testing was performed by Abbott Nutrition in one of their facilities. The report is available upon request at AOAC.

Method

The full method description is given in Annex B.

Participating laboratories

Twenty six laboratories tentatively agreed to participate in the study. The complete list can be found in Annex C. Random codes were attributed to the laboratories for identification.

Abreviations

SPIFAN: Stakeholder Panel on Infant Formula and Adult Nutritionals
MLT: Multi-Laboratory Testing
UHPLC: Ultra High Performance Liquid Chromatography
HPLC: High Performance Liquid Chromatography
UV: Ultraviolet
S_r: Standard deviation of repeatability
RSD_r: Relative standard deviation of repeatability
S_R: Standard deviation of reproducibility
RSD_R: Relative standard deviation of reproducibility

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Forms

Cover Letters

Accompanying cover letters were addressed to participants together with practice and MLT samples, they can be found in Annex D.

Sample Receipt Forms

The practice and study materials receipt forms can be found in Annex E.

Reporting Templates

Electronic templates were provided to the participants for data reporting (see Annex F). Moreover raw data (i.e. sample and standard chromatograms) were required either electronic or paper-copy. All chromatograms were expected to be clearly identified with sample identification or standard concentration.

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INSTRUCTIONS TO PARTICIPANTS

Part 1: Method set up and qualification of participants

Practice Samples Receipt

All participant laboratories received two practice samples. The "SPIFAN Practice Samples Receipt Form" (see Annex E) was to be filled and sent back to the Study Director.

Before undertaking the analysis, were instructed to keep the samples at room temperature, away from direct sunlight. Once open, the containers were to be kept at 4 °C in tightly closed containers for the duration of the study.

Analysis

The laboratories set up the method described in Annex B. It was highlighted to closely follow the method described in this document, since small adaptations might have been included with respect to the previously published method.

The laboratories were asked to analyze each of the two practice samples in duplicate (two extractions from each reconstituted sample). Any deviation, such as necessity to substitute reagents, columns, apparatus or instruments, was to be recorded and reported.

Timeline

The results on the two practice samples were to be sent to the Study Director within 6 weeks from sample reception.

Reporting

An electronic template was provided for data reporting (see Annex F).

Participating laboratories were required to report peak areas in the standard curve, as well as in the sample extracts. Furthermore, detailed information on the different masses and volumes used during sample preparation as indicated in the method, as well as raw data (chromatograms of standards and samples) were requested.

Laboratories were asked to report final results in mg ascorbic acid/100 g of "reconstituted powder" for powder samples or "as is" for liquid products, with 3 significant figures.

Laboratory Qualification

After review by the Study Director, results within a range of expected levels identified the laboratories which had the capability to run the analysis successfully. They were thus qualified for the second part of the study. The laboratories received notification within 2 weeks from data reporting.

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Part 2: Multi-Laboratory Test Participation

MLT Samples Receipt

All qualified laboratories received a second shipment containing twenty samples for the MLT. The “SPIFAN MLT Samples Receipt Form” (Annex E) was to be filled and sent back to the Study Director.

Analysis

The laboratories were asked to analyze all the samples (single extraction from each reconstituted sample) on two days (10 samples per day). Each sample was assigned to either day 1 or day 2 (see Annex A).

The samples were analyzed singly and individual values reported. It was of critical importance to analyze the samples on their assigned day. It was also highlighted to the participants that this was a study of the method, not the laboratory; the method set up in the first part of the study should be closely followed. Any deviation was to be recorded and reported.

All powdered samples were required to be analyzed on a reconstituted basis, using 25 grams of material and 200 grams of water, as stated in the method, with the exception of MLT Sample 2 (EKVJ578) and MLT Sample 6 (VJKY373). These two samples were to be reconstituted by dissolving 10 grams of powder in 90 grams of water (see Annex A for reconstitution rates).

If there were any questions, the laboratories were instructed to directly address them to the Study Director.

Timeline

The results on the MLT samples were to be provided within 6 weeks from sample reception.

Reporting

An electronic template was provided for data reporting (see Annex F).

Participating laboratories were asked to report peak areas in the standard curve, as well as in the sample extracts. Furthermore, detailed information on the different masses and volumes used during sample preparation as indicated in the method, as well as raw data (chromatograms of standards and samples) were requested.

Laboratories were required to report final results in mg ascorbic acid/100 g of “reconstituted powder” for powder samples or “as is” for liquid products, with 3 significant figures.

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RESULTS

Part 1. Method set up and qualification of participants

Participation

Twenty six laboratories initially agreed to participate to the MLT. Two laboratories dropped out during Part 1 due to issues related to availability of resources.

Method set up

All twenty four laboratories managed to easily set up the method as described in the protocol. Fourteen laboratories used UPLC conditions as described in the method, while nine laboratories used HPLC conditions as previously published (Fontannaz et al., 2006).

During the method set up, it was brought to the attention of the Study Director the need to establish a suitability test to ensure proper chromatographic separation between ascorbic acid, isoascorbic acid and orotic acid. This will be included in the final method.

Practice samples results

One of the laboratories did not manage to receive the practice samples due to Customs restrictions; the laboratory qualified using results from known samples.

After data compilation, average and standard deviation of repeatability and reproducibility were calculated. Laboratories reporting data above or below (average ± 2 * S_R) were flagged as possible outliers and informed about it. Nevertheless, they were accepted to continue since their results, although questionable, were still within (± 3 * SD_R).

Full set of data is shown in Annex G.

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Part 2. Multi Laboratory Test

Participation to MLT

From the 24 laboratories that initially reported results for practice samples, two of them did not receive the MLT samples due to Customs restrictions. The remaining 22 laboratories reported valid data.

Results

Summarized results of the full MLT set of samples can be found in the Table below. Full set of data is given in Annex H.

Requirements (SMPR 2012.012)			≤ 5 %	≤ 10 %	
Sample	**n**	**Mean**	**RSD_r** (%)	**RSD_R** (%)	**HorRat**
Adult Nutritional RTF High Fat	21	17-6	4.2	11.3	1.54
SRM 1849a	17	8.1	3.5	3.7	0.45
Child Formula Powder	19	4-9	2.6	4.5	0.51
Adult Nutritional Powder Milk Protein Based	19	6.3	1.4	3.2	0.37
Infant Formula Powder Soy Based	17	10.3	1.6	6.0	0.75
Infant Formula RTF Milk Based	19	3.5	25.6	30.6	3.27
Adult Nutritional Powder Low Fat	21	11.0	31.8	33.0	4.19
Adult Nutritional RTF High Protein	18	19-7	1.7	9.3	1.29
Infant Elemental Powder	21	34-0	7.3	11.4	1.72
Infant Formula Powder Part Hyd Soy Based	22	19.5	2.4	8.0	1.11

n = number of laboratories (after outliers removal)
RSD_r : relative standard deviation of repeatability
RSD_R : relative standard deviation of reproducibility

Two samples showed much higher variability numbers than the rest (Infant Formula RTF Milk Based and Adult Nutritional Powder Low Fat).

Ready-to-Feed products are much more sensitive to suffer from degradation during storage, being most likely the reason why the RTF Formula showed much higher than expected repeatability and reproducibility values. It was noted by some participants that, in general, liquid products were no longer homogeneous. Although most of the liquid formulas presented results within acceptable ranges it might be desirable to exclude them from future testing.

Adult Nutritional Powder Low Fat showed a problem in either homogeneity of the sample itself, storage spoilage or can mislabeling. Being unable to identify the problem, it is proposed to disregard results on this particular sample.

In addition, no significant differences could be observed between laboratories using HPLC or UHPLC conditions, provided that the suitability conditions (separation of orotic acid from ascorbic acid) were respected.

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Part 2. Multi Laboratory Test, Continued

Results (continued)

In general, the precision results (repeatability and reproducibility) are well within the limits stated in the SMPR. Repeatability ranged from 1.4 to 7.3 %, in accordance with data obtained during SLV[1], with reported RSD_r from 0.5 to 2.5 %. Meanwhile reproducibility ranged from 3.7 to 11.4 %. Finally the HorRat values are all below 2, from 0.45 to 1.54. Except for the two samples already discussed above.

[1] Internal Nestlé document RDLS-RD130018; Single Laboratory Validation – AOAC First Action Method 2012.22 Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula by UPLC-UV; E. Campos Giménez; February 14th 2013.

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CONCLUSIONS

Conclusions

The precision results (repeatability and reproducibility) obtained during the MLT showed that AOAC Official method 2012.22 comply with thre requirements set in the corresponding SMPR, and thus is fit for purpose for the analysis of ascorbic acid (vitamin C) in infant formula and adult/pediatric nutritionals.

A suitability test will be included in the final method to ensure proper separation between ascorbic acid, isoascorbic acid and orotic acid.

It is proposed to include both HPLC and UHPLC conditions in the final method to increase method applicability in all laboratories, it has been shown that the results are not different provided that suitability conditions are respected.

Two samples (Infant Formula RTF Milk Based and Adult Nutritional Powder Low Fat) were suspected to have suffered from spoilage during sample storage, it is recommended to remove them from the study.

The Study Director recommends that this method should be proposed for AOAC Final Action Official Method status.

Acknowledgments

The Study Director sincerely thanks all the participating laboratories and their staff for the interest in the method and their valuable contribution to this study

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ANNEXES

List of Annexes

Annex A: List of Materials
Annex B: Method
Annex C: List of participating laboratories
Annex D: Cover letters to participants
Annex E: Practice and MLT samples receipt forms
Annex F: Reporting templates
Annex G: Raw data practice samples
Annex H: Raw data MLT samples
Annex I: Graphical representation of data

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Annex A: List of Materials

Practice Samples

Sample	Code	Reconstitution rate
Practice Sample A	YKLP059	25 g + 200 g water
Practice Sample B	EPXW887	25 g + 200 g water

MLT Samples

Sample	Code	Day	Reconstitution rate
MLT Sample 1	VFJL091	1	As is
MLT Sample 2	EKVJ578	1	10 g + 90 g water
MLT Sample 3	GEUH577	1	25 g + 200 g water
MLT Sample 4	GLVC238	1	25 g + 200 g water
MLT Sample 5	LARU224	1	25 g + 200 g water
MLT Sample 6	VJKY373	1	10 g + 90 g water
MLT Sample 7	EPXW887	1	25 g + 200 g water
MLT Sample 8	GLBW236	1	25 g + 200 g water
MLT Sample 9	MNGN284	1	25 g + 200 g water
MLT Sample 10	YATV077	1	As is
MLT Sample 11	MOPG098	2	As is
MLT Sample 12	SNPZ056	2	25 g + 200 g water
MLT Sample 13	LKAU043	2	As is
MLT Sample 14	FHTX798	2	25 g + 200 g water
MLT Sample 15	FRZK569	2	25 g + 200 g water
MLT Sample 16	ADVZ021	2	25 g + 200 g water
MLT Sample 17	SJLQ035	2	As is
MLT Sample 18	LUJP087	2	25 g + 200 g water
MLT Sample 19	LHTK069	2	As is
MLT Sample 20	CBNJ010	2	25 g + 200 g water

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Annex B: Method

AOAC First Action Official Method 2012.22 - Vitamin C (ascorbic acid) in Infant Formula and Adult/Pediatric Nutritional Formula by UHPLC-UV

A. Principle

Ascorbic acid is extracted using trichloroacetic acid in the presence of TCEP (*Tris (2-carboxyethyl)-phosphine hydrochloride)* as a reducing agent to ensure dehydroascorbic acid is reduced to ascorbic acid before extraction. Ascorbic acid is then determined by liquid chromatography with UV detection at 265 nm. Separation takes place on a C_{18} column with sodium acetate (pH = 5.4) as eluent, combined with TCEP, and decylamine as pairing agent.

B. Apparatus

a. *Balances.-* With readability of 0.1 mg and 0.01 g
b. *pH meter.-* Metrohm 691 (Herisau, Switzerland) or equivalent
c. *LC column.-* Waters Acquity UPLC® BEH C_{18} column, 1.75 µm, 2.1 x 100 mm or equivalent
d. *LC system.-* UHPLC system equipped with a UV or photodiode array detector (e.g. Waters Acquity UPLC® or equivalent).

C. Reagents and standards

a. Acetonitrile.- HPLC grade, Merck (Geneva, Switzerland) or equivalent.
b. Ascorbic acid.- > 99 % (Sigma-Aldrich, Switzerland) or equivalent
c. Decylamine.- Aldrich (Switzerland) or equivalent
d. Phosphoric acid.- 85 %, Merck (Geneva, Switzerland) or equivalent
e. Purified water.- Millipore (Switzerland), or equivalent
f. Sodium acetate trihydrate.- Merck (Geneva, Switzerland) or equivalent.
g. Trichloroacetic acid (TCA).- Merck (Geneva, Switzerland) or equivalent
*h. Tris [2-carboxyethyl] phosphine hydrochloride (TCEP).- (*Sigma, S*witzerland) or equivalent.*

D. Preparation of solutions

a. Sodium acetate solution pH 5.4.- Into a 500 mL volumetric flask, weigh 34.0 g sodium acetate trihydrate, add 400 mL water and dissolve. Adjust pH to 5.4 with phosphoric acid 85 %. Make up to volume with water.
b. Trichloroacetic acid (TCA) 15 %.- Into a 500 mL volumetric flask, weigh 75.0 g of TCA, dissolve and make up to volume with water.
c. Tris (2-carboxyethyl)-phosphine hydrochloride (TCEP) 250 µg/mL.- Into a 500 mL volumetric flask, weigh 125 mg of TCEP, dissolve and make up to volume with water.
d. Mobile phase for LC.- Into a 250 mL flask, mix 0.4 g decylamine, 2.5 mL acetonitrile, 25 mL sodium acetate solution pH 5.4 (a.) and 205 mL of water. Adjust pH to 5.4 with phosphoric acid 85 %. Add 10 mg TCEP and mix well. *Precipitation may occur; a clear solution is obtained once the pH is adjusted.*

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Annex B: Method, Continued

E. Preparation of standards

Warning: Vitamin C is sensitive to light and oxygen, conduct operations under subdued light, or use amber glassware. Keep all solutions away from direct light.

a. *Ascorbic acid stock solution (500 µg/mL).-* Into a 25 mL amber glass volumetric flask, weigh 12.5 mg ascorbic acid. Dissolve and make up to volume with TCEP solution. This solution can be kept for 3 months if stored at 4 °C away from light.

b. *Ascorbic acid intermediate standard solution (50 µg/mL).-* Into a 10 mL amber glass volumetric flask, pipet 1.0 mL of stock solution. Make up to volume with TCEP solution. This solution can be used for 1 month if stored at 4 °C away from light.

c. *Ascorbic acid calibration standard solutions (0.5, 1.0, 2.0, 3.0, 5.0, 7.5, 10.0 µg/mL).-* Into 10 mL amber glass volumetric flasks, pipet 0.1, 0.2, 0.4, 0.6, 1.0, 1.5 and 2.0 mL of intermediate standard solution. Make up to volume with mobile phase.

