The Scientific Association Dedicated to Analytical Excellence®

AOAC INTERNATIONAL

Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN)

Working Group for Contaminants

Sodium Fluoroacetate (compound 1080)

Monday, March 16, 2015

AOAC INTERNATIONAL
2275 Research Blvd., Suite 300
Rockville, MD, 20850
UNITED STATES
dboyd@aoac.org
301.924.7077 x126

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.

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.

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

AOAC INTERNATIONAL

Stakeholder Panel for Infant Formula and Adult Nutritionals (SPIFAN)

Meeting at Hilton Washington DC North/Gaithersburg

620 Perry Parkway, Gaithersburg, MD 20877

CONTAMINANTS WORKING GROUP - DRAFT MEETING AGENDA

Monday, March 16, 2015

Meeting Start Time: 9:00AM (Eastern US)

SPIFAN Chair: Darryl Sullivan

(Covance Laboratories)

Location: Salon A/B

Registration Opens at 8:00AM

I. **INTRODUCTION (Sullivan – 9:00AM-9:10AM)**

Darryl Sullivan will call the Working Group meeting to order.

II. **STANDARD METHOD PERFORMANCE REQUIREMENT (SMPR) ORIENTATION/EDUCATION SESSION (Coates – 9:10AM-9:40AM)**

Scott Coates (AOAC) will provide information/education on the development of SMPRs.

III. **DEVELOPMENT AND CONSENSUS OF STANDARD METHOD PERFORMANCE REQUIREMENT (SMPR) DOCUMENTS (Boison-Working Group Chair – 9:40AM-12:45PM)**

The Working Group Chair will lead the Working Group discussions, review and reach consensus on SMPR.

1. **WORKING GROUP CHAIR, Joe Boison (CFIA)**
   LOW LEVEL PESTICIDE – SODIUM FLUOROACETATE (COMPOUND 1080)
   *(SMPR)

MORNING BREAK (10:30AM-10:45AM)

LUNCH (12:00PM – 12:45PM)

IV. **WRAP-UP (Sullivan – 12:45PM-1:00PM)**

Darryl Sullivan will wrap up all discussions and answer any additional questions.

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Darryl Sullivan, SPIFAN Chair

Darryl Sullivan of Covance Laboratories is the Chairperson for the Stakeholder Panel on Infant Formula and Adult Nutritionals.

Appointed by President Gayle Lancette in July 2010, Darryl Sullivan has been a champion in previous AOAC stakeholder efforts on nutrients in infant formula and adult nutritionals. He 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. Sullivan also served a three-year term as a director on the AOAC Research Institute Board of Directors. He was a founding member 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 becoming Chair of the OMB, he served as a member and then Chair of the Methods Committee on Commodity Foods and Commodity Products. Darryl Sullivan has been involved with methods validation for over 25 years. In addition to being involved as a Study Director for several AOAC *Official Methods*^{SM}. Sullivan's expertise in methods validation is frequently called upon by AOAC and a number of other scientific associations. 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 quite 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.

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Scott Coates, AOAC INTERNATIONAL
Chief Scientific Officer (CSO)

Scott Coates is a 21-year AOAC veteran now serving as the AOAC Chief Scientific Officer. Dr. Coates joined AOAC in 1992 as a manager for the AOAC Research Institute, and ran the *Performance Method Tested* program until 2009 when he was promoted to become AOAC's Chief Scientific Officer (CSO). As CSO, Coates is involved in every major AOAC project, ranging from biological threat agent detection, food/environmental microbiology, and nutritional chemistry of infant formula. Coates was the lead author of the *Guideline for Standard Methods Performance Requirements* in the 19th edition of the *Official Methods of Analysis.* Coates is a University of Maryland alumni has a B.S. in microbiology and a M.S. in Biotechnology Management.

The Scientific Association Dedicated to Analytical Excellence®

STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

Standard Method Performance Requirement (SMPR) Orientation

Scott Coates, CSO
AOAC INTERNATIONAL
March 16, 2015

1

The Scientific Association Dedicated to Analytical Excellence®

- Introduction
- Background
- Format
- Process
- Guideline for Development of SMPRs
- Performance parameters

The Scientific Association Dedicated to Analytical Excellence®

Standard Methods Performance Requirements

- Commonly referred to as:
  - SMPRs
  - "Smipper"s

AOAC SMPR 2011.006

Standard: Method Performance Requirements for Folate in Infant Formula and Adult/Pediatric Nutritional Formula

The Scientific Association Dedicated to Analytical Excellence®

SMPRs

- documents a community's analytical method needs.
- very detailed description of the analytical requirements.
- includes method acceptance requirements.
- published as a standard.

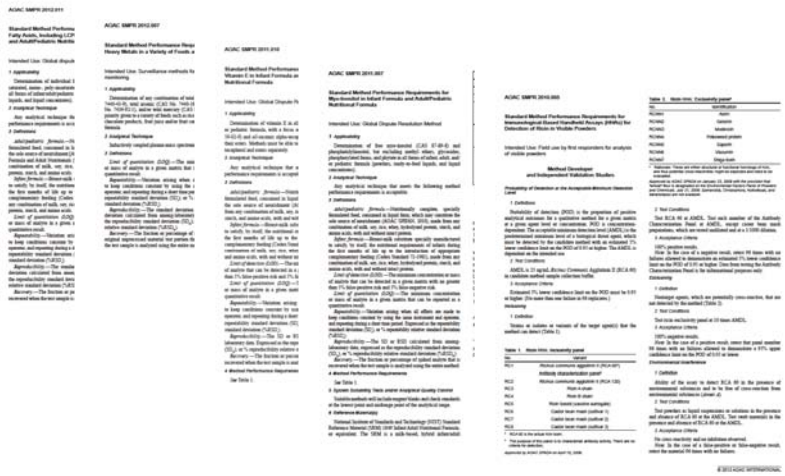
The Scientific Association Dedicated to Analytical Excellence®

Uses of SMPRs

- Basis for method acceptance and approval.
- Guidance to method developers for the development of new methods.
- Advance the state-of-the-art in a particular direction.
- Address specific analytical needs.
- Allow AOAC to reach a broader community of method developers and users.

The Scientific Association Dedicated to Analytical Excellence®

AOAC has adopted 50+ SMPRs



The Scientific Association Dedicated to Analytical Excellence®

SMPR Format

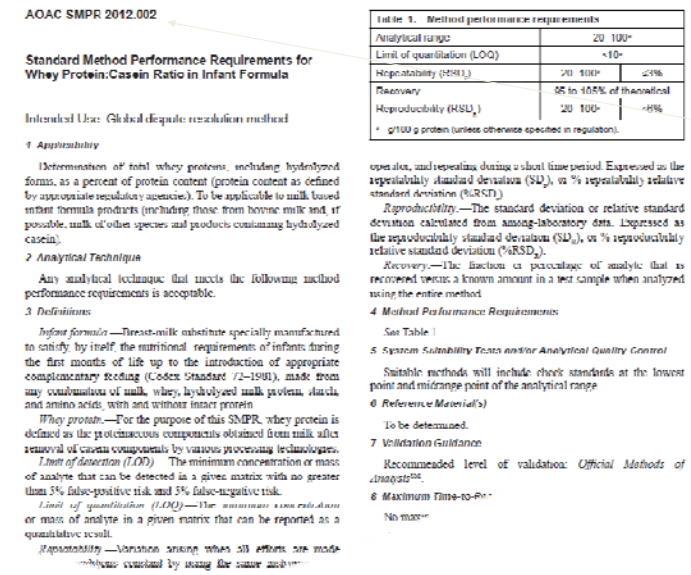
- Intended use
- Applicability
- Analytical technique
- Definitions

The Scientific Association Dedicated to Analytical Excellence®

SMPR Format

- System suitability
- Reference materials
- Validation guidance
- Maximum time-to-determination
- Method performance requirements table

The Scientific Association Dedicated to Analytical Excellence®



AOAC SMPR 2012.002

Standard Method Performance Requirements for Whey Protein:Casein Ratio in Infant Formula

Intended Use: Global dispute resolution method

1 Applicability

Determination of total whey proteins, including hydrolyzed forms, as a percent of protein content (protein content as defined by appropriate regulatory agencies). To be applicable to milk based infant formula products (including those from bovine milk and, if possible, milk of other species and products containing hydrolyzed casein).

2 Analytical Technique

Any analytical technique that meets the following method performance requirements is acceptable.

3 Definitions

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 (Codex Standard 72–1981), made from any combination of milk, whey, hydrolyzed milk protein, starch, and amino acids, with and without intact protein

Whey protein.—For the purpose of this SMPR, whey protein is defined as the proteinaceous components obtained from milk after removal of casein components by various processing technologies.

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 analyst

Table 1. Method performance requirements		
Analytical range	20–100*	
Limit of quantitation (LOQ)	≤10*	
Repeatability (RSD_r)	20–100*	≤3%
Recovery	95 to 105% of theoretical	
Reproducibility (RSD_R)	20–100*	≤6%

* g/100 g protein (unless otherwise specified in regulation).

operator, and repeating during a short time period. Expressed as the repeatability standard deviation (SD_r), or % repeatability relative standard deviation (%RSD_r).

Reproducibility.—The standard deviation or relative standard deviation calculated from among-laboratory data. Expressed as the reproducibility standard deviation (SD_R), or % reproducibility relative standard deviation (%RSD_R).

Recovery.—The fraction or percentage of analyte that is recovered versus a known amount in a test sample when analyzed using the entire method

4 Method Performance Requirements

See Table 1

5 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include check standards at the lowest point and midrange point of the analytical range

6 Reference Material(s)

To be determined.

7 Validation Guidance

Recommended level of validation: *Official Methods of Analysis*℠.

8 Maximum Time-to-Re

No max

SMPRs are published in the OMA.

SMPR ID numbers use the year and 3 numerals.

OMA ID numbers use the year and 2 numerals.

The Scientific Association Dedicated to Analytical Excellence®

SMPRs can be developed for all types of methods:

Quantitative methods

- Trace components: arsenic in food.
- Main components: nutrients in infant formula.