F. Sample preparation

a. Reconstitute powder samples
   i. Weigh 25.0 g ± 0.1 g (m1) of powder into a brown glass 250 mL beaker. Add 10 mg TCEP
   ii. Add 200.0 g ± 0.1 g (m2) warm water (40 °C ± 5 °C). Mix well until complete dissolution making sure there are no lumps.

Note: the powder samples must be reconstituted freshly before the analysis. Discard any unused portion.

b. Extraction
   i. Weigh 2.0 g ± 0.1 g (m) of liquid or reconstituted sample into a 10 mL (V_1) amber-glass volumetric flask.
   ii. Add 4 mL of TCEP solution and 2 mL of TCA 15%.
   iii. Bring up to volume with water.
   iv. Filter solution through folded paper filter.
   v. Transfer 1.0 mL (V_2) of filtrate into a 10 mL (V_3) amber glass volumetric flask containing 1 mL acetate solution (pH 5.4) and bring up to volume with mobile phase.

Filter about 2 mL through 0.22 µm membrane into a LC vial

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Annex B: Method, Continued

G. Analysis

a. Chromatographic conditions
   i. Injection volume, 5 µL
   ii. Autosampler temperature: 10 °C
   iii. Column temperature: 25 °C
   iv. Flow rate, 0.35 mL/min
   v. Run time, 4.0 minutes
   vi. Mobile phase for LC, see (D.d)

Note: *At the end of each analytical series, rinse column with 50% acetonitrile:water for 10 minutes at 0.4 mL/min*.

b. *System suitability test*.- Equilibrate the chromatographic system for ≥ 0.5 h. Inject a working standard solution at least 6 times and check peak retention times and response (peak height or area). Inject working standard solutions on a regular basis within a series of analyses.

c. *Calibration*.- Make single injections of each of the working standard solutions at least at the beginning and the end of each analytical series. Establish the calibration curve (7-point) by plotting peak response (height or area) vs ascorbic acid concentration. Calculate the linear regression parameters. Calculate slope (S) and intercept (I).

d. *Analysis*.- Make single injections of sample solutions.

e. *Identification*.- Identify ascorbic acid peak in the chromatograms of the sample solutions by comparison with the retention time and UV spectrum of the corresponding peak in the standard solution (see example chromatograms).

H. Calculations

Calculate the concentration of vitamin C, in mg ascorbic acid/100 g expressed in product “as is” for liquid products or as “reconstituted powder” for powder samples, as follows:

$$C = \frac{(A - I) \times V_1 \times V_3 \times 100}{S \times m \times V_2 \times 1000}$$

Where:

A = response (height or area) of the ascorbic acid peak obtained for the sample solution

I = intercept of the calibration curve

S = slope of the calibration curve

m = weight of the test portion, in g (2.0 g)

V_1 = volume of the test solution (volume used to dissolve the test portion) in mL (10 mL)

V_2 = volume used in the sample dilution (1.0 mL)

V_3= volume of the final sample dilution (10 mL)

100 = conversion to 100 g basis

1000 = conversion from µg to mg.

Note: if results expressed in powder sample are needed, use the reconstitution rate to calculate (c*225 g/25 g or c*100 g/10 g).

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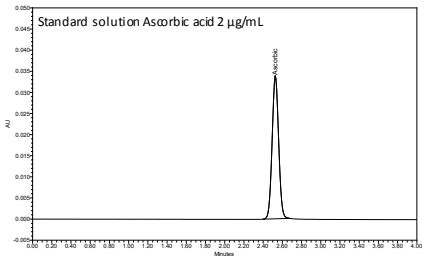
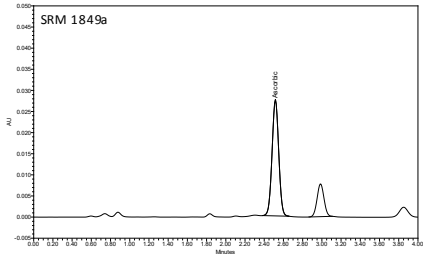
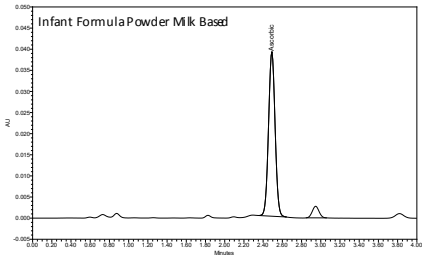
Annex B: Method, Continued

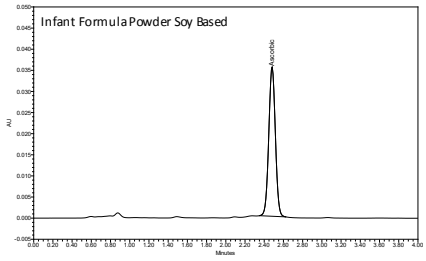
I. Example chromatograms

Infant formula powders/Certified reference material

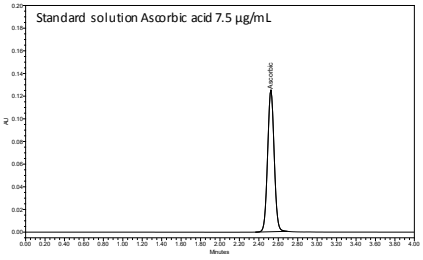


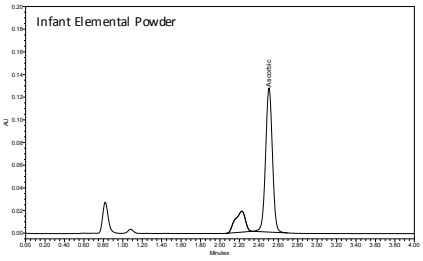


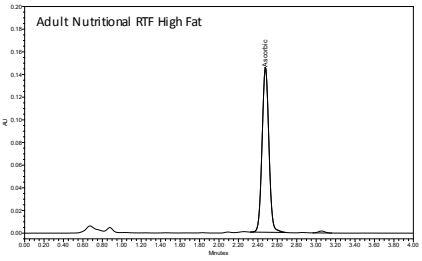




Nutritional products







References

(1) Fontannaz, P., Kilinc, T., and Heudi, O. (2006) *Food Chemistry.* **94,** 626-631.

(2) Campos-Giménez, E., Fontannaz, P., Redeuil, K., Kilinc, T. (2013) *Journal of AOAC International*, **96**, 1065-1067.

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Annex C: List of participants

John Austad Covance 3301 Kinsman Blvd. Madison, WI 53704 USA	Soo Hui Chooi Nestlé Quality Assurance Center Shah Alam Nestlé Manufacturing (M) Sdn Bhd Jalan Playar 15/1, P.O. Box 7010 40700 Shah Alam, Selangor Darul Ehsan Malaysia
WU Bolong Chinese Academy of Inspection and Quarantine A3, Gao Bei Dian North Road Chao Yang District, Beijing People Republic of China	Joanne Chia ALS Technichem 14 Little Road #07-01 Tropical Ind Bldg Singapore
Karen Schimpf Abbott Laboratories 3300 Stelzer Road Columbus, OH 43219 USA	Sabine Meng Jensen Eurofins Steins Laboratorium A/S Ladelundvej 85 DK-6600 Vejen Denmark
Shankar Bhattacharyya Certified Laboratories, Inc 200 Express Street Plainview, NY USA	David Woollard PhD Hill laboratories 1 Clyde Street, Private Bag 3205 Hamilton 3240 New Zealand
Estella Kneeteman Instituto Nacional de Tecnología Industrial Centro Agroalimentos – Edificio 40 Avenida General Paz 5445 1650 San Martín Provincia de Buenos Aires Argentina	Dr. Matthias Reutter LUFA-ITL GmbH Dr. Hell Strasse 6 D 24107 Kiel Germany
George Joseph Asure Quality 131 Boundary Road Auckland 1140 New Zealand	Ton Noorloos Nestlé Quality Assurance Center Nunspeet Laan 106 8071 JC Nunspeet The Netherlands
Michael Hoard Arizona Nutritional Supplements 210 S Beck Ave Chandler, AZ 85226 USA	Scott Cristiansen Perrigo Nutritionals 147 Industrial Park Road Georgia, VT 05468 USA

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Annex C: List of participants, Continued

Isabelle Malaviole Aquanal 151 bis avenue Jean Jaurès 33600 Pessac France	Denis Piot Premium Lab s.a. Ctra. Del Prat 9-11 08830 Sant Boi de Llobregat (Barcelona) Spain
Dalal Aoude –Werner Aérial Rue Laurent Fries- B.P. 40443 F-67412 Illkirch CEDEX France	Wenjuan Elaine Jobgen Eurofins Scientific Inc 2200 Ritthenhouse St. Suite 150 Des Moines, IA 50321 USA
Pascal González Silliker Ibérica C/ Transversal 6 n° 19 08040 Barcelona Spain	Martijn Vermeulen, PhD TNO Triskelion bv Utrechtseweg 45 3704 HE Zeist The Netherlands
Olivia Hernández Mead Johnson & company Carretera Panamérica Km 1573 Entronque Las Varas Ciudad Delicias, Chihuahua 3300 México	Greg Jaudzems Nestlé Quality Assurance Center Dublin 6625 Eiterman Rd Dublin, OH 43016-8727 USA
Guy Weerasekera Mead Johnson Nutrition Y6, 2400 W Lloyd Expy Evansville, IN 47721 USA	Cai Weihong Guangzhou Quality Supervision and testing Institute Room 301, N° 38, Baqi 2nd Road Guangzhou, 510110 People Republic of China

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Annex D: Cover letters to participants

Cover letter: practice samples

Nestlé Research Center
Lausanne

VERS-CHEZ-LES-BLANC
P.O. BOX 44
1000 LAUSANNE 26 (SWITZERLAND)

TEL. +41 (0)21 785 81 11
TELEFAX +41 (0)21 785 89 25

Department Analytical Sciences
Direct Phone +41 21 785 94 29
Direct Fax +41 21 785 85 53
E-mail esther.campos-gimenez@rdls.nestle.com

To : «Contact_person»
«Laboratory»
«Address»
«City»
«Country»

NRC/AS EsC/ July 30th ,2014
E. Campos Giménez

Dear participant,

Thank you for your participation in the Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Multi-Laboratory Testing (MLT) for the validation of the AOAC Official Method **2012.22** "Vitamin C (ascorbic acid) in Infant Formula and Adult/Pediatric Nutritional Formula by UHPLC-UV".

We would appreciate it if you could ensure that the contents of the parcel has not been damaged during transit (see list of contents below), and complete the enclosed "SPIFAN Practice Samples Receipt Form" and fax or email to Esther Campos Giménez at +41 21 785-8553 or esther.campos-gimenez@rdls.nestle.com.

The parcel contains the following items:

a) A "SPIFAN Practice Samples Receipt Form" form

b) 2 units of practice samples

Please closely follow the instructions sent to you electronically for the analysis of these practice samples and data reporting. If you have any questions, do not hesitate to contact the Study Director for assistance.

Your participation in this Multi-Laboratory Testing study is greatly appreciated.

Yours sincerely,

Sunil Kochhar
Analytical Sciences Pillar Head
NESTEC LTD

Esther Campos Giménez
Study Director
NESTEC LTD

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Annex D: Cover letters to participants, Continued

Cover letter: MLT samples

Nestlé Research Center
Lausanne

VERS-CHEZ-LES-BLANC
P.O. BOX 44
1000 LAUSANNE 26 (SWITZERLAND)

TEL. +41 (0)21 785 81 11
TELEFAX +41 (0)21 785 89 25

Department Analytical Sciences
Direct Phone +41 21 785 94 29
Direct Fax +41 21 785 85 53
E-mail esther.campos-gimenez@rdls.nestle.com

To : «Contact_person»
«Laboratory»
«Address»
«City»
«Country»

NRC/AS EsC/ September xx th ,2014
E. Campos Giménez

Dear participant,

Thank you for your participation in the Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Multi-Laboratory Testing (MLT) for the validation of the AOAC Official Method **2012.22** "Vitamin C (ascorbic acid) in Infant Formula and Adult/Pediatric Nutritional Formula by UHPLC-UV".

We would appreciate if you could ensure that the contents of the parcel has not been damaged during transit (see list of contents below), and complete the enclosed "SPIFAN MLT Samples Receipt Form" and fax or email to Esther Campos Giménez at +41 21 785-8553 or esther.campos-gimenez@rdls.nestle.com.

The parcel contains the following items:

a) A "SPIFAN MLT Samples Receipt Form" form

b) MLT samples (see Samples Receipt Form for details)

Please closely follow the instructions sent to you electronically for analysis of these MLT samples and data reporting. If you have any questions, do not hesitate to contact the Study Director for assistance.

Your participation in this Multi-Laboratory Testing study is greatly appreciated.

Yours sincerely,

Sunil Kochhar
Analytical Sciences Pillar Head
NESTEC LTD

Esther Campos Giménez
Study Director
NESTEC LTD

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Annex E: Receipt Forms

Practice Samples Receipt Form

AOAC 2012.22 Multi-Laboratory Study - Practice Samples Receipt Form

Participant:

«Contact_person»
«Laboratory»
«Address»
«City»
«Country»

Please ensure the items listed below have been received undamaged, insert date of receipt, and circle the relevant statement:

Contents of parcel

- Practice Sample A: Code YKLP059
- Practice Sample B: Code EPXW887

Date of Receipt	
All items have been received undamaged	Yes/No
Items are missing/damaged	Yes/No
List missing/damaged items needing replacement, if a whole series is not needed:	
I require an additional series of samples	Yes/No

Please fax or email the completed form to:

Esther Campos Giménez
Fax: +41 21 785-8553
esther.campos-gimenez@rdls.nestle.com.