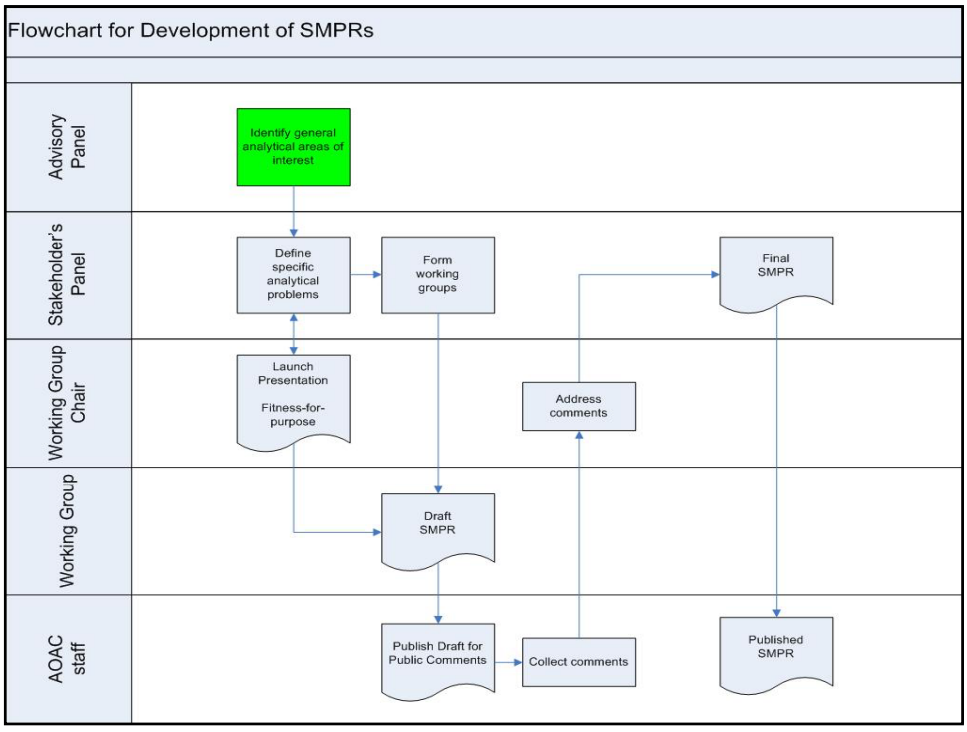
Qualitative methods

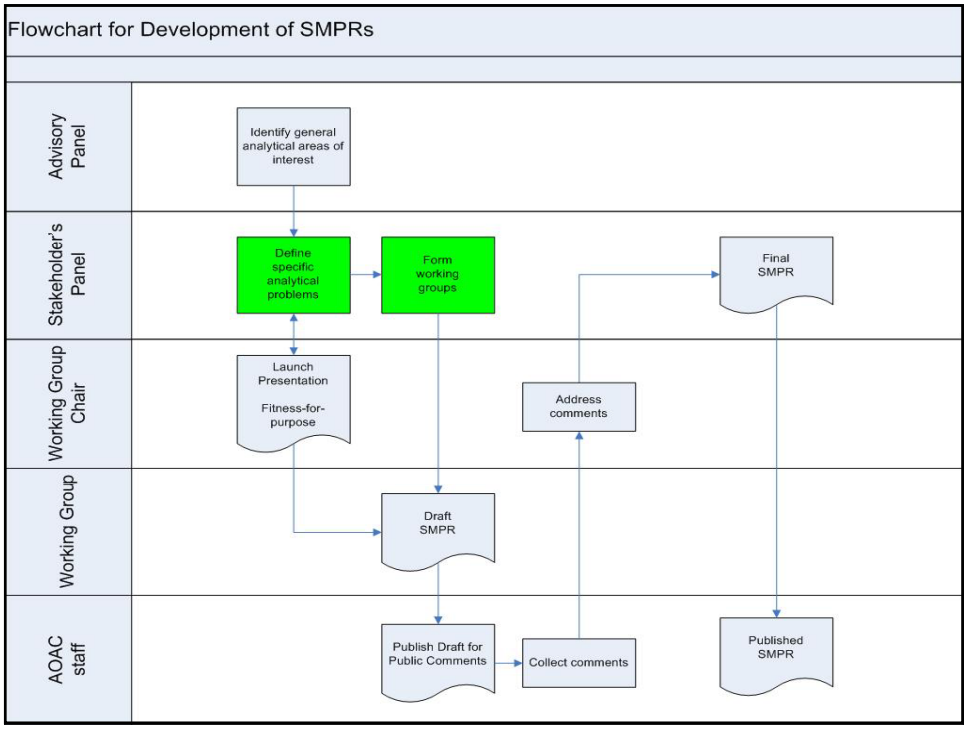
- Trace components: *Listeria* in cheese.
- Main components: chondroitin sulfate.

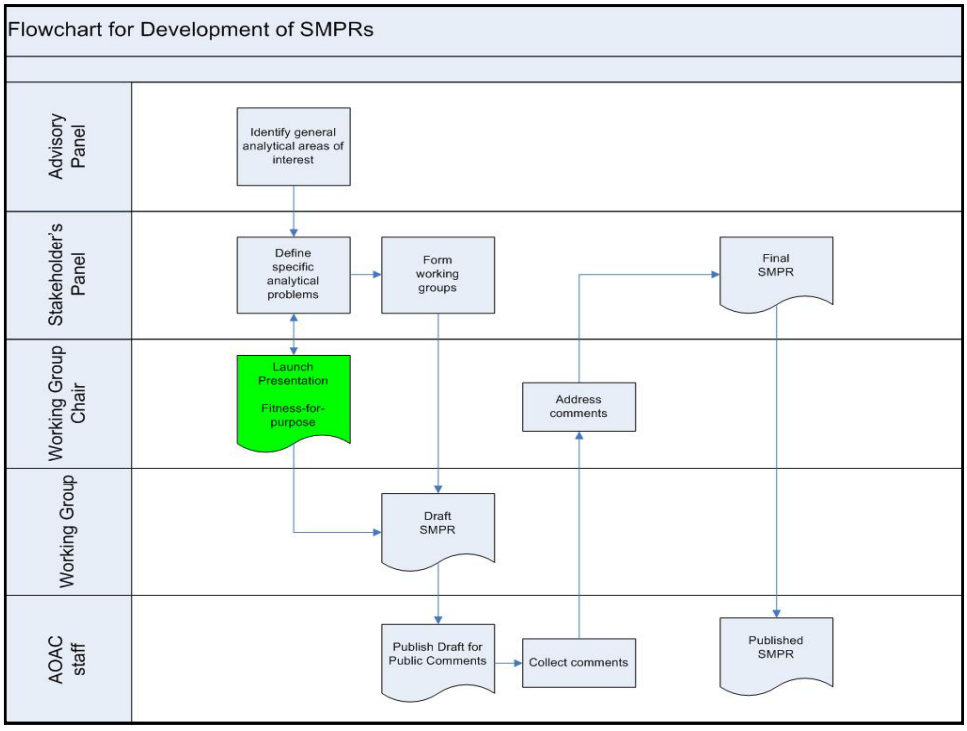
Identification methods: PDE5-Inhibitors in supplements.

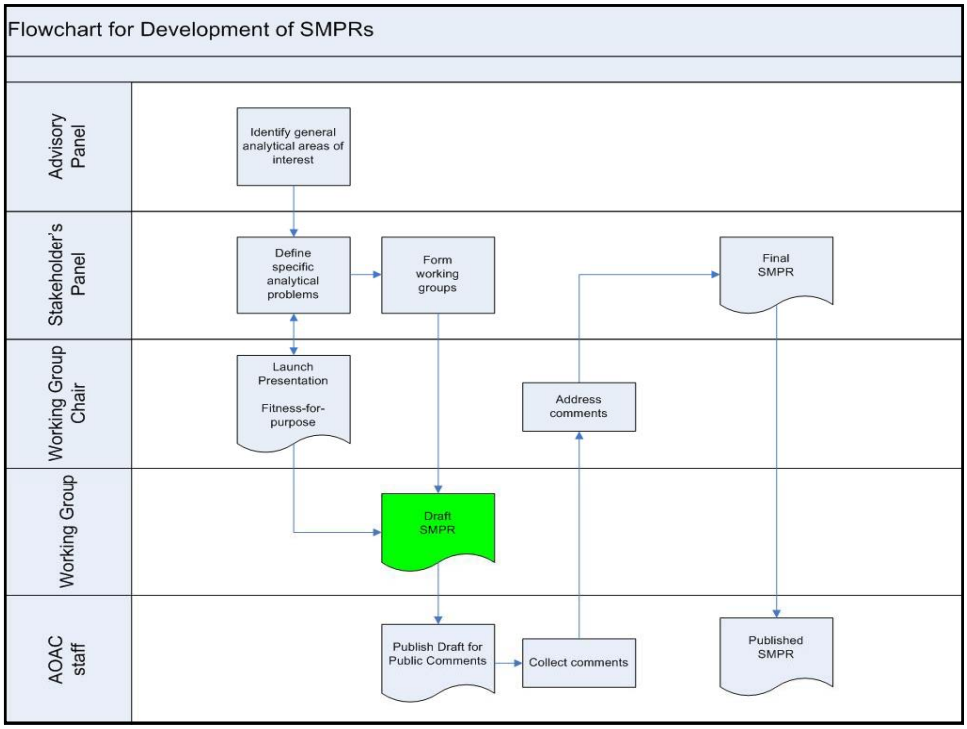
The Scientific Association Dedicated to Analytical Excellence®