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Annex E: Receipt Forms, Continued

MLT Samples Receipt Form

AOAC 2012.22 Multi-Laboratory Study - MLT Samples Receipt Form

Participant:
«Contact_person»
«Laboratory»
«Address»
«City»
«Country»

Please ensure the items listed below have been received undamaged, insert date of receipt, and circle the relevant statement:

Contents of parcel

	Code	Number of Containers	Day
MLT Sample 1	VFJL091	2	1
MLT Sample 2	EKVJ578	2	1
MLT Sample 3	GEUH577	1	1
MLT Sample 4	GLVC238	1	1
MLT Sample 5	LARU224	1	1
MLT Sample 6	VJKY373	2	1
MLT Sample 7	EPXW887	1	1
MLT Sample 8	GLBW236	1	1
MLT Sample 9	MNGN284	1	1
MLT Sample 10	YATV077	2	1
MLT Sample 11	MOPG098	2	2
MLT Sample 12	SNPZ056	1	2
MLT Sample 13	LKAU043	2	2
MLT Sample 14	FHTX798	1	2
MLT Sample 15	FRZK569	1	2
MLT Sample 16	ADVZ021	1	2
MLT Sample 17	SJLQ035	2	2
MLT Sample 18	LUJP087	1	2
MLT Sample 19	LHTK069	2	2
MLT Sample 20	CBNJ010	1	2

Date of Receipt	
All items have been received undamaged	Yes/No
Items are missing/damaged	Yes/No
List missing/damaged items needing replacement, if a whole set is not needed:	
I require an additional set of samples	Yes/No

Please fax or email the completed form to:

Esther Campos Giménez
Fax: +41 21 785-8553
esther.campos-gimenez@rdls.nestle.com

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Annex F: Reporting templates

Practice samples

Vitamin C (ascorbic acid) in Infant Formula and Adult/Pediatric Nutritional Formula by UHPLC-UV
AOAC First Action 2012.22: Multi-Laboratory Study

Name:	
Compagny/Institution:	
Country:	

Calibration curve

		Peak Area			
	Concentration (ng/mL)	Ascorbic acid		Regression parameters	
Calib level 1				Slope:	
Calib level 2				Intercept:	
Calib level 3					
Calib level 4					
Calib level 5					
Calib level 6					
Calib level 7					

Vitamin C (ascorbic acid) in Infant Formula and Adult/Pediatric Nutritional Formula by UHPLC-UV
AOAC First Action 2012.22: Multi-Laboratory Study

Name:	
Laboratory:	
Country:	

		Sample reconstitution		Extraction		Practice samples results			
		Sample (g)	Water (g)	Mass (g)		Peak Area		Results (mg/100 g)	
	Code	m1	m2	m		Ascorbic acid		Ascorbic acid	
Practice Sample A	YKLP059								
Practice Sample B	EPXW887								

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Annex F: Reporting templates, Continued

MLT samples

Vitamin C (ascorbic acid) in Infant Formula and Adult/Pediatric Nutritional Formula by UHPLC-UV
AOAC First Action 2012.22: Multi-Laboratory Study

Name:	
Compagny/Institution:	
Country:	

Calibration curve DAY 1

		Peak Area			
	Concentration (ng/mL)	Ascorbic acid		Regression parameters	
Calib level 1				Slope:	
Calib level 2				Intercept:	
Calib level 3					
Calib level 4					
Calib level 5					
Calib level 6					
Calib level 7					

Calibration curve DAY 2

		Peak Area			
	Concentration (ng/mL)	Ascorbic acid		Regression parameters	
Calib level 1				Slope:	
Calib level 2				Intercept:	
Calib level 3					
Calib level 4					
Calib level 5					
Calib level 6					
Calib level 7					

Vitamin C (ascorbic acid) in Infant Formula and Adult/Pediatric Nutritional Formula by UHPLC-UV
AOAC First Action 2012.22: Multi-Laboratory Study

Name:	
Laboratory:	
Country:	

			Sample reconstitution		Extraction	Practice samples results	
			Sample (g)	Water (g)	Mass (g)	Peak Area	Results (mg/100 g)
		Code	m1	m2	m	Ascorbic acid	Ascorbic acid
Day 1	MLT Sample 1	VFJL091	not applicable	not applicable			
	MLT Sample 2	EKVJ578					
	MLT Sample 3	GEUH577					
	MLT Sample 4	GLVC238					
	MLT Sample 5	LARU224					
	MLT Sample 6	VJKY373					
	MLT Sample 7	EPXW887					
	MLT Sample 8	GLBW236					
	MLT Sample 9	MNGN284					
	MLT Sample 10	YATV077	not applicable	not applicable			
Day 2	MLT Sample 11	MOPG098	not applicable	not applicable			
	MLT Sample 12	SNPZ056					
	MLT Sample 13	LKAU043	not applicable	not applicable			
	MLT Sample 14	FHTX798					
	MLT Sample 15	FRZK569					
	MLT Sample 16	ADVZ021					
	MLT Sample 17	SJLQ035	not applicable	not applicable			
	MLT Sample 18	LUJP087					
	MLT Sample 19	LHTK069	not applicable	not applicable			
	MLT Sample 20	CBNJ010					

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Annex G: Raw data practice samples

Raw data practice samples

Laboratory Code	Practice sample 1: code YKLP059				Practice sample 2: code EPXW887			
			Avg	CV			Avg	CV
1	12.0	11.7	11.8	2.4%	10.3	10.3	10.3	0.2%
2	11.0	10.9	11.0	0.9%	9.8	9.7	9.7	0.9%
3	11.6	11.2	11.4	3.5%	10.0	10.3	10.2	3.0%
4	11.4	11.0	11.2	3.7%	9.4	9.9	9.7	5.6%
5	10.6	10.6	10.6	0.1%	9.5	9.3	9.4	1.3%
6	11.2	11.4	11.3	1.5%	10.6	11.0	10.8	3.7%
7	12.7	12.8	12.8	0.8%	10.8	10.7	10.8	0.9%
8	14.5	14.5	14.5	0.4%	13.0	13.1	13.1	0.5%
9	11.6	11.3	11.5	2.6%	10.9	10.6	10.8	2.8%
10	12.2	12.1	12.1	1.2%	10.7	10.9	10.8	2.5%
11	12.6	12.6	12.6	0.1%	11.3	11.3	11.3	0.2%
12	12.5	12.5	12.5	0.5%	10.8	10.8	10.765	0.3%
13	10.3	10.2	10.2	1.0%	8.2	8.1	8.2	0.9%
14	11.2	11.1	11.2	0.7%	9.0	8.9	8.9	0.3%
15	14.7	14.4	14.5	2.7%	12.2	12.3	12.3	0.9%
16	13.4	13.3	13.4	0.7%	12.1	12.4	12.3	2.4%
17	12.3	12.2	12.2	0.8%	11.0	11.1	11.0	1.1%
18	12.0	11.8	11.9	1.7%	11.0	10.9	11.0	0.9%
19	11.4	11.2	11.3	1.5%	10.4	10.3	10.3	0.8%
20	Not analysed							
21	11.4	11.3	11.4	0.9%	9.0	9.1	9.1	0.4%
22		11.3				10.6		
23	11.5	11.6	11.5	0.5%	10.5	10.4	10.5	0.7%
24	11.5	12.2	11.9	5.7%	10.0	10.4	10.2	3.6%

Average	**11.9**
SD_b	1.11
S_r	0.167
RSD_r	**1.4%**
S_R	1.115
RSD_R	**9.3%**

Average	**10.5**
SD_b	1.14
S_r	0.149
RSD_r	**1.4%**
S_R	1.142
RSD_R	**9.6%**

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Multi Laboratory Test – AOAC First Action Method 2012.22 Ascorbic Acid (Vitamin C) in Infant Formula and Adult/Pediatric Nutritionals.
RDLS-RD150006 E. Campos Giménez (NRC, Lausanne)

Annex H: Raw data MLT samples

	MLT sample 1	MLT sample 10			MLT sample 2	MLT sample 6			MLT sample 3	MLT sample 8			MLT sample 4	MLT sample 5			MLT sample 7	MLT sample 9		
	Adult Nutritional RTF High Fat				SRM 1849 a				Child Formula Powder				Protein Based				Based			
	VFJL091	YATV077			EKVJ578	VJKY373			GEUH577	GLBW236			GLVC238	LARU224			EPXW887	MNGN284		
			Avg	CV			Avg	CV			Avg	CV			Avg	CV			Avg	CV
1	14.3	13.7	14.0	4%	8.3	8.2	8.3	1%	5.1	5.1	5.1	1%	6.3	6.3	6.3	1%	4.0	10.4	7.2	88%
2	16.8	15.9	16.4	6%	8.1	8.0	8.1	2%	4.9	4.9	4.9	0%	6.5	6.2	6.3	4%	9.8	9.9	9.9	1%
3	16.5	15.9	16.2	4%	7.8	8.0	7.9	3%	4.7	4.8	4.8	2%	6.4	6.3	6.3	0%	9.7	10.1	9.9	4%
4	17.3	16.0	16.6	8%	7.9	7.7	7.8	3%	4.6	4.5	4.6	1%	6.1	5.9	6.0	4%	10.1	10.0	10.1	1%
5	19.0	17.2	18.1	10%	8.2	8.0	8.1	2%	5.1	4.6	4.8	10%	6.3	6.3	6.3	0%	10.3	10.3	10.3	0%
6	18.8	19.1	19.0	2%	8.5	7.5	8.0	13%	4.9	5.2	5.0	7%	6.3	6.2	6.2	2%	9.6	9.9	9.8	3%
7	17.8	17.4	17.6	2%	7.9	8.2	8.1	4%	4.9	4.6	4.7	6%	6.5	6.4	6.4	1%	10.0	9.9	10.0	1%
8	19.8	19.6	19.7	1%	9.5	9.3	9.4	2%	5.0	5.2	5.1	3%	6.8	6.7	6.7	2%	10.3	6.8	8.6	41%
9	17.5	19.5	18.5	11%	7.9	8.7	8.3	9%	4.8	5.0	4.9	4%	6.5	6.5	6.5	0%	11.0	11.1	11.1	1%
10	18.6	19.1	18.8	3%	8.3	8.1	8.2	3%	4.8	4.8	4.8	2%	6.4	6.6	6.5	3%	10.8	10.2	10.5	6%
11	19.5	19.3	19.4	1%	9.0	9.3	9.1	3%	5.2	5.3	5.2	1%	6.9	7.1	7.0	3%	11.7	11.8	11.7	1%
12	12.8	12.8	12.8	0%	8.4	8.1	8.2	3%	4.5	4.6	4.6	3%	6.1	6.0	6.1	1%	10.1	10.0	10.1	1%
13	16.8	16.6	16.7	1%	7.9	7.7	7.8	3%	5.1	5.0	5.0	3%	6.2	6.4	6.3	2%	10.5	10.4	10.5	1%
14	15.1	16.7	15.9	10%	7.8	7.7	7.7	1%	4.8	4.9	4.8	2%	6.3	6.4	6.4	1%	9.2	9.1	9.1	1%
15	20.4	21.4	20.9	5%	8.3	8.5	8.4	3%	5.3	6.0	5.7	12%	7.3	7.4	7.3	1%	11.7	10.2	11.0	14%
16	19.4	18.4	18.9	5%	8.5	8.2	8.3	3%	5.1	5.1	5.1	1%	6.7	6.7	6.7	0%	10.9	11.0	11.0	1%
17	not analysed				8.7	8.0	8.3	9%	3.8	3.6	3.7	6%	6.3	6.1	6.2	3%	7.8	8.4	8.1	7%
18	19.1	19.5	19.3	2%	8.5	8.4	8.4	1%	5.3	5.2	5.2	3%	6.1	6.0	6.0	2%	10.7	10.5	10.6	2%
19	17.2	18.4	17.8	7%	6.9	7.7	7.3	11%	4.9	5.0	5.0	1%	6.4	6.4	6.4	1%	10.3	10.7	10.5	3%
20	19.1	18.2	18.6	5%	10.1	10.0	10.1	1%	5.8	5.8	5.8	0%	7.1	7.3	7.2	3%	9.3	11.4	10.4	21%
21	16.0	17.9	17.0	11%	7.3	not analysed	7.3		4.7	4.9	4.8	4%	6.2	6.2	6.2	0%	9.7	9.7	9.7	0%
22	16.4	17.2	16.8	5%	8.1	8.0	8.1	1%	5.1	5.1	5.1	0%	6.3	6.2	6.2	1%	10.6	10.6	10.6	0%

	MLT sample 11	MLT sample 17			MLT sample 12	MLT sample 20			MLT sample 13	MLT sample 19			MLT sample 14	MLT sample 15			MLT sample 16	MLT sample 18		
	Infant Formula RTF Milk Based				Adult Nutritional Powder Low Fat				Adult Nutritional RTF High Protein				Infant Elemental Powder				Infant Formula Powder Partially Hydrolysed Soy Based			
	MOPG098	SJLQ035			SNPZ056	CBNJ010			LKAU043	LHTK069			FHTX798	FRZK569			ADVZ021	LUJP087		
			Avg	CV			Avg	CV			Avg	CV			Avg	CV			Avg	CV
1	2.5	3.0	2.8	19%	12.6	5.1	8.8	85%	21.8	21.4	21.6	2%	32.8	28.0	30.4	16%	19.5	20.4	20.0	4%
2	3.7	4.5	4.1	21%	9.1	5.3	7.2	53%	20.2	19.9	20.1	1%	28.4	31.4	29.9	10%	19.7	19.6	19.7	1%
3	2.3	2.3	2.3	1%	12.4	11.2	11.8	10%	18.7	18.8	18.7	1%	31.9	27.7	29.8	14%	19.5	19.0	19.2	3%
4	3.1	3.1	3.1	0%	8.5	13.3	10.9	44%	19.8	20.5	20.2	3%	35.8	35.6	35.7	1%	18.5	18.8	18.7	1%
5	4.5	3.1	3.8	37%	8.6	13.0	10.8	40%	19.9	19.1	19.5	4%	28.7	33.7	31.2	16%	19.1	19.4	19.3	1%
6	4.9	4.0	4.4	19%	15.8	7.8	11.8	68%	20.1	20.1	20.1	0%	36.0	42.4	39.2	16%	19.5	20.0	19.7	3%
7	6.2	4.0	3.0	73%	12.9	4.8	8.8	91%	19.8	19.6	19.7	1%	30.6	35.2	32.9	14%	19.0	19.4	19.2	2%
8	2.4	4.3	3.3	56%	9.0	13.2	11.1	38%	20.9	20.2	20.6	3%	32.9	32.8	32.8	0%	16.2	17.8	17.0	10%
9	3.4	3.3	3.4	1%	14.9	14.7	14.8	1%	16.5	20.7	18.6	23%	36.3	40.4	38.4	11%	21.7	21.1	21.4	3%
10	2.5	3.0	2.8	19%	13.4	13.3	13.3	1%	20.9	20.1	20.5	4%	36.0	35.5	35.7	1%	19.7	19.5	19.6	1%
11	5.1	3.3	4.2	42%	14.3	14.5	14.4	2%	21.4	20.7	21.0	3%	37.7	34.4	36.1	9%	20.6	20.4	20.5	1%
12	2.5	2.4	2.4	6%	4.9	4.9	4.9	0%	15.9	15.7	15.8	1%	27.1	32.8	30.0	19%	18.3	18.5	18.4	1%
13	5.4	2.7	4.1	65%	not analysed				18.3	18.4	18.4	1%	not analysed				19.2	19.7	19.5	3%
14	3.5	1.8	2.6	62%	14.9	15.9	15.4	6%	16.3	16.8	16.6	3%	32.1	33.7	32.9	5%	17.8	18.8	18.3	5%
15	7.2	5.1	6.2	34%	14.8	11.9	13.4	21%	24.0	23.2	23.6	3%	41.1	40.6	40.8	1%	22.3	24.0	23.1	7%
16	2.9	4.5	3.7	45%	13.8	5.8	9.8	81%	20.4	20.3	20.4	0%	36.8	32.0	34.4	14%	20.7	20.6	20.7	0%
17	not analysed				12.9	13.0	12.9		not analysed				37.6	36.2	36.9	4%	15.9	16.4	16.1	3%
18	3.0	2.9	3.0	4%	9.3	14.0	11.7	40%	21.9	18.9	20.4	15%	36.9	37.5	37.2	2%	21.4	21.2	21.3	1%
19	4.5	3.6	4.0	23%	12.9	3.1	8.0	122%	20.5	18.2	19.3	12%	34.1	31.7	32.9	7%	20.1	19.9	20.0	1%
20	2.2	2.3	2.2	7%	13.0	7.2	10.1	57%	19.4	19.4	19.4	0%	36.6	32.7	34.7	11%	21.0	20.8	20.9	1%
21	<LoQ	2.7	2.7		11.3	12.0	11.7	6%	17.5	17.6	17.6	1%	25.8	29.3	27.6	13%	18.5	18.6	18.6	1%
22	5.5	4.2	4.9	27%	11.0	6.2	8.6	56%	20.6	20.5	20.6	0%	33.8	35.1	34.5	4%	18.3	17.9	18.1	2%