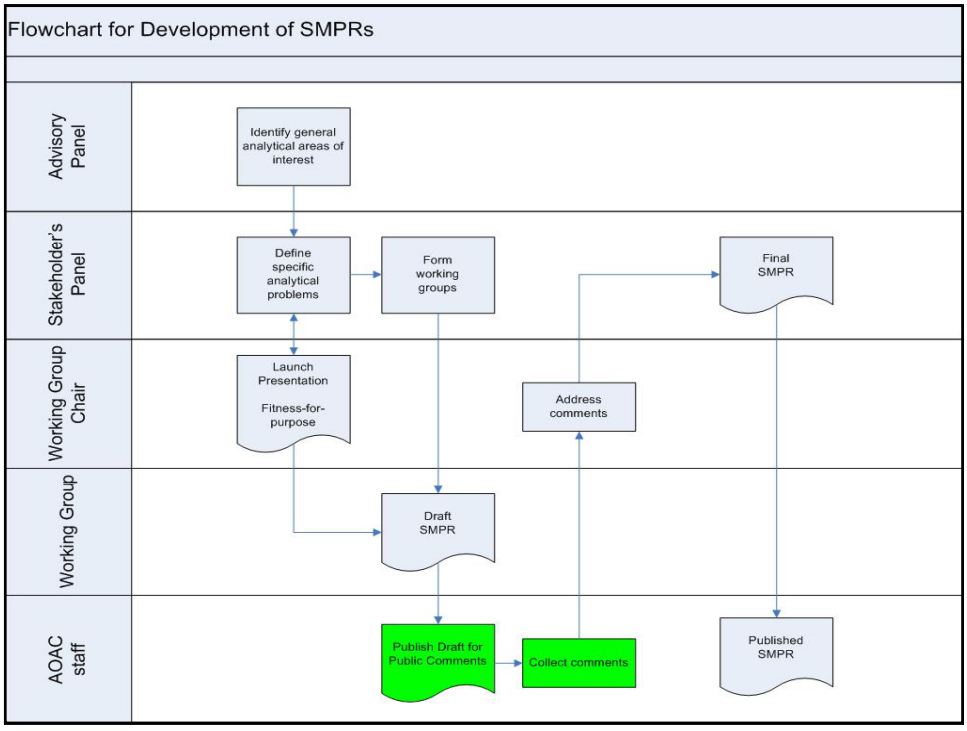
SMPR Process

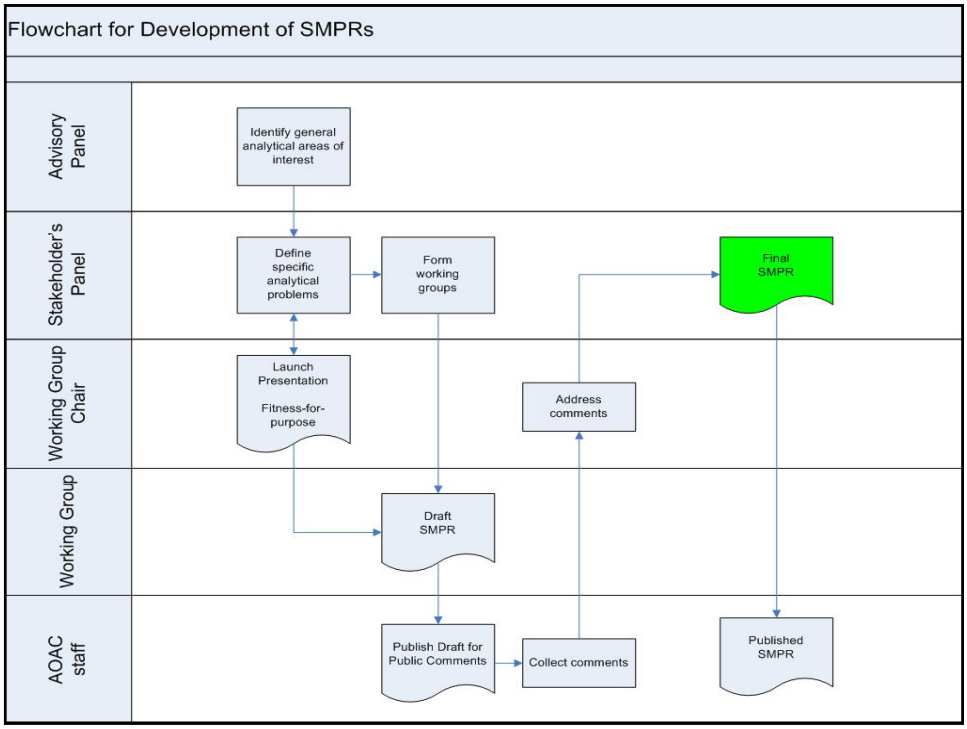


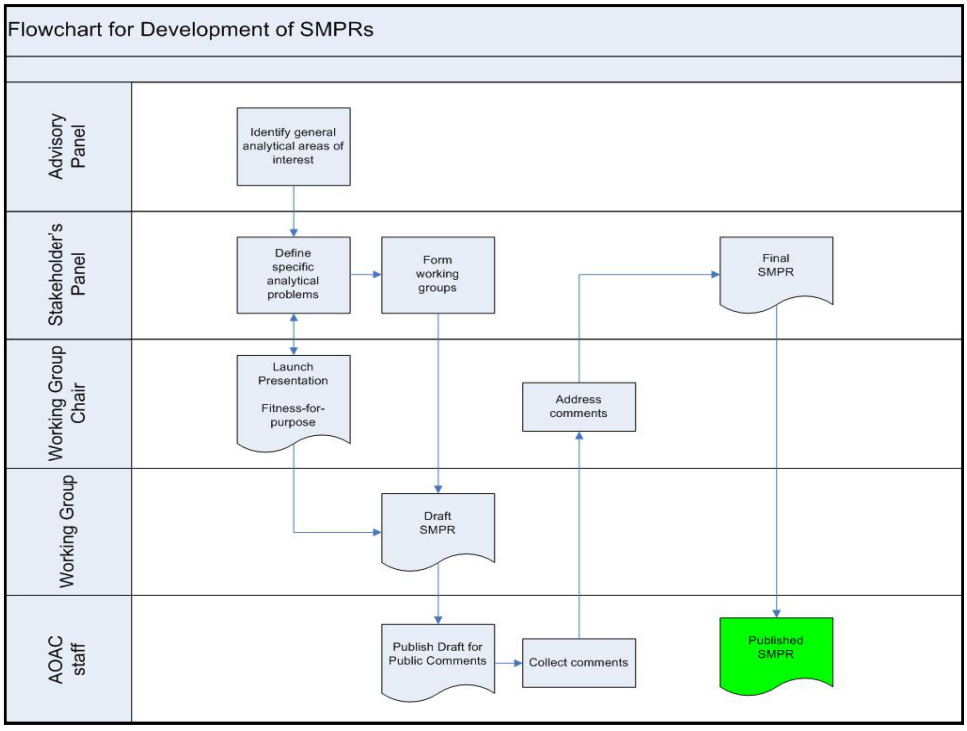

Flowchart for Development of SMPRs
Advisory Panel
Stakeholder's Panel
Working Group Chair
Working Group
AOAC staff
Identify general analytical areas of interest
Define specific analytical problems
Form working groups
Final SMPR
Launch Presentation
Fitness-for-purpose
Address comments
Draft SMPR
Publish Draft for Public Comments
Collect comments
Published SMPR


Flowchart for Development of SMPRs
Advisory Panel
Stakeholder's Panel
Working Group Chair
Working Group
AOAC staff
Identify general analytical areas of interest
Define specific analytical problems
Form working groups
Final SMPR
Launch Presentation
Fitness-for-purpose
Address comments
Draft SMPR
Publish Draft for Public Comments
Collect comments
Published SMPR


Flowchart for Development of SMPRs
Advisory Panel
Stakeholder's Panel
Working Group Chair
Working Group
AOAC staff
Identify general analytical areas of interest
Define specific analytical problems
Form working groups
Final SMPR
Launch Presentation
Fitness-for-purpose
Address comments
Draft SMPR
Publish Draft for Public Comments
Collect comments
Published SMPR


Flowchart for Development of SMPRs
Advisory Panel
Stakeholder's Panel
Working Group Chair
Working Group
AOAC staff
Identify general analytical areas of interest
Define specific analytical problems
Form working groups
Final SMPR
Launch Presentation
Fitness-for-purpose
Address comments
Draft SMPR
Publish Draft for Public Comments
Collect comments
Published SMPR


Flowchart for Development of SMPRs
Advisory Panel
Stakeholder's Panel
Working Group Chair
Working Group
AOAC staff
Identify general analytical areas of interest
Define specific analytical problems
Form working groups
Final SMPR
Launch Presentation
Fitness-for-purpose
Address comments
Draft SMPR
Publish Draft for Public Comments
Collect comments
Published SMPR


Flowchart for Development of SMPRs
Advisory Panel
Stakeholder's Panel
Working Group Chair
Working Group
AOAC staff
Identify general analytical areas of interest
Define specific analytical problems
Form working groups
Final SMPR
Launch Presentation
Fitness-for-purpose
Address comments
Draft SMPR
Publish Draft for Public Comments
Collect comments
Published SMPR

The Scientific Association Dedicated to Analytical Excellence®

Fitness-for-Purpose

- Very early in process
- General statement of method performance
- No or few acceptance criteria
- 1 or 2 paragraphs
- No formal format
- Not a standard

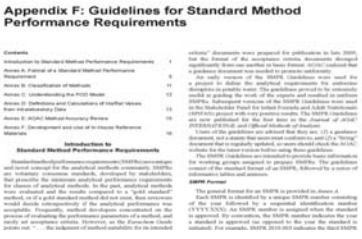
SMPR

- A deliverable
- Very detailed specification of method performance requirements
- Acceptance criteria
- 2 to 3 pages
- Standard format
- Formal AOAC standard
- Published in the OMA

The Scientific Association Dedicated to Analytical Excellence®

Appendix F: Guideline to SMPRs

- **Complete** guidance describing SMPRs and general validation requirements.
- 19th ed. of OMA
- On-line at: http://www.eoma.aoac.org/app_f.pdf


Appendix F: Guidelines for Standard Method Performance Requirements

Contents

Introduction to Standard Method Performance Requirements

The Scientific Association Dedicated to Analytical Excellence®

Performance Parameters

The Scientific Association Dedicated to Analytical Excellence®

Quantitative methods

- Analytical range
- Limit of detection
- Limit of Quantitation
- Repeatability
- Recovery
- Reproducibility

4. Method Performance Requirements

Analytical range	0.01–5.0[a]	
Limit of detection (LOD)	≤0.004[a]	
Limit of quantitation (LOQ)	≤0.01[a]	
Repeatability (RSD_r)	0.01[a]	≤15%
	0.2[a]	≤7%
	0.5[a]	
	5.0[a]	
Recovery	0.01[a]	90–110%
	0.2[a]	
	0.5[a]	
	5.0[a]	
Reproducibility (RSD_R)	0.3	≤11%
	0.6	
	1.0	
	2.5	
	5.0	
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.		
[a] µg/100 g expressed as cyanocobalamin in reconstituted final product.		

The Scientific Association Dedicated to Analytical Excellence®

Qualitative methods

- Probability of Detection (POD)
- Acceptable Limit of Detection (AMDL)
- Inclusivity
- Exclusivity

The Scientific Association Dedicated to Analytical Excellence®

Summary

- SMPRs provide a logical way to define what we need in a method.
- SMPRs provide a way to standardize inclusivity/exclusivity panels.
- The process allows a community to agree on and set the minimum performance requirements for a class of methods.

The Scientific Association Dedicated to Analytical Excellence®

Summary

- SMPRs provide an objective standard to judge candidate methods.
- SMPRs are unique in the analytical community.
- AOAC and its volunteers have produced 50+ SMPRs in 4 years, even for the toughest analytes.