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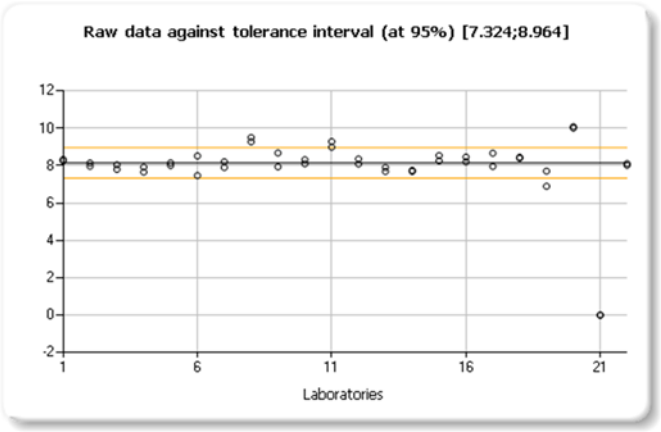
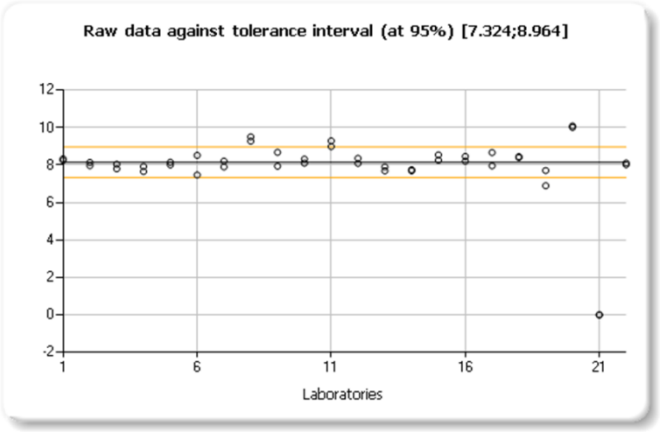
Annex I: Graphical representation of data

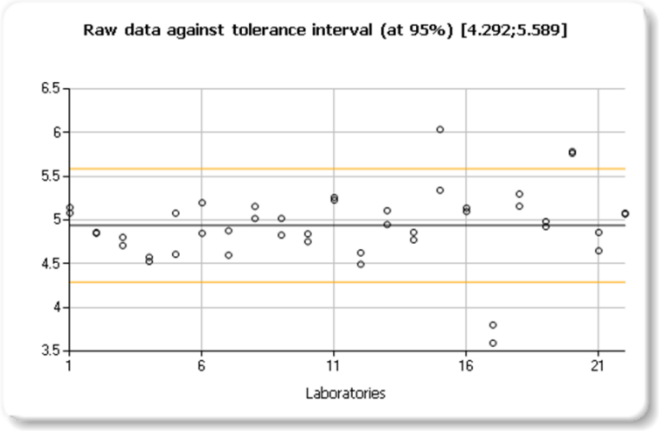
Adult Nutritional High Fat



SRM 1849 a



Child Formula Powder



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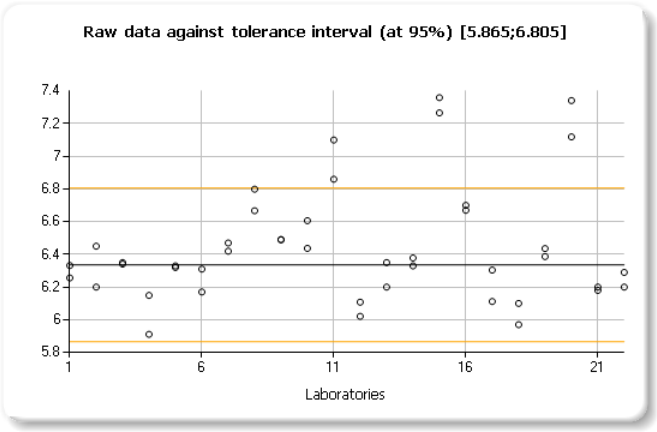
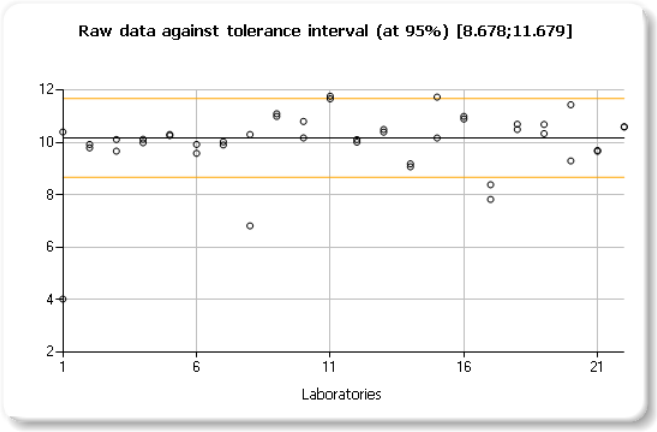
Annex I: Graphical representation of data, Continued

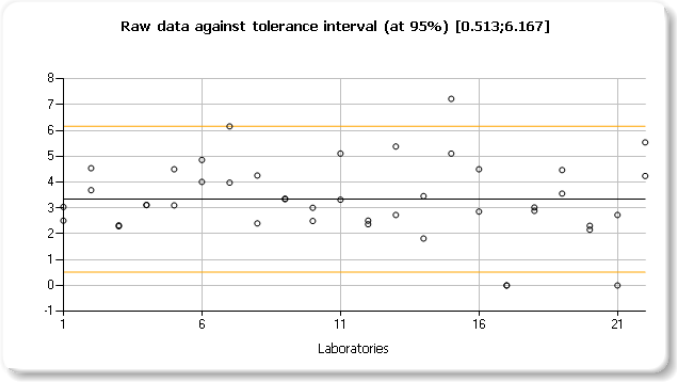
Adult Nutritional Powder Milk Protein Based



Infant Formula Powder Soy Based



Infant Formula RTF Milk Based



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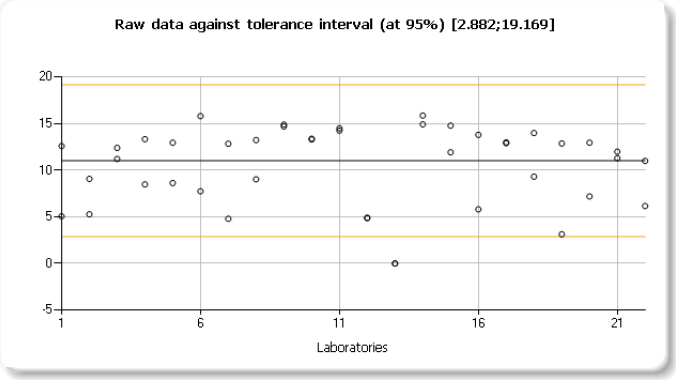
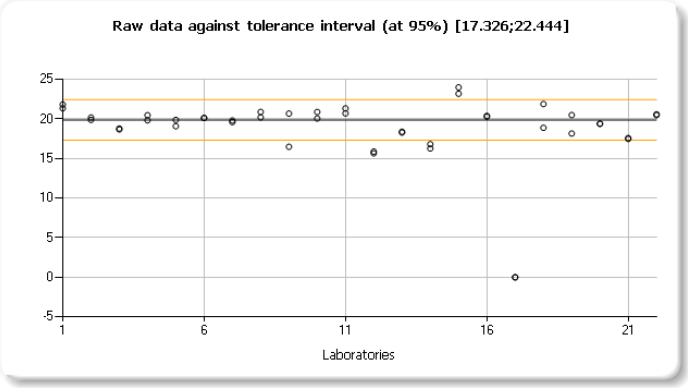
Annex I: Graphical representation of data, Continued

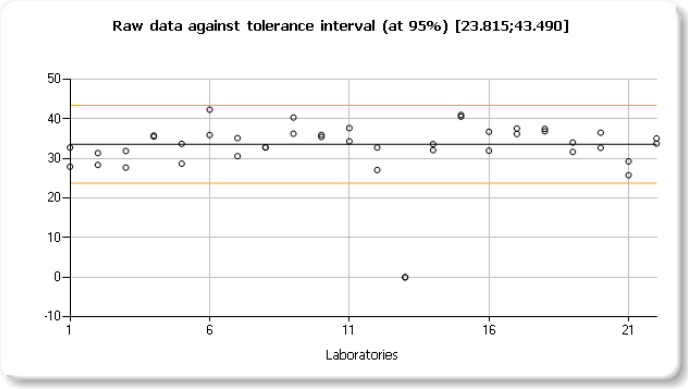
Adult Nutritional Powder Low Fat



Adult Nutritional RTF High Protein



Infant Elemental Powder



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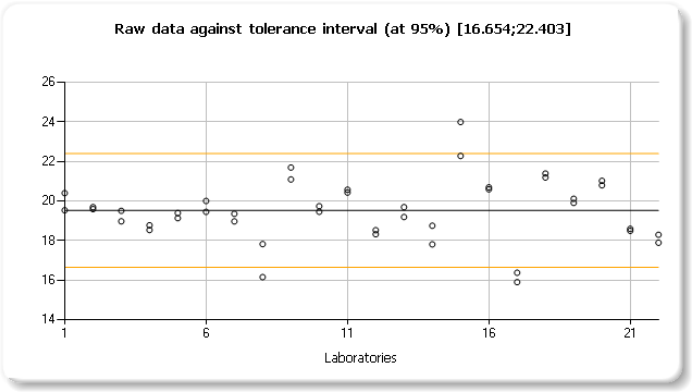
Annex I: Graphical representation of data, Continued

Infant Formula Powder Partially Hydrolysed Soy Based



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AOAC INTERNATIONAL

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Meeting held at

Hilton Washington DC North/Gaithersburg

Wednesday, March 18, 2015 - 8:30am (Eastern US)

REPORT OF THE EXPERT REVIEW PANEL (ERP) PROCEEDINGS

Expert Review Panel Members (in attendance):

Darryl Sullivan	***Covance Labs*** *(Chair)*
John Austad	Covance Labs
Esther Campos-Gimenez/Adrienne McMahon	Nestlé/Wyeth Nutrition (formerly Pfizer)
Scott Christiansen	Perrigo/PBM Nutritionals
Jon DeVries	General Mills/Medallion Labs
Harvey Indyk	Fonterra
Estela Kneeteman	INTI
Maria Ofitserova	Pickering Labs, Inc.
Melissa Phillips/Kate Rimmer	NIST
Shay Phillips	Mead Johnson Nutrition
Günther Raffler	CLF-Eurofins
Karen Schimpf	Abbott Nutrition
Jinchuan Yang	Waters Corp.

Expert Review Panel Members (unable to attend):

Sneh Bhandari	Mérieux NutriSciences & OMB
Sarwar Gilani	Consultant
Brendon Gill	Fonterra
Don Gilliland	Abbott Nutrition
Min Huang	Frontage Labs, Inc.

AOAC Staff Includes:

Delia Boyd
E. James Bradford
Scott Coates
Arlene Fox
Deborah McKenzie
Alicia Meiklejohn
Tien Milor
Bob Rathbone
Gar Riegler

Observers:

Martin Alewijn, *RIKILT*
Sean Austin, *Nestlé Research Center*
Brad Barrett, *Sciex*
Anne Bienvenue, *U.S. Dairy Export Council*
Christopher Blake, *Nestlé Research Center*
Bob Clifford, *Shimadzu*
Hans Cruijsen, *FrieslandCampina Domo*
Marcel deVreeze, *NEN/ISO*
Jaap Evers, *IDF Rep. (Fonterra Co-op.)*
Jennifer Fruth, *Mead Johnson Nutrition*
Christophe Fuerer, *Nestlé Research Center*
Jim Griffiths, *CRN*
Jim Harnly, *USDA*
Phillip Haselberger, *Abbott Nutrition*
Steve Holroyd, *IDF Rep. (Fonterra Co-op.)*
Gregory Hostetler, *Perrigo/PBM Nutritionals*
Harvey Indyk, *Fonterra Co-op.*
Wesley Jacobs, *Abbott Nutrition*
Greg Jaudzems, *Nestlé*
George Joseph, *AsureQuality*
Bert Klarenbeek, *FrieslandCampina Domo*
Erik Konings, *Nestlé Research Center*
Frederic Martin, *Nestlé Research Center*
Josh Messerly, *Eurofins*
Paul Milne, *Keurig Green Mountain Inc.*
Deepali Mohindra, *Thermo Fisher Scientific*
Matt Noestheder, *Sciex*
Mike Nygaard, *U.S. Dairy Export Council*
Lawrence Pacquette, *Abbott Nutrition*
Bert Popping, *Mérieux NutriSciences*
Robert Ragan, *Abbott Nutrition*
Robert Rankin, *INCA*
Rick Reba, *Nestlé USA, Inc.*
Murali Reddy, *Abbott Nutrition*
Lars Reimann, *Eurofins*
Kate Rimmer, *NIST*
Shauna Roman, *Reckitt Benckiser (RB)*
Joe Romano, *Waters Corporation*
Steve Royce, *Agilent Technologies, Inc.*
Louis Salvati, *Abbott Nutrition*
Dan Schmitz, *Abbott Nutrition*
Olga Shimelis, *SUPELCO/Sigma-Aldrich*
Brian Shira, *Mead Johnson Nutrition*
Matthew Sliva, *Perrigo/PBM Nutritionals*
Karla Steele, *Mead Johnson Nutrition*
John Szpylka, *Merieux NutriSciences*
Joseph J. Thompson, *Abbott Nutrition*
Linda Thompson, *Abbott Nutrition*
Melissa Thompson, *Covance Laboratories*
Marina Torres Rodriguez, *LATU*
Wil Van Loon, *FrieslandCampina*
Martijn Vermeulen, *TNO*
Wayne Wargo, *Abbott Nutrition*
Laura Wood, *NIST*
David Woollard, *Hill Laboratories*
Wayne Wolf, *USDA (Retired)*
Jason Wubben, *Archer Daniels Midland Co.*
Jinchuan Yang, *Waters Corporation*
Joyce Zhu, *Jamieson Lab*
Richard Zywicki, *Covance Laboratories*

I. WELCOME AND INTRODUCTIONS

Darryl Sullivan welcomed all participants to the ERP meeting and introduced the ERP members.

II. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FIRST ACTION *OFFICIAL METHOD*^{SM} STATUS – AOAC SPIFAN I

For each method, the ERP/Working Group Co-Chairs discussed methods submitted.

- **Folate – *Chair:*** Erik Konings (Nestlé)

- **Carnitine – *Co-Chairs:*** John Austad (Covance) & Günther Raffler (CLF-Eurofins)

  Choline – *Co-Chairs:* Sneh Bhandari (Silliker) & Nick Cellar (Abbott)

Method	Method Title	Reviewer(s)	Vote	Comments
Folate	*AOAC Official Method 2011.06 (Fol-22) - Validation of A LC-MS/MS Method for Folate Analysis in Infant Formula and Adult Nutritional Samples*	Adrienne McMahon	Adrienne McMahon recommended method proceed in AOAC SPIFAN process (DRM) *Method retains First Action *Official Method*^{SM} status	▪ Method meets SMPR ▪ Detects the poly glutamate ▪ Process is long ▪ SLV data is available ▪ Folate reported as total folate ▪ Needs % of folate ▪ Standard corrective for water; 8% ▪ Accuracy that doesn't have methyl; non folic ▪ 5 methyl being different
Carnitine	*Carn-07 - Analysis of Free and Total Carnitine and Choline in Infant Formula and Adult Nutritionals*	Günther Raffler Sneh Bhandari (by evaluation form)	Günther Raffler moved & Melissa Phillips second *Motion: recommended method to First Action *Official Method*^{SM} status & proceed in AOAC SPIFAN process (DRM) **Yes- 11/ No-0 /Abstain-1**	▪ Recovery rates are good ▪ SLV report complete ▪ Meets requirements

#The ERP has requested combining the two (2) methods (Chlor-02 & Chlor-04)

III. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FIRST ACTION *OFFICIAL METHOD*^{SM} STATUS – AOAC SPIFAN II

For each method, the ERP/Working Group Co-Chairs discussed methods submitted. Five (5) methods received First Action *Official Method*^{SM} status with two (2) retaining the original status for a total of seven (7).

Method	Method Title	Reviewer(s)	Vote	Comments
Amino Acid	*Amino-01 - Determination of amino acids in infant and adult/pediatric nutritional formula by UHPLC/UV*	Maria Ofitserova Shay Phillips	Method not recommended for First Action at this time	▪ Method is well written; sound methodology ▪ Study author should use all AOAC SPIFAN samples and provided the information ▪ Analytical range; LOQ ▪ Lysteine has limited range ▪ Title change – total amino acid ▪ Does not capture tryptophan ▪ Proprietary technique ▪ Recovery over 110% ▪ Method has potential; needs optimization
Biotin	*Bio-01 - An inter-laboratory study to extend the scope of the CEN biotin method by HPLC with post-column derivatization and fluorimetric detection*	Estela Kneeteman Scott Christiansen	Method not recommended for First Action at this time	▪ Five (5) different samples used ○ Infant milk powder ▪ Simple method ▪ No LOQ data or recovery ▪ Need more information on the method
	Bio-02 - Determination of Biotin by High Performance Liquid Chromatography coupled with EASI-EXTRACT Biotin Immunoaffinity column cleanup extraction	Scott Christiansen Karen Schimpf	Method not recommended for First Action at this time	▪ Semi proprietary method ▪ No chromatography ▪ Two (2) samples used ▪ Free or total? ▪ Use NIST 1849a as reference ▪ Not enough SLV data ▪ Columns from two (2) different manufacturers
	Boi-03 - Simultaneous Determination of Seven Water Soluble Vitamins in Products by LC-MS/MS	Adrienne McMahon Estela Kneeteman	Method not recommended for First Action at this time	▪ Lower LOQ ▪ Needs full recovery ▪ Needs more AOAC SPIFAN samples ▪ Bound forms need to be captured
Chloride	*Chlor-01 - AOAC Official Method 986.26 Chloride in Milk-Based Infant Formula. Final action 1988.*	Brendon Gill Karen Schimpf Bill Mindak	Method not recommended for First Action at this time	▪ Applicable to milk based infant formula ▪ May help to have figures; can't distinguish ▪ No AOAC SPIFAN matrices ▪ For medical nutritionals please provide information
	#Chlor-02 - Infant Formula and Adult Nutritionals Chloride by Potentiometry	Günther Raffler Shay Phillips Bill Mindak	Scott Christiansen moved Jon DeVries second *Motion: move to First Action Yes- 10/ No-2 /Abstain-1 ——————— Second vote Yes- 10/ No-2 /Abstain-1	▪ Hydrolyzed method ▪ No SLV data included ▪ Simple method ▪ Address issue with high protein & fat in adult nutritionals ▪ Recovery/repeatability meets the SMPR
	Chlor-03 - Determination of Chloride in Infant Formula	Shay Phillips Günther Raffler Bill Mindak	Method not recommended for First Action at this time	▪ Different approach ▪ Needs AOAC SPIFAN SLV ▪ Newer technology ▪ Needs reagents ▪ Performance based method is needed not equipment

#The ERP has requested combining the two (2) methods (Chlor-02 & Chlor-04)

	#Chlor-04 - Chlorine in Infant Formula and Adult/Pediatric Nutritional Formula by Potentiometric Titration	Adrienne McMahon Bill Mindak	Moved second *Motion: move to First Action Yes- 12/ No-0 /Abstain-0	▪ No recovery completed
Fluoride	*Fluor-01 - Determination of fluoride in dietetic food products by ISE*	John Austad Melissa Phillips Bill Mindak	Method not recommended for First Action at this time	▪ No SLV data ▪ May not meet the analytical range ▪ 5-200mg 100% ▪ 2.5 = 200/250 high end
	Fluor-02 - Determination of Fluoride in Infant Food	John Austad Melissa Phillips Bill Mindak	Method not recommended for First Action at this time	▪ Not a full set of SLV data available ▪ Promising method, but needs more information ▪ Specific to the Dionex ▪ Ion chromatography
Fructans	*Fos-01 - AOAC Official Method 997.08 Fructans in Food Products - Ion Exchange Chromatographic Method*	Sean Austin Estela Kneeteman	Method not recommended for First Action at this time	▪ Method looks promising; awaiting additional data ▪ High content of free sugars ▪ SLV data not complete ▪ No LOQ or recovery information
	Fos-02 - Determination of Fructans in Foods	Sean Austin Brendon Gill	Method not recommended for First Action at this time	▪ Basic principle-hydrolyzed sucrose ▪ Method should realize more saccharides ▪ Significant lose in fructose ▪ Need raw materials ▪ Reference to the Nestlé method not cited ▪ May meet SMPR ▪ looks promising; awaiting additional data
	Fos-03 - Determination of Fructans in Infant Formula and Adult Nutritionals (High-Performance Anion-Exchange Chromatography with Pulsed Amperometric Detection)	Jon DeVries Karen Schimpf	Method not recommended for First Action at this time	
	Fos-04 - Determination of Fructans in Infant and Adult/Pediatric Nutritional Formulas as well as ingredient commodities	Jon DeVries Sean Austin	Method not recommended for First Action at this time	
GOS	*Gos-01 - Single Lab Validation Report for GOS in Infant Formula and Adult Nutritionals*	Estela Kneeteman Maria Ofitserova	Estela Kneeteman moved Maria Ofitserova second *Motion: move to First Action Yes- 1/ No-8 /Abstain-2 Method not recommended for First Action at this time	▪ HPLC method ▪ No data on LOQ ▪ Significant gaps that need to be addressed ▪ Direct quantification of the Gos ▪ Current AOAC SPIFAN matrices may not be the best to use
	Gos-02 - Determination of trans-Galacto-oligosaccharides (TGOS) in Infant Milk Formula (Ion-Exchange Chromatography)	Sean Austin Maria Ofitserova	Method not recommended for First Action at this time	▪ Specific for Gos ▪ Sample prep not written clearly ▪ Lengthy sample prep, but improves the existing method ▪ Send SLV data to ERP ▪ Lactose from Gos is confusing ▪ With the clean up, how specific is the removal of lactose or other di-saccharides? ▪ Need additional data

#The ERP has requested combining the two (2) methods (Chlor-02 & Chlor-04)

Minerals & Trace Elements	*MTE-01 - 2013 AOAC INTERNATIONAL AOAC Official Method 2011.14 Calcium, Copper, Iron, Magnesium, Manganese, Potassium, Phosphorus, Sodium, and Zinc in Fortified Food Products*	Bill Mindak Jinchuan Yang	*Method retains First Action *Official Method*[SM] status	▪ Good method; great update ▪ SLV used pertinent samples ▪ Method meets most of the SMPR ▪ LOQ meets SMPR ▪ Spiked recovery meeting SMPR (90-110%) ▪ Analytical range recovered higher ▪ Did not use AOAC SPIFAN samples
	MTE-02 - Determination of Na, Mg, P, K, Ca, Cr, Mn, Fe, Cu, Zn, Se, and Mo by ICP-MS	Bill Mindak Jinchuan Yang	Moved second *Motion: move to First Action Yes- 9/ No-2 /Abstain-1 ——————— Second vote Yes- 10/ No-2 /Abstain-2	▪ Too much instrument details ▪ Internal standard added before ▪ Meets most of the SMPR ▪ Carbon buffer ▪ Used AOAC SPIFAN samples ▪ No scope applicability ▪ SRM too high ▪ Written for only one model ▪ Potassium has high RSD ▪ Need to see modified write up/data
	MTE-03 - Milk and milk products Determination of calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium and zinc contents - Inductive coupled plasma atomic emission spectrometric method (ICP-AES)	Bill Mindak Jinchuan Yang	Bill Mindak moved Jinchuan Yang second Method withdrawn/tabled until data can be reviewed by ERP	▪ No internal standard ▪ Copper did not meet the low range ▪ Remove the “dry ash” from the method ▪ Microwave digestion with internal standard
Vitamin K	*VitK-01 - Validation of A LC-MS/MS Method for Vitamin K Analysis in Infant Formula and Adult Nutritional Samples*	Esther Campos-Gimenez Scott Christiansen	Method not recommended for First Action at this time	▪ Peak in the chromatograms are not labeled correctly ▪ Extraction procedure; separation of the cis/trans could be compromised ▪ Method seems promising; has potential ▪ LOQ/accuracy meets the SMPR ▪ No primary stock standard used ▪ Variability & precision is a concern ▪ No purity check on the standard
	VitK-02 - Determination of Trans Vitamin K1 by HPLC and Fluorescence Detection	Scott Christiansen Esther Campos-Gimenez	Scott Christiansen moved Esther Campos-Gimenez second *Motion: move to First Action Yes- 10/ No-0 /Abstain-1	

#The ERP has requested combining the two (2) methods (Chlor-02 & Chlor-04)

IV. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FINAL ACTION *OFFICIAL METHOD*^{SM} STATUS

The Expert Review Panel (ERP) reviewed four (4) methods for Final Action *Official Methods*^{SM} status. Two (2) were recommended to the Official Methods Board (OMB) for Final Action *Official Method*^{SM} consideration.

Method	Method Title	Reviewer(s)	Vote	Comments
Iodine	*2012.15 - Determination of Total Iodine in Infant Formula and Adult/Pediatric Nutritional Formula by Inductively Coupled Plasma - Mass Spectrometry (ICP-MS)*	Esther Campos-Gimenez	Esther Campos-Gimenez moved Jon DeVries second *Motion: move to Final Action Yes-11/ No-0 /Abstain-1	▪ Fourteen (14) labs participated; only thirteen (13) submitted data ▪ Used red dye #3 (strawberry drink mix) ▪ Six (6) matrices/one (1) SRM ▪ Used three (3) different suppliers ▪ Three (3) labs used microwave digestion ▪ Complete method ▪ May need maintenance ▪ Add precautions ○ Lens stack ⮝ Replace or have a dedicated set for iodine only
Pantothenic Acid	*2012.16 - AOAC Official Method 2012.16 Pantothenic Acid (Vitamin B5) in Infant Formula and Adult/Pediatric Nutritional Formula*	John Austad Don Gilliland/ Karen Schimpf	John Austad moved Karen Schimpf second *Motion: move to Final Action Yes- 12/ No-0 /Abstain-1	▪ Sixteen (16) labs participated ○ One (1) lab dropped out ○ One (1) lab did not qualify ○ Fourteen (14) labs provided data ⮝ Two (2) labs provided data as one (1) ▪ Consider a way to dry ○ Need moisture content addressed
Vitamin C	*2012.22 - Vitamin C (ascorbic acid) in Infant Formula and Adult/Pediatric Nutritional Formula by UHPLC-UV*	Jon DeVries Brendon Gill/ Harvey Indyk	Jon DeVries moved Scott Christiansen second Motion: move to Final Action Yes- 4/ No-4 /Abstain-4 *Method retains First Action *Official Method*^{SM} status	▪ Twenty-six (26) labs originally participated ○ Two (2) labs failed ○ Twenty- four (24) labs provided data ⮝ Fourteen (14) labs provided data using UPLC ⮝ Nine (9) labs provided data using HPLC ⮝ Due to customs restrictions, one (1) lab used known samples ○ Two (2) labs slightly passed ▪ Method needs more guidance ○ Stability ○ Timing ▪ May be oxidized ▪ Samples should be in sealed containers with the same lot number ▪ System suitability included ▪ Precision data from the two (2) sample types ▪ Add a control

#The ERP has requested combining the two (2) methods (Chlor-02 & Chlor-04)

Vitamin D	*2011.11 - Vitamin D - Determination of Vitamin D2 and D3 in Infant and Adult/Pediatric Nutritionals and Utilizing Ultra High Performance Liquid Chromatography/Tandem Mass Spectrometry (UHPLC-MS/MS)*	Sneh Bhandari (via review form) Brendon Gill/ Harvey Indyk	Method not recommended for Final Action *Method retains First Action *Official Method*^{SM} status	▪ Method author needs to publish two (2) sets of data ○ Second set of data should stand alone ▪ Clearly identify which data was previously used and which in new ⅄ Do not exclude data ⅄ Need outliers in the report ▪ Clarify labs that participated in the study Remediation ○ Clean up data ⅄ UPLC ⅄ HPLC

V. NEXT STEPS/FEEDBACK FROM ERP

Darryl Sullivan provided next steps.