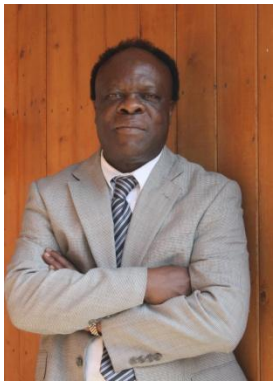
The Scientific Association Dedicated to Analytical Excellence®

Don’t worry -

- It’s a great process.
- We’ll be there at your side every step of the way.


The Scientific Association Dedicated
to Analytical Excellence®
Questions ?

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)



Joe Boison, Canadian Food Inspection Agency (CFIA)
SPIFN Contaminants Working Group Chair- Sodium Fluoroacetate - (compound 1080)

Dr. Boison is a Senior Research Scientist with the Canadian Food Inspection Agency (CFIA), and holds 2 Adjunct Professor Faculty positions (one in the Chemistry Department and the other in the Department of Veterinary Biomedical Sciences) at the University of Saskatchewan. In 2003, he was appointed a Fellow of the World Innovation Foundation (FWIF), was awarded the CFIA President's National Award for Leadership Excellence in 2010 and in 2012, he was appointed a Fellow of the AOACI.

Dr. Boison has been a member of the Food Safety Research Network Team responsible for reviewing and evaluating research proposals submitted by scientists from Agriculture & Agri-Food Canada and the Canadian Food Inspection Agency for funding considerations. He is an executive member of the Spectroscopy Society of Canada, a member of the Standards and Measurement Committee for the American Society for Mass Spectrometry (ASMS), a member of the AOAC International, and a member of the Canadian Delegation to the Codex Committee on Residues of Veterinary Drugs in foods (CCRVDF).

Dr. Boison is regularly consulted within and outside Government (primary producers, program managers, test kit manufacturers, fellow scientists) with regards to residue testing methods for in-plant and on-farm use. In his current role as AOAC International's General Referee (GR) on Veterinary Drugs, Dr. Boison authors an annual review paper on the methods of analysis used in the regulatory analysis of veterinary drugs.

Dr. Boison's research and academic interests include development of chromatographic and mass spectrometric methods for the identification and confirmation of veterinary drug residues in biological fluids and tissues in support of regulatory enforcement and/or for pharmacokinetic and pharmacodynamic studies. 2. Development and adaptation of commercially available rapid tests for field and laboratory screening of drug residues in biological fluids and tissues. 3. Automation of laboratory methods for the analysis of veterinary and human drugs. 4. Teaching and development of graduate and undergraduate students to acquire expertise in bio-analytical mass spectrometry, metabolism and pharmacokinetic studies.

Draft AOAC SMPR 2015.XXX; Version 3; March 12, 2015

Determination of sodium fluoroacetate ("Compound 1080") in infant and adult/pediatric nutritional formula

Purpose: AOAC SMPR's describe the minimum recommended performance characteristics to be used during the evaluation of a method. The evaluation may be an on-site verification, a single-laboratory validation, or a multi-site collaborative study. SMPRs are written and adopted by AOAC Stakeholder Panels composed of representatives from the industry, regulatory organizations, contract laboratories, test kit manufacturers, and academic institutions. AOAC SMPRs are used by AOAC Expert Review Panels in their evaluation of validation study data for method being considered for *Performance Tested Methods* or AOAC *Official Methods of Analysis*, and can be used as acceptance criteria for verification at user laboratories.

Approved by: Stakeholder Panel for Infant Formula and Adult Nutritionals

Intended Use: Surveillance and monitoring of infant formula, and adult / pediatric formula by trained technicians.

1. **Applicability:**
   Determinations of total sodium fluoroacetate in all forms of infant, adult, and/or pediatric formula (powders, ready-to-feed liquids, and liquid concentrates).

2. **Analytical Technique:**
   Any analytical technique that meets the following method performance requirements is acceptable.

3. **Definitions:**
   Accuracy[1]
   The closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value.

   Adult/Pediatric Formula
   Nutritionally complete, specially formulated food, consumed in liquid form, which may constitute the sole source of nourishment, made from any combination of milk, soy, rice, whey, hydrolyzed protein, 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[2], made from any 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.

[1] Corresponds to the VIM definition for "truness".
[2] Codex Standard 72 – 1981.

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. Expressed as the repeatability standard deviation (SD_r); or % repeatability relative standard deviation (%RSD_r).

Reproducibility
The standard deviation or relative standard deviation calculated from among-laboratory data. Expressed as the reproducibility relative standard deviation (SD_R); or % reproducibility relative standard deviation (% RSD_R).

Sodium fluoroacetate
The active ingredient in "Compound 1080", a rodenticide. IUPAC name: Sodium 2-fluoroacetate. CAS number: 62-74-8. See Figure 1.

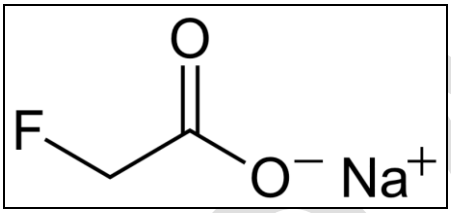


Figure 1: Chemical structure of sodium fluoroacetate.

4. Method Performance Requirements:

Analytical range	X – Y *
Limit of Detection (LOD)	Z*
Limit of Quantitation (LOQ)	≤ X*
Accuracy	± 20%
Repeatability (RSD_r)	≤ 14%
Reproducibility (RSD_R)	≤ 20%
Concentrations apply to: a) 'ready-to-feed" liquids "as is"; b) re-constituted powders (25 g into 200 g of water); and c) liquid concentrates diluted 1:1 by weight.	

*µg /100 g reconstituted final product.

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):**
   Follow ANNEX F: Development and Use of In-House Reference Materials in Appendix F: Guidelines for Standard Method Performance Requirements in the *Official Method of Analysis of the AOAC INTERNATIONAL* compendium.