#The ERP has requested combining the two (2) methods (Chlor-02 & Chlor-04)

Nestlé R&D Center
Lausanne

R&D Note

Additional data on Multi-Laboratory Validation – Vitamin C method AOAC First Action 2012.22

Objective Question	The objective of the study is to validate the current method (AOAC First Action 2012.22) by determining its precision figures (repeatability and reproducibility) with an additional multi-laboratory testing (MLT) on two matrices.
Authors People to ask	F. Martin, NRC/AS, E. Campos Giménez, NRC/AS
Summary Answer	The results presented in this document show that AOAC Official method 2012.22 comply with the requirements set in the corresponding SMPR, and thus is fit for purpose for the analysis of ascorbic acid (vitamin C) in infant formula and adult/pediatric nutritionals. The authors recommend that the method should be proposed for AOAC Final Action Official Method status.
Date of issue	23.Nov.2015
Project	DNUT-100472 / SPIFAN

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BACKGROUD

Multi-Laboratory Testing (MLT) data on SPIFAN matrices for First Action method AOAC 2012.22 "Vitamin C (ascorbic acid) in Infant Formula and Adult/Pediatric Nutritional Formula by UHPLC-UV" was sent to the Expert Review Panel (ERP) in January 2015[1].

Based on the aforementioned data, the method was not recommended to move forward to Final Action status due to high reproducibility values obtained for two samples (Infant Formula RTF Milk Based and Adult Nutritional Powder Low Fat).

The Expert Review Panel offered the method authors the opportunity to test fresh samples from the new SPIFAN kit. An additional MLT testing on these two matrices was thus organized. The aim of this document is to present the results obtained on these two fresh samples.

[1] RDLS-RD50006 Multi Laboratory Test – AOAC First Action Method 2012.22 Ascorbic Acid (Vitamin C) in Infant Formula and Adult/Pediatric Nutritionals, January 16th, 2015.

EXPERIMENTAL

Method

AOAC 2012.22 was applied as described before[1], without any change.

Matrices

The additional study took place using two SPIFAN matrices, Infant Formula RTF Milk Based and Adult Nutritional Powder Low Fat.

Participating laboratories

Twelve laboratories agreed to participate in this study. The complete list can be found in Annex A.

RESULTS AND CONCLUSION

Participation to MLT

From the 12 laboratories that initially initially accepted to participate, two of them did not receive the MLT samples due to customs restrictions. The remaining 10 laboratories reported valid data.

Results

Summarized results of the additional MLT set of samples can be found in the table below. Full set of data is given in Annex B.

Requirements (SMPR 2012.012)			**≤ 5 %**	**≤ 10 %**	
Sample	**n**	**Mean** (mg/100 g RTF)	**RSD_r** (%)	**RSD_R** (%)	**HorRat**
Adult Nutritional Powder Low Fat	10	17.6	1.5	6.5	0.88
Infant Formula RTF Milk Based	10	12.0	10.7	13.2	1.70

n = number of laboratories (after outliers removal)

RSD_r : relative standard deviation of repeatability

RSD_R : relative standard deviation of reproducibility

The results for the Adult Nutritional Powder Low Fat product are now well within the SMPR requirements. The repeatability went down from 31.8 % for the first round to 1.5 % in the present study, whereas the reproducibility went down from 33.0 % to 6.5 %. The hypothesis that during the first round the high precision data came from either homogeneity of the sample itself, storage spoilage or can mislabelling seems to be confirmed.

Regarding the Infant Formula RTF Milk Based, even if the precision numbers improved (repeatability down from 25.6 % to 10.7 %, reproducibility from 30.6 % to 13.2 %), they remained slightly outside of the requirements.

One of the participant laboratories analysed duplicate samples the four bottles they received. The data are presented in the table below:

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MLT code	Bottle #	Conc (mg/100g)
XKIP216	1	12.7
		12.6
	2	10.6
		10.5
HYJU890	1	14.9
		15.1
	2	11.6
		11.6

While the duplicates from the same bottle present excellent CV (from 0.1 % to 0.9%). The range of concentration spans from 10.5 to 15.1 mg/100 g. It can indicate that the high precision data obtained for the Infant Formula RTF is due to the variability within the samples and not on the method.

To confirm these findings, it was decided to analyse samples at NRC, in duplicates, using a different method (AOAC Official method 985.33). This method is based on a different chemical approach: the reduction of the dye 2,6-dichlorophenolindophenol (DCPIP) by ascorbic acid. The results obtained can be found in the table below:

MLT code	Bottle #	Conc (mg/100g)
XKIP216	1	14.5
XKIP216	1	14.9
XKIP216	2	11.4
XKIP216	2	11.7
HYJU890	1	14.9
HYJU890	1	14.8
HYJU890	2	13.7
HYJU890	2	13.7

For these samples the range of concentrations spans from 11.4 to 14.9 mg/100 gr.

Both tables tend to indicate that the high precision data collected during this additional MLT could come from the variability of the samples, and not from the method AOAC 2012.22. Moreover this variability has been observed using two distinct analytical methodologies.

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CONCLUSION

This additional MLT was organized to collect new precision data (repeatability and reproducibility) of samples which presented higher variability numbers than the rest of the matrices during the MLT. Two fresh samples (Infant Formula RTF Milk Based and Adult Nutritional Powder Low Fat) were dispatch to twelve laboratories.

The results for the Adult Nutritional Powder Low Fat product are now well within the SMPR requirements. Regarding the Infant Formula RTF Milk Based, even if the precision numbers improved, they remained slightly outside of the requirements.

One of the participant lab decided to analyse the four bottles received in duplicates. To mirror this experiment the decision was made to also analyse the samples at NRC, using a different method (AOAC Official method 985.33). Both sets of data suggest that the higher variability observed for the RFT sample come from variability within the samples, and not from the method.

These results show that AOAC Official method 2012.22 comply with the requirements set in the corresponding SMPR, and thus is fit for purpose for the analysis of ascorbic acid (vitamin C) in infant formula and adult/pediatric nutritionals. The authors thus recommend that the method should be proposed for AOAC Final Action Official Method status.

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Distribution List

Name, Location	Name, Location	Name, Location
E. Konings, NRC/FSQ	R. Bowling, NRC/AS	J. O'Brien, NRC/FSQ
G. Daix, NRC/FSQ	Vitamins & Phytonutrients group, NRC/AS	AOAC Expert Review Panel

ANNEX A: LIST OF PARTICIPANTS

John Austad Covance 3301 Kinsman Blvd. Madison, WI 53704 USA	Soo Hui Chooi NQAC Shah Alam, Nestlé Manufacturing (M) Sdn Bhd Jalan Playar 15/1, P.O. Box 7010 40700 Shah Alam, Selangor Darul Ehsan Malaysia
WU Bolong Chinese Academy of Inspection and Quarantine A3, Gao Bei Dian North Road Chao Yang District, Beijing China	Karen Schimpf Abbott Laboratories 3300 Stelzer Road Columbus, OH 43219 USA
George Joseph Asure Quality 131 Boundary Road Auckland 1140 New Zealand	Michael Hoard Arizona Nutritional Supplements 210 S Beck Ave Chandler, AZ 85226 USA
Lifu M. Ma Certified Laboratories, Inc 200 Express Street Plainview, NY USA	Pascal González Silliker Ibérica C/ Transversal 6 n° 19 08040 Barcelona Spain
Guy Weerasekera Mead Johnson Nutrition Y6, 2400 W Lloyd Expy Evansville, IN 47721 USA	Cai Weihong Guangzhou Quality Supervision and testing Institute Room 301, N° 38, Baqi 2nd Road Guangzhou, 510110 People Republic of China
Isabelle Malaviole Aquanal 151 bis avenue Jean Jaurès 33600 Pessac France	Olivia Hernández Mead Johnson & Company Carretera Panamerica Km 1573, Entronque Las Varas Ciudad, Delicias, Chihuahua 3300 México

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ANNEX B: RAW DATA

	Mini MLT sample 1	Mini MLT sample 3	Mini MLT sample 2	Mini MLT sample 4
	Adult Nutritional Powder Low Fat		Infant Formula RTF Milk Based	
Lab 1	17.5	18.0	13.1	13.0
Lab 2	20.0	20.1	12.9	12.2
Lab 3	18.2	18.0	11.7	14.1
Lab 4	17.7	17.6	12.5	10.9
Lab 5	17.5	17.3	13.2	12.0
Lab 6	18.0	17.7	12.7	15.0
Lab 7	16.0	15.3	13.8	9.8
Lab 8	16.4	17.0	11.5	10.5
Lab 9	17.1	17.5	10.7	11.0
Lab 10	17.8	17.9	9.0	9.8

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AOAC INTERNATIONAL

Stakeholder Panel for Infant Formula and Adult Nutritionals (SPIFAN)

Meeting at the Gaithersburg Marriott Washingtonian Center
9751 Washingtonian Boulevard
Gaithersburg MD 20878, USA

Wednesday, March 16, 2016 - 10:30am (Eastern US)

REPORT OF THE EXPERT REVIEW PANEL (ERP) PROCEEDINGS

Expert Review Panel Members (in attendance):

Darryl Sullivan	***Covance Labs*** *(Chair)*
John Austad	Covance Labs
Sean Austin	Nestlé Research Centre
Scott Christiansen	Perrigo Nutritionals
Hans Cruijsen	FrieslandCampina
Brendon Gill	Fonterra Cooperative
Don Gilliland/Karen Schimpf	Abbott Nutrition
Estela Kneeteman	INTI
Adrienne McMahon	Wyeth/Nestlé
Bill Mindak	FDA CFSAN
Maria Ofitserova	Pickering Labs, Inc.
Melissa Phillips/Kate Rimmer	NIST
Shay Phillips	Mead Johnson Nutrition
Günther Raffler	Eurofins/CLF
David Woollard	Eurofins (formerly of Hill Labs)
Jinchuan Yang	Waters Corp.

Expert Review Panel Members (unable to attend):

Sneh Bhandari	Mérieux NutriSciences & OMB
Esther Campos-Giménez	Nestlé
Jon DeVries	Consultant
Sarwar Gilani	Consultant
Min Huang	Frontage Labs, Inc.
Harvey Indyk	Fonterra Cooperative
Wil van Loon	FrieslandCampina

AOAC Staff Includes:

Delia Boyd
E. James Bradford
Scott Coates
Arlene Fox
Deborah McKenzie
Alicia Meiklejohn
Tien Milor

Working Group Chairs:

Amino Acids:	Ping Feng (Wyeth) & Wes Jacobs (Abbott)
Biotin	George Joseph (AsureQuality) & Jean-Luc Deborde (SCL)
B Vitamins:	Louis Salvati (Abbott)
Carotenoids:	Greg Hostetler (Perrigo)
Chloride/Fluoride:	Christopher Blake (Nestlé)
Choline:	Sneh Bhandari (Silliker) & Nick Cellar (Abbott)
Folate:	Erik Koinings (Nestlé)
Fructans (FOS) & GOS:	Sean Austin (Nestlé)
Vitamin D:	Don Gilliland (Abbott)

Observers:

Joe Boison, *CFIA*
Bob Clifford, *Shimadzu*
Marcel deVreeze, *NEN-ISO*
Stefan Ehling, *Abbott Nutrition*
Ping Feng, *Wyeth Nutrition*
Andrew Fussell, *PANalytical*
Philip Haselberger, *Abbott Nutrition*
Greg Hostetler, *Perrigo Nutritionals*
Wes Jacobs, *Abbott Nutrition*
Greg Jaudzems, *Nestlé USA, Inc.*
Martha Jennens, *Covance*
George Joseph, *AsureQuality*
Erik Konings, *Nestlé*
Marcus Lacorn, *R-Biopharm*
SooKwang Lee, *FDA*
Qi Lin, *Abbott Nutrition*
Vicky Manti, *Danone*
Elaine Marley, *R-Biopharm Rhone*
Frederic Martin, *Nestlé*
Mary McBride, *Agilent Technologies*
Josh Messerly, *Eurofins*
Paul Milne, *Keurig Green Mountain*
Deepali Mohindra, *Thermo Fisher Scientific*
Shang-Jing Pan, *Abbott Nutrition*
Robert Rankin, *INCA*
Rick Reba, *Nestlé*
Jeff Rohrer, *Thermo Fisher Scientific*
Shauna Roman, *Reckitt Benckiser*
Joe Romano, *Waters Corp.*
Louis Salvati, *Abbott Nutrition*
Angela Song, *Abbott Nutrition*
Monique Steegmans, *Tienen Miher/Beneo Orafti*
Karla Steele, *Mead Johnson Nutritionals*
Cheryl Stephenson, *Eurofins*
Joan Stevens, *Agilent Technologies*
John Szpylka, *Mérieux NutriSciences*
Steve Tennyson, *Perrigo Nutritionals*
Joe Thompson, *Abbott Nutrition*
Marina Torres, *LATU*
Socrates Trujillo, *FDA*
Martijn Vermeulen, *Ausnutria Hyproca*
Wayne Wargo, *Abbott Nutrition*
Wayne Wolf, *USDA (Retired)*
Laura Wood, *NIST*
Dorothy Yang, *Agilent Technologies*
Zhou Yao, *SH-CIQ*
William Xue, *Accucaps*
Joyce Zhu, *Jamieson*

I. WELCOME AND INTRODUCTIONS

Darryl Sullivan welcomed all participants to the ERP meeting and introduced the ERP members.

II. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FIRST ACTION *OFFICIAL METHOD*^{SM} STATUS – AOAC SPIFAN I

For each method, the ERP/Working Group Chairs including (Co-Chairs) discussed methods submitted.

Method	Method Title	Reviewer(s)	Vote	Comments
Choline	*Chol-08 - Determination of Free and Total Choline and Carnitine in Infant Formula and Adult/Pediatric Nutritional Formula by Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS), AOAC 2015.10.*	Sneh Bhandari	Scott Christiansen (moved) Shay Phillips (second) Yes-14/No-0/Abstain-1 Method adopted as First Action *Official Method*^{SM} status; OMA# 2015.10	▪ Method is clearly written with a comprehensive report ▪ May want to do a comparison with the SPIFAN I & II samples

III. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FIRST ACTION *OFFICIAL METHOD*^{SM} STATUS – AOAC SPIFAN II

For each method, the ERP/Working Group Co-Chairs discussed methods submitted. Nine (9) methods were received and reviewed and one (1) method received First Action *Official Method*^{SM} status.

Method	Method Title	Reviewer(s)	Vote	Comments
Amino Acid	*Amino-03 - Amino Acids in Infant Formula and Adult/Pediatric Formulas - Ultra High Performance Liquid Chromatography*	Maria Ofitserova Shay Phillips	No Action recommended: Method not adopted as First Action *Official Method*^{SM} status	▪ Method is three (3) methods in one (1); uses three (3) separate digestions ▪ It is hard to determine how many samples were completed and in how many days ▪ The intermediate precision was completed over two (2) days and six (6) replicates daily; the information should be presented clearer. ▪ Method is promising, but lacks SLV data ▪ One weakness is optimizing the method ▪ Internal standards should be brought in earlier; internal standard is added after hydrolysis o No tryptophan in the internal standards; should investigate and correct ▪ Full SPIFAN SLV study should be completed ▪ Follow instructions in the use of the AOAC SPIFAN samples ▪ Suitability step should be built in the method to check the column for separation suitability
Biotin	*Bio-02 - Determination of Biotin By Liquid Chromatography Coupled with Immunoaffinity Column Clean-Up Extraction*	Scott Christiansen Karen Schimpf	Scott Christiansen (moved) Karen Schimpf (second) Yes-13/No-1/Abstain-0 Second vote: Yes-13/ No-0/Abstain-1 Method adopted as First Action *Official Method*^{SM}	▪ Method did not use example calculations ▪ Method did not include the calibration and standard curve or sequence for balance o Add system suitability and calculations ▪ Calibration description and sample preparation ▪ For spiked recovery for accuracy, four (4) placebos sample used in three (3) days in triplicate ▪ Point of clarification for spiking the recovery materials.
	Bio-03 - Determination of Biotin in Infant, Pediatric and Adult Nutritionals by HPLC and Fluorescence Detection	Adrienne McMahon Estela Kneeteman	Adrienne McMahon (moved) Estela Kneeteman (second) Yes-10/ No-2/Abstain-2 Second vote: Yes-11/No-1/Abstain-1 Method adopted as First Action *Official Method*^{SM}	▪ The method is well written ▪ Safety and chromatograms are straight forward ▪ Concerns include that the SMPR® states "total" biotin, vs. "free" as the in the method ▪ Method should have added a hydrolysis or enzyme ▪ The analytical range doesn't meet the SMPR® ▪ To fix the linear range, adjust the sample size ▪ Check the Codex # ▪ Check the low end ▪ Bound vs. unbound ▪ Error on pg. 10 o should be 1mcg/ 100 gram

AOAC SPIFAN Expert Review Panel Report
March 16, 2016
Final Version

B Vitamins	*BVit-02 - Simultaneous Determination of Total Vitamin B3 in Infant Formula Products by LC-MS/MS Using Enzymatic Digestion (COMPARISON)*	Scott Christiansen Estela Kneeteman David Woollard	Estela Kneeteman (moved) David Woollard (second) Yes-3/No-10/Abstain-2 Motion failed.	▪ Method is for "total" B vitamin ▪ Samples completed in a single day ▪ Low recovery ▪ No spike and recovery data presented ▪ Meets SMPR® requirement ▪ No LOQ data provided ▪ Needs clarity of concentration of the enzymes
	BVit-03 - Determination of B-Vitamins in Infant Formula and Adult/Pediatric Formulas ESI LC-MSMS	Brendon Gill David Woollard	No Action recommended: Method not adopted as First Action *Official Method*^{SM} status	▪ Method does not include the measurement of phosphorylated forms as specified in the SMPR® applicability ▪ Method does not meet the SMPR®
Carotenoids	*Carot-01 - Determination of Carotenoids in Infant Formula and Adult/Pediatric Nutritional Formula using High-Performance Liquid Chromatography with Photo Diode Array Detection.*	Jon DeVries Adrienne McMahon	No Action recommended: Method not adopted as First Action *Official Method*^{SM} status	▪ See ERP Review Form
	Carot-02 - Determination of Lutein and β-Carotene in Infant Formula and Adult Nutritionals	Maria Ofitserova Jon DeVries Adrienne McMahon	No Action recommended: Yes-14/No-0/Abstain-1 Method not adopted as First Action *Official Method*^{SM} status	▪ Method has issues with lycopene and alpha carotene ▪ Method is clearly written and has sound methodology, but doesn't meet the scope o Expand scope to include α-carotene and lycopene ▪ No data provided on alpha carotene ▪ No safety concerns ▪ Method has the potential to meet the SMPR® ▪ Method only analyzed three (3) matrices ▪ Reassemble the working group to review the comments for the SMPR® ▪ This nutrient may require four (4) SMPRs® or some variation ▪ Set order of priority ▪ SLV may be requirement for beta carotene and lutein
Chloride	*Combined AOAC 1st action methods 2015.07 and 2015.08 (Chlor-02/04) - Chloride in Milk, Milk Powder, Whey Powder, Infant Formula and Adult Nutritionals Potentiometric titration method - For AOAC / ISO / IDF MLT study*	Günther Raffler Shay Phillip Bill Mindak	Günther Raffler (moved) Bill Mindak (second) Vote: Unanimous Method to receive a new OMA # Method recommended for reproducibility testing	▪ Both methods have already received First Action status and was combined into one method ▪ The combined method is easy to perform and doesn't require highly sophisticated instruments ▪ Recommend that the combined method move forward for reproducibility testing ▪ Method is lacking safety information
	Chlor-03 -Single Laboratory Validation for Chloride Analysis in Infant Formula and Adult Nutritionals: AOAC SMPR® 2014.015	Bill Mindak Günther Raffler Shay Phillip	No Action recommended: Estela Kneeteman (moved) David Woollard (second) Vote: Yes-11/No-1/Abstain-0 Method not adopted as First Action *Official Method*^{SM} status	▪ The only reagent used in the method is from Waters Corp. (trademarked/branded) ▪ The SRM was analyzed at a higher level ▪ The method needs clarity in the point o Accuracy/recovery o Precision ▪ The NIST reference values are not certified ▪ The method needs to be harmonized to compare results ▪ IC vs. titrations
Fluoride	*Fluor-02 - Single Laboratory Validation for Fluoride Analysis in Infant Formula and Adult Nutritionals: AOAC SMPR® 2014.016*	Bill Mindak Günther Raffler Shay Phillip	No Action recommended: Method not adopted as First Action *Official Method*^{SM} status	▪ The repeatability does not meet the accuracy ▪ The fluoride peak is small, but there is still a concern ▪ May need to reassemble the working group to review the SMPR® o Is precision & accuracy required to comply with regulation?

Folate	*Fol-20 - Analysis of Folic acid and 5-Methyltetrahydrofolate in Infant and Adult Nutritional formula using Ultra-Performance Liquid Chromatography-Tandem Mass Spectrometry*	Adrienne McMahon Melissa Phillips	No Action recommended:	▪ See ERP Review form
	*OMA# 2013.13 (Fol-21) - **NOTES ONLY** - Contribution of minor folates to the total folate content of infant formula and adult/pediatric nutritionals*	Shay Phillips	*OMA# 2013.13* - Method has First Action *Official Method*[SM] designation	▪ ***ERP DISCUSSION ON FOLATES*** o Additional information is required on the minor folates o Need to add decongulate
	OMA# 2011.06 (Fol-22) - Validation of A LC-MS/MS Method for Folate Analysis in Infant Formula and Adult Nutritional Samples (Folate-22, OMA 2011.06) using SPIFAN II Sample Kit	Adrienne McMahon	*OMA# 2011.06* - Method has First Action *Official Method*[SM] designation	
Fructans (FOS)	*Fos-01 - Determination of Fructans in Infant and Adult/Pediatric Nutritional Formulas as well as ingredient commodities*	Estela Kneeteman Sean Austin Hans Cruijsen	Hans Cruijsen (moved) Estela Kneeteman (second) Yes-1/No-7/Abstain-0 --- Method not adopted as First Action *Official Method*[SM] status	▪ The method used SPIFAN I kit with only four (4) samples containing fructans (FOS) o Method only measured fructose ▪ Method is missing LOQ data ▪ Method is also used widely ▪ Sucrose contents exceeds three (3) times the total fructans content ▪ Two (2) samples did not meeting the SMPR® ▪ Needs calculation of glucose from fructose
	Fos-04 - Determination of Fructans in Infant and Adult/Pediatric Nutritional Formula as well as ingredient commodities High-Performance Anion-Exchange Chromatography with Pulsed Amperometric Detection	Jon DeVries Sean Austin Hans Cruijsen	Hans Cruijsen (moved) Sean Austin (second) Yes-14/No-0/Abstain-1 --- Method adopted as First Action *Official Method*[SM]	▪ The method is straight forward and equipment is readily available ▪ Must specify the purity in the method; need to have purity check on the standard
Vitamin D	*VitD-17 - Determination of Vitamin D in Milk Products by UPLC-MS-MS with 4-Phenyl-1,2,4-triazoline-3,5-dione (PTAD) Derivatization*	Brendon Gill Don Gilliland Jinchuan Yang	No Action recommended: Method not adopted as First Action *Official Method*[SM] status	▪ There is a bias against the NIST reference ▪ The method meets the SMPR® on spiked recovery ▪ Validation did not include the SPIFAN kit ▪ Pre D is measured directly ▪ Requires purity check for the standard
	VitD-18 - Analysis of Vitamin D2 and Vitamin D3 by LC-MS/MS in Milk Powders, Infant Formulas, and Adult Nutritionals	Don Gilliland Sneh Bhandari Jinchuan Yang	Don Gilliland (moved) David Woollard (second) Yes-13/No-1/Abstain-1 --- Second vote: Yes-13/No-1/Abstain-1 Method adopted as First Action *Official Method*[SM] status	▪ The method is well written & thorough ▪ The method meets the SMPR® ▪ The method uses very complete data sets ▪ The ERP recommends that the study director work with CDC-SH (VitD-17) to combine the methods

IV. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FINAL ACTION *OFFICIAL METHOD*[SM] STATUS

The Expert Review Panel (ERP) reviewed Two (2) methods for Final Action *Official Methods*[SM] status. Zero (0) methods were recommended to the Official Methods Board (OMB) for Final Action *Official Method*[SM] consideration.

Method	Method Title	Reviewer(s)	Vote	Comments
Vitamin C	***OMA# 2012.22 - Vitamin C (VitC-03) AOAC First Action Official Method 2012.22 - Vitamin C (ascorbic acid) in Infant Formula and Adult/Pediatric Nutritional Formula by UHPLC-UV***	Sneh Bhandari Brendon Gill/ Harvey Indyk	Brendon Gill (Moved) John Austad (Second) Yes-13/No-0/Abstain-1 --- Method recommended for Final Action *Official Method*[SM] status	o Assemble the working group to review the SMPR® for Codex levels ➢ Post information for comments

IV. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR REPRODUCIBILITY TESTING

The ERP will collectively discuss the methods and select a single method to move forward through the AOAC SPIFAN process for reproducibility testing.

Method Evaluation Forms - Methods processed via the numbering system:

Method	Method Title	Number Voting	Comments
Biotin	*Bio-02 - Determination of Biotin By Liquid Chromatography Coupled with Immunoaffinity Column Clean-Up Extraction*	**~Move to reproducibility testing** **657**	
	Bio-03 - Determination of Biotin in Infant, Pediatric and Adult Nutritionals by HPLC and Fluorescence Detection	**639**	
Choline	*Chol-08 - Determination of Free and Total Choline and Carnitine in Infant Formula and Adult/Pediatric Nutritional Formula by Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)*	**~Move to reproducibility testing**	
Folate	*OMA# 2013.13 (Fol-21) - Contribution of minor folates to the total folate content of infant formula and adult/pediatric nutritionals*	**1011**	
	OMA# 2011.06 (Fol-22) - Validation of A LC-MS/MS Method for Folate Analysis in Infant Formula and Adult Nutritional Samples (Folate-22, OMA 2011.06) using SPIFAN II Sample Kit	**~Move to reproducibility testing** **1019**	
Vitamin D	*VitD-18 - Analysis of Vitamin D2 and Vitamin D3 by LC-MS/MS in Milk Powders, Infant Formulas, and Adult Nutritionals*	**~Move to reproducibility testing**	
Fructans (FOS)	*Fos-04 - Determination of Fructans in Infant and Adult/Pediatric Nutritional Formula as well as ingredient commodities High-Performance Anion-Exchange Chromatography with Pulsed Amperometric Detection*		Method not proceeding until September 2016

V. NEXT STEPS/FEEDBACK FROM EXPERT REVIEW PANEL

Darryl Sullivan provided next steps including suggestions from the Expert Review Panel requesting that some of the SMPRs® be revisited by the respective working group(s).

1. Investigate reconvening the following working groups:
    a. Amino Acids
    b. Carotenoids
    c. Fluoride
    d. GOS
    e. Vitamin B_3 (Niacin)

❖ **To view the ERP Reviewer forms please click here or http://cld.bz/dHMmBmw**

Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula Ultra-Performance Liquid Chromatography with Ultraviolet Detection

(Applicable to the determination of vitamin C (L-ascorbic acid) in infant formula and adult/pediatric nutritional formula by ultra-performance LC (UPLC®)-UV.

Caution: Refer to Material Safety Data Sheets prior to use of chemicals. Use appropriate personal protective equipment when performing testing.

A. Principle

Ascorbic acid is extracted from the sample using trichloroacetic acid (TCA) in the presence of Tris[2-carboxyethyl]phosphine (TCEP) as a reducing agent. Ascorbic acid is then determined by UHPLC-UV at 265 nm. Separation takes place on a C_{18} column with sodium acetate (pH = 5.4) as eluent, combined with TCEP and decylamine as ion-pairing agent.

B. Apparatus

(a). *Balances.*— With readability of 0.1 mg and 0.01 g.

(b). *pH meter.*— Metrohm 691 (Herisau, Switzerland), or equivalent.

(c). *LC column.*—Waters Acquity UPLC® ethylene bridged hybrid (BEH) C_{18} column, 1.75 µm, 2.1 x 100 mm, or equivalent.

(d). *UHPLC system.*— Waters Acquity UPLC® system equipped with a Waters Acquity UPLC® photodiode array detector, or equivalent.

C. Reagents and standards

(a). *Acetonitrile.*— HPLC grade, Merck (Geneva, Switzerland), or equivalent.

(b). *Ascorbic acid.*- Fluka (Buchs, Switzerland), or equivalent.

(c). *Decylamine.*- Fluka, or equivalent.

(d). *Phosphoric acid. —85 %,* Merck, or equivalent.

(e). *Purified water.*—Millipore (Le Mont-sur-Lausanne, Swizerland), or equivalent.

(f). *Sodium acetate trihydrate.*— Merck, or equivalent.

(g). *TCA* — Merck, or equivalent.

(h). *TCEP*.—Fluka, or equivalent.

(i). *Isoascorbic acid*.—Fluka, or equivalent.