7. **Validation Guidance**:
   Recommended level of validation: *Official Methods of Analysis*^{SM}

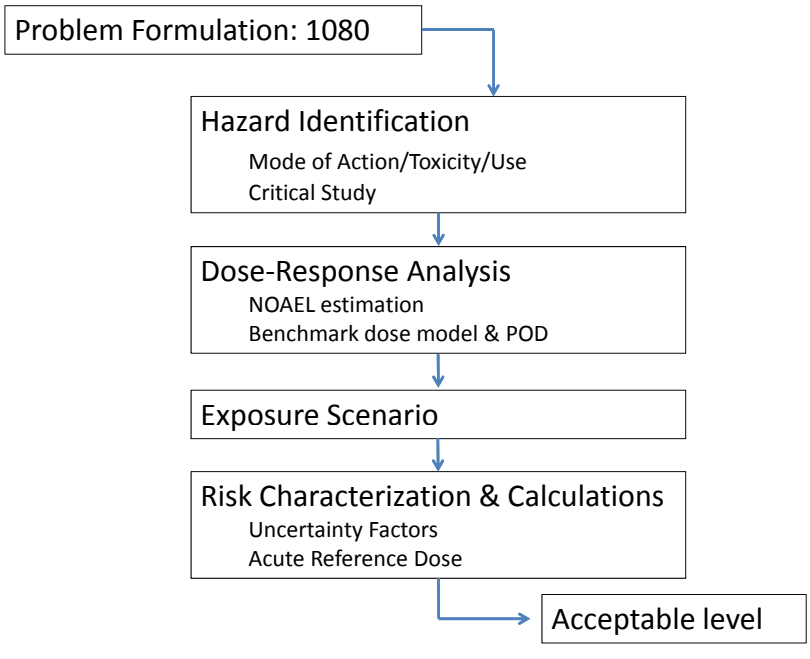
8. **Maximum Time-To-Result**: No maximum time.

Sodium Monofluoroacetate [Compound 1080]

Focused Risk Assessment

Dave Stone, Ph.D.
Pesticide Toxicology

March 16, 2015

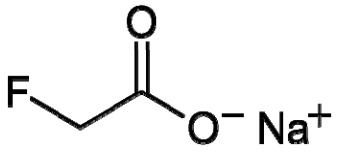


Problem Formulation

As a result of a recent threat to maliciously adulterate infant formula in New Zealand with 1080, a focused risk assessment was developed to determine the acute risk to infants and potential for short-term exposures to 1080. An acute reference dose is proposed to address concentrations of 1080 that are unlikely to result in clinically evident signs of poisoning. This focused risk assessment does not consider long-term exposures and chronic effects, persistent sources of 1080 from environment contamination, or adulteration of formula at retail establishments.

1080 Properties and Use

CASRN: 62-74-8
Mol Formula:
$C_2H_2FNaO_2$
Melting Pt: > 200 ^{0}C
High water solubility

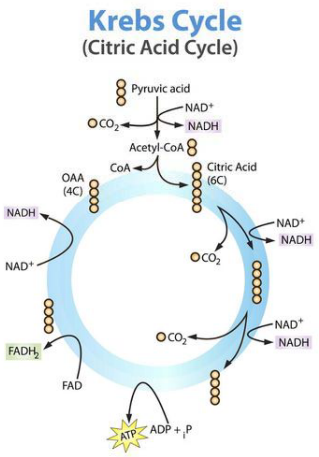


Limited in U.S. to livestock protection collars specific to coyotes. No recent human health risk assessments by EPA.

Majority of world's use occurs in New Zealand to control many vertebrate pests and as a conservation tool to control invasive species. Both aerial and ground control operations target brush possums (vectors for bovine TB).

1080's Toxicology

It is a metabolic poison targeting the Kreb's cycle. The metabolite, fluorocitrate, inhibits the Krebs cycle, resulting in accumulation of citrate. The Krebs cycle is universal across organisms and throughout the lifespan.



1080 is not mutagenic or thought to have carcinogenic potential. The dose-response curve is steep and well defined across several species. Signs/symptoms appear rapidly (~ 30 min – hours) in high dose, acute exposures.

Critical Study

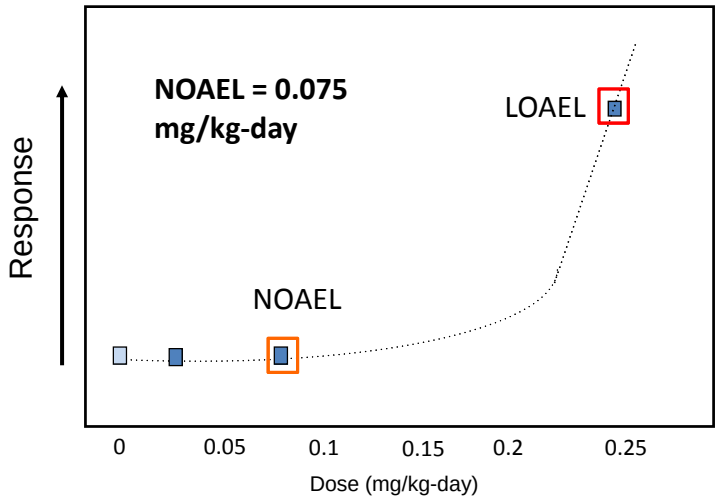
90-day subchronic feeding study on 6-week old Sprague-Dawley rats. Dosed at 0.025, 0.075 and 0.25 mg/kg-day.

A clear dose-response curve and well-established distinction between the NOAEL and LOAEL was observed. At the LOAEL, which corresponded to the highest dose group of 0.25 mg/kg-day, microscopic changes were detected in male rats to the heart and testes.

No changes in body weight, food consumption, hematology, and clinical chemistry suggest that the sublethal toxicity of 1080 is specific to target organs.

Eason and Turck (2002)

Dose Response



Eason & Turck 2002

Benchmark Dose Model

Researchers in NZ's Ministry of Health conducted a comprehensive review on 1080. They determined the testicular and cardiac effects noted in Eason & Turck's study were suitable for risk assessment.

To improve and refine the risk assessment, they applied a benchmark dose model using a response of 10% additional risk compared to background ($BMDL_{10}$).

$BMDL_{10}$ = 0.1 mg/kg-day

This value serves as the point-of-departure for the proposed reference value of this focused assessment.

Foronda et al. 2007

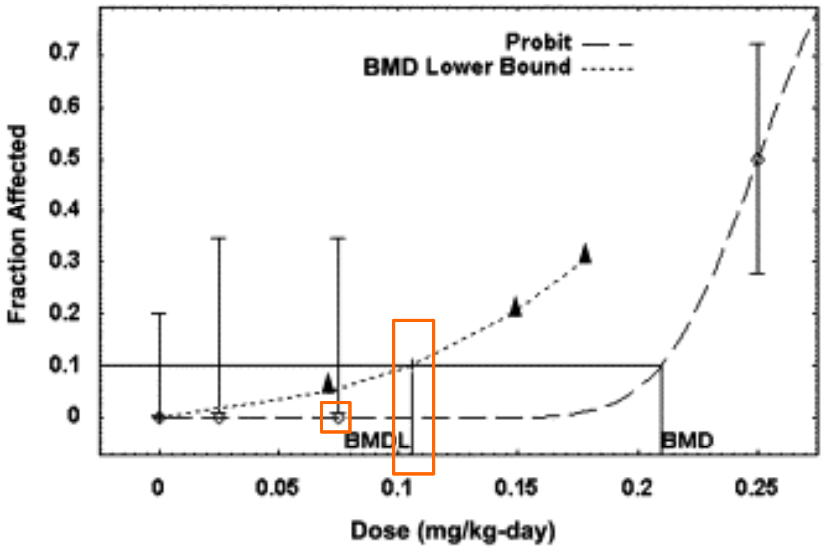


Illustration of benchmark dose with corresponding models for 1080 critical data for testicular and male cardiac effects (Foronda et al. 2007).

Uncertainty Factors

-interspecies variation (when the POD relies on animal models)

-intraspecies variation (to account for sensitive subpopulations)

-incomplete database

-extrapolation from acute to chronic exposure/effects

-additional safety/modifying factors as necessary

Uncertainty Factors

Interspecies uncertainty factor: The Eason and Turck study (2002) relied on rats to estimate toxicity. A standard UF of 10X is appropriate to extrapolate these findings to humans given possible differences in the toxicokinetics and toxicodynamics of 1080 between rats and humans.

Intraspecies uncertainty factor: Standard risk assessment practice is to include an uncertainty factor (UF) to account for sensitive sub-populations, such as infants and children. This UF is appropriate for this assessment and is set at 10X.

Uncertainty Factors

Incomplete database: This UF can be applied if critical studies are absent, if the MOA is poorly understood or other residual concerns remain. Robust studies have been conducted on 1080 and the MOA is well understood. As this assessment is focused on a short-term exposure and acute, clinically evident signs of poisoning, chronic studies are not relevant. As a result, an UF of 1X was applied.

Extrapolation to chronic exposure duration: Given the scope of this risk assessment, chronic exposure and the potential for chronic effects are not addressed. Therefore, an UF of 1X was applied to this risk assessment.

Safety/modifying Factors

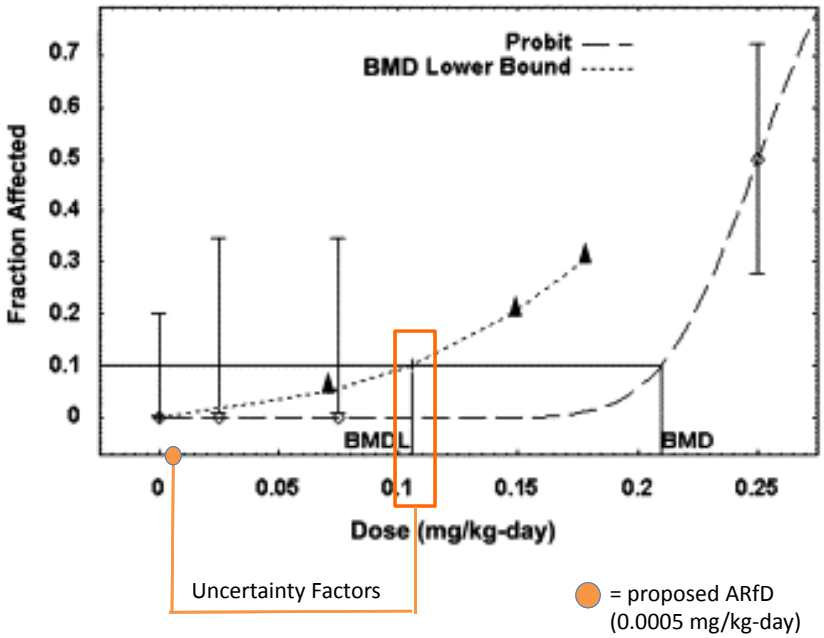
The mechanism of action of 1080 is to inhibit the proper functioning of the Krebs, or citric acid, cycle. It is essential to all life and operational through the lifespan. While infants have a higher metabolic rate compared with adults, no information was identified suggesting 1080's MOA against the Krebs cycle would be different. Despite any information to indicate higher sensitivity among infants, an additional 2X safety factor was applied given higher metabolic activity.

A total UF of 200 was selected in this focused risk assessment.

Acute Reference Dose

To reflect the exposure scenario and scope of this report, an acute reference dose (ARfD) was proposed to address the potential for clinically evident signs of poisoning. The ARfD is based on the premise that clinically evident signs of poisoning are more prominent, occur at much higher doses and have a rapid onset compared to the subchronic effects noted in the critical study used for the POD.

ARfD = 0.1 mg/kg-day/ 200 = 0.0005 mg/kg-day



Exposure Scenario

1080 should not be found in the diet. This deterministic exposure assessment addresses the recent threat of intentional adulteration of infant formula in New Zealand with 1080. This scenario assumes:

-a newborn infant weighing 3 kg
-56.6 g infant formula per day (equivalent to 95 kCal)
-infant formula constitutes 100% of diet
-to account for the possibility of acute, clinically evident effects in newborn infants
-short-term exposure duration

Risk Calculations

C_{ha} = (ARfD x BW)/IR, *where:*

C_{ha} = highest acceptable conc. of 1080 in formula (mg/kg)
ARfD = 0.0005 mg/kg-day
BW = 3 kg
IR = ingestion rate, 0.0566 kg formula/day

C_{ha} = 0.0265 mg/kg, or 27 µg 1080 per kg formula

Limitations

No risk assessment can consider all possible hazards and exposure scenarios, particularly when assessing the potential for a malicious or intentional activity. This focused risk assessment is specific to the manufacturing stage of infant formula and does not evaluate the potential for adulteration at retail establishments or other venues where formula is sold.

Uncertainty, and how to apply factors to account for uncertainty, is inherently subjective and often a matter of professional judgment, opinion or policy.

This report is not an appropriate basis to develop reference values such as a tolerable daily intake (TDI) or chronic oral reference dose.