(j). *Orotic acid*.- Sigma, or equivalent.

D. Preparation of Solutions

(a). *Sodium acetate solution 500 mmol/L (pH 5.4)*.— Into a 500 mL volumetric flask, weigh 34.0 g sodium acetate trihydrate, add about 400 mL of water and dissolve well. Adjust pH to 5.4 with phosphoric acid 85 % and make up to volume with water.

(b). *TCA (15 %)* .—Into a 500 mL volumetric flask, weigh 75.0 g of TCA, dissolve and make up to volume with water

(c). *TCEP (250 µg/mL)*.— Into a 500 mL volumetric flask, weigh 125 mg of TCEP, dissolve and make up to volume with water.

(d). *Mobile phase for UHPLC*.- Into a 250 mL flask, mix 0.4 g decylamine, 2.5 mL acetonitrile, 25 mL sodium acetate solution 500 mmol/L (pH 5.4) and 205 mL of water. No making up to volume is preferred. Adjust pH to 5.4 with phosphoric acid 85 %. Add 10 mg TCEP.

E. Preparation of Standards

(Note: Vitamin C is sensitive to light and oxygen, conduct operations under subdued light, or use amber glassware. Keep all solutions away from direct light.)

(a). *Ascorbic acid stock solution (500 µg/mL)*.— Into a 25 mL amber glass volumetric flask, weigh 12.5 mg ascorbic acid. Dissolve and make up to volume with TCEP solution. This solution can be kept for 3 months if stored at 4 °C away from light.

(b). *Ascorbic acid intermediate standard solution (50 µg/mL).*- Into a 10 mL amber glass volumetric flask, pipet 1 mL stock solution. Make up to volume with TCEP solution. This solution can be used for 1 month if stored at 4 °C away from light.

(c). *Ascorbic acid calibration standard solutions (0.5, 1.0, 2.0, 3.0, 5.0, 7.5, 10.0 µg/mL).*- Into 10 mL amber glass volumetric flasks, pipet 0.1, 0.2, 0.4, 0.6, 1.0, 1.5 and 2.0 mL of intermediate standard solution. Make up to volume with mobile phase to prepare the respective concentrations given above.

F. Sample preparation

(a). *Reconstitution of powder samples*.-

1. Weigh 25 g of powder into a brown glass 250 mL beaker, add 10 mg TCEP.
2. Add 200 g warm water (40 °C). Mix well until complete dissolution, make sure there are no lumps.

(b). *Extraction*.-

1. Weigh 2 g of liquid or reconstituted sample into a 10 mL amber-glass volumetric flask.
2. Add 4 mL TCEP solution and 2 mL TCA 15 %.
3. Bring up to volume with water.
4. Filter solution through folded grade 597½ or greater filter paper (Schleider & Schuell, Dassel, Germany).
5. Transfer 1 mL of filtrate into a 10 mL amber glass volumetric flask containing 1 mL acetate solution (pH 5.4) and bring up to volume with mobile phase.
6. Filter about 2 mL through 0.22 µm membrane into a HPLC vial.

G. Analysis

(a). *Chromatographic conditions*.-

1. Injection volume.- 5µL.
2. Autosampler temperature.- 10 °C.
3. Column temperature.- 25 °C.
4. Flow rate.- 0.35mL/min
5. Run time.- 4.0 minutes
6. Mobile phase.- Sodium acetate (50 mmol/L, pH 5.4), decylamine (1.6g), acetonitrile (1 %), TCEP (40 mg/L).

NOTE: *At the end of each analytical series, rinse column with acetonitrile-water (1+1, v/v) for 10 minutes at 0.4 ml/min*.

(b). *System suitability test*.- Equilibrate the chromatographic system for ≥0.5 h. Inject a working standard solution of ascorbic acid at least 6 times and check peak retention times and response (peak height or area). Inject working standard solutions on a regular basis within a series of analyses. Ensure orotic acid and isoascorbic acid are fully resolved from ascorbic acid by injecting separated standard solutions of both compounds (prepared as stated for ascorbic acid). If not resolved, the pH of the mobile phase may be decreased to 5.0, or the amount of acetonitrile increased.

(c). *Calibration*.- Make single injections of working standard solutions at least at the beginning and the end of each analytical series. Establish the calibration curve (seven points) by plotting peak response (height or area) versus ascorbic acid concentration. Perform linear regression. Calculate the slope (S) and intercept (I) of the calibration curve.

(d). *Analysis*.- Make single injections of sample solutions.

(e). *Identification*.- Identify the ascorbic acid peak in the chromatograms of the sample solutions by comparison with the retention time and UV spectrum of the corresponding peak in the standard solution.

H. Calculations

Calculate the concentration of vitamin C, in mg ascorbic acid/100 g expressed in product "as is" for RTF (ready to feed) products or as "reconstituted powder" for powder samples, as follows:

$$C = \frac{(A - I) \times V_1 \times V_3 \times 100}{S \times m \times V_2 \times 1000}$$

where A = response (height or area) of the ascorbic acid peak obtained for the sample solution, m = weight of the test portion, in g (2.0 g of product as is or reconstituted powder), V_1 = volume of the test solution (volume used to dissolve the test portion) in mL (10 mL), V_2 = volume used in the sample dilution (1.0 mL), V_3= volume of the final sample dilution (10 mL).

Note: if results expressed in powder sample are needed, use the reconstitution rate to calculate (c *225/25).

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 22, 2016

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: IVa-b. OMB Awards

Candidates for the 2016 OMB Awards are on the AOAC website in the secure OMB section.

RECOMMENDATION: For OMB to review candidates and render consensus on recipients

ATTACHMENTS: Go to AOAC web site

***OFFICIAL METHODS*[SM] PROGRAM AWARDS**

Contents

Team Awards:

Award in Recognition of Technical and Scientific Excellence

Expert Review Panel of the Year

Individual Achievement Awards:

Technical Service Award

Method of the Year

AWARD IN RECOGNITION OF TECHNICAL AND SCIENTIFIC EXCELLENCE

Selection Criteria

The purpose of this award is for the Official Methods Board (OMB) to recognize a team, stakeholder panel or working group that has published a major document or other body of work that demonstrates a unique or particularly noteworthy level of technical and scientific expertise.

The minimum criteria for selection are:

a. The body of work includes major initiatives or technical guidelines accepted, completed or published within the last three years.
b. The team has been instrumental in developing or modifying technical guidelines or method validation processes.
c. The team product demonstrates significant merit as to the scope of the project, the involvement of a diverse and/or international group of stakeholders or an innovative approach to difficult analytical challenges.
d. The award recognizes teamwork that enhances the reputation of the Association and fosters the mission of AOAC INTERNATIONAL.

Selection Process:

a. The chair of the OMB solicits the OMB members for nominees.
b. Written recommendations and supporting information will be submitted to the OMB chair. The information will be distributed to the members of the OMB.
c. The OMB selects the recipient of this award. The winner is selected by a 2/3 vote. If necessary, the OMB chair may cast the tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the recipient(s) of this award. The winner will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. All members participating in the winning team will be acknowledged at the annual meeting, receive an award and a letter of appreciation. The name of the winner, with supporting story, will be carried in the announcement in the *ILM*.

EXPERT REVIEW PANEL OF THE YEAR

Selection Criteria

The minimum criteria for selection are:

a. The expert review panel must have completed a significant milestone (e.g. First Action Method, Final Action Method, method modification) within the last three years.
b. Generally, some unique or particularly noteworthy aspect of the ERP's work is highlighted as making the ERP worthy of the award, such as innovative technology or application, breadth of applicability, critical need, difficult analysis, or timeliness.
c. The panel report demonstrates significant merit as to the scope of the project, the involvement of a diverse and/or international group of recognized experts or an innovative approach to difficult analytical challenge.

Selection Process:

a. AOAC staff lists all eligible panels for consideration and forwards that list along with the ERP report to the Chair of the Official Methods Board (OMB).
b. The OMB Chair forwards the list along with any supporting information to the OMB.
c. The OMB selects the Expert Review Panel of the Year. Winner is selected by a 2/3 vote. If necessary, the OMB chair may cast tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the members of the winning Expert Review Panel. The winning panel will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. All panelists participating in the winning panel will be acknowledged at the annual meeting, receive an award and a letter of appreciation. The name of the winning ERP, with supporting story, will be carried in the announcement in the *ILM*.

TECHNICAL SERVICE AWARD

More than one volunteer may be selected in this category each year. In each case the area of expertise should be noted at the time of presentation of the award.

Selection Criteria includes:

a. Has demonstrated timely, competent, and continuous service in an exemplary manner to a Stakeholder Panel (SP), Expert Review Panel (ERP), Working Group (WG), Section, Community, and Committee and/or to the Official Methods Board (OMB).
b. Has donated this service within the three years prior to nomination.
c. Gives outstanding expert guidance and support in all technical aspects as needed and requested.

Additional support for selection is exemplary performance in one or more of the areas below:

a. Has provided guidance on safety, statistical, technical matters, or process expertise.
b. Has been instrumental in developing, modifying or validating a high quality method for publication in the Official Methods of Analysis.
c. Communicates related activities through the appropriate channels, either through the panel/group/community chairs, the Committee on Statistics or Safety or through the Chief Scientific Officer or other staff designees.
d. Contributes significantly to AOAC INTERNATIONAL over a period of years with other accomplishments related to his/her area of expertise (e.g symposium presentations, poster presentations, publications, workshops, meetings).
e. Contributes to the development and improvement of AOAC INTERNATIONAL guidelines, OMA methods, statistics or safety programs.
f. Helps guide AOAC in the decision-making process to make the organization a leader in the field of analytical science.

Selection Process

a. The Official Method Board (OMB) will solicit the Chairs of the Stakeholder Panels, Expert Review Panels, Working Groups, Committees, Community, and the Association membership for nominees. Recommendations based on input from anyone qualified to discuss the contribution of the nominee can be submitted.
b. Written recommendations and supporting information must be submitted to the OMB Chair. The OMB chair will distribute the information to the members of the OMB.
c. The OMB selects the winner(s) of the Technical Service Award by a 2/3 vote. If necessary, the OMB chair may cast tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the recipient(s) of this award. The winner will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. The recipient(s) will be acknowledged at the annual meeting, receive an award and a letter of appreciation. The name of the winner, with supporting story, will be carried in the announcement in the *ILM*.

METHOD OF THE YEAR

OMB may select more than one method in this category each year.

Selection Criteria

The minimum criteria for selection are:

a. The method must have been approved for first or final action within the last three years.
b. Generally, some unique or particularly noteworthy aspect of the method is highlighted as making it worthy of the award, such as innovative technology or application, breadth of applicability, critical need, difficult analysis, and/or range of collaborators.
c. The method demonstrates significant merit in scope or is an innovative approach to an analytical problem.

Selection Process:

a. AOAC staff lists all eligible methods for consideration and forwards that list with supporting documentation (e.g. ERP chair recommendation(s)) to the Chair of the Official Methods Board (OMB).
b. The Chair forwards the list along with any supporting information to the members of the OMB.
c. The OMB selects the Method of the Year. The winner is selected by 2/3 vote. If necessary, the OMB chair may cast tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the author(s) of the winning method. The corresponding author will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. All authors will be acknowledged at the annual meeting, will receive an award and a letter of appreciation. The name of the winner(s), with supporting story, will be carried in the announcement in the *ILM*.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: June 22, 2016

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: Va-c. Annual Meeting Activities and OMB Meetings

There are a number of AOAC stakeholder panel related meetings and expert review panel meetings taking place between August and the end of the AOAC Annual Meeting. Attached is a list of activities and summaries of the stakeholder related activities.

Additionally, Roman and Crowley will initiate a discussion on OMB meetings at the Annual Meetings and other OMB face to face meetings.

RECOMMENDATION: Pending OMB discussion.

ATTACHMENTS: AOAC Annual Meeting Summary

AOAC Meeting Activities

STAKEHOLDER PANEL MEETINGS

Meetings at AOAC INTERNATIONAL in Rockville, Maryland, USA			
August 30, 2016	9:00am – 5:00pm	AOAC Stakeholder Panel on Agent Detection Assays (SPADA)	Working groups will present draft standard method performance requirements (SMPRs®) for botulinum neurotoxin A, *Bruscella*, *Burkholderia* and *Variola*.

Meetings at AOAC Annual Meeting and Exposition in Dallas, Texas, USA			
September 16, 2016	8:30am – 5:00pm	AOAC Stakeholder Panel on Dietary Supplements (SPDS)	WGs will present draft standard method performance requirements (SMPRs®) for Aloe Vera, protein, and vitamin B12. Three new WGs will be launched for ginger, free amino acids, and vitamin K1 and K2.
September 17, 2016	8:30am – 5:00pm	AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN)	Stakeholders will receive updates on related international activities, related AOAC Official Methods and there will be a discussion led by the working group chair for carotenoids.
September 17, 2016	8:30am – 5:00pm	AOAC SPDS Working Groups	New WGs will be launched for ginger, free amino acids, and vitamin K1 and K2.
September 18, 2016	(8:30am – 12:30pm	AOAC Stakeholder Panel on Strategic Food Analytical Methods (SPSFAM)	Anticipated working groups for cannabis and proanthocyanidins will be launched during the SPSFAM. Agenda is in formation.
September 18, 2016	8:30am – 5:00pm	AOAC International Stakeholder Panel on Alternative Methodology (ISPAM)	Anticipated working groups for food allergens will be launched during the ISPAM meeting. Agenda is in formation.

EXPERT REVIEW PANELMEETINGS

Meetings at AOAC INTERNATIONAL in Rockville, Maryland, USA		
August 2, 2016	9:00am – 5:00pm	AOAC Expert Review Panel for SPDS – Aloin, Cinnamon, and Tea

Meetings at AOAC Annual Meeting and Exposition in Dallas, Texas, USA		
September 18, 2016	1:00pm – 3:00pm	AOAC Expert Review Panel for SPSFAM Ethanol in Kombucha
September 19, 2016	1:30pm – 3:30pm	AOAC Expert Review Panel for SPSFAM Selected Food Allergens in Foods
September 19, 2016	4:00pm – 6:00pm	AOAC Expert Review Panel for Fertilizers
September 19, 2016	6:30pm – 8:30pm	AOAC Expert Review Panel for Solids in Syrups
September 20, 2016	8:30am – 5:00pm	AOAC Expert Review Panel for SPIFAN Nutrient Methods
September 20, 2016	8:30am – 12:00pm	AOAC Expert Review Panel for Microbiology Methods for Foods and Environmental Surfaces
September 21, 2016	8:00am –10:00am	AOAC Expert Review Panel for Food Allergens – Gluten

THURSDAY POST BUSINESS MEETING MEETINGS		
September 22, 2016	8:00am – 12:00pm	AOAC Editorial Board
September 22, 2016	10:00am – 6:00pm	AOAC Official Methods Board Meeting