1 **DRAFT AOAC Allergen SMPR Version 2; December 15, 2015**
2
3 **Detection and Quantitation of Selected Allergens**
4
5 **Intended Use**:   Reference method for cGMP compliance.
6
7 **1. Purpose:**   AOAC SMPRs describe the minimum recommended performance characteristics
8   to be used during the evaluation of a method.   The evaluation may be an on-site
9   verification, a single-laboratory validation, or a multi-site collaborative study.   SMPRs are
10   written and adopted by AOAC Stakeholder Panels composed of representatives from the
11   industry, regulatory organizations, contract laboratories, test kit manufacturers, and
12   academic institutions.   AOAC SMPRs are used by AOAC Expert Review Panels in their
13   evaluation of validation study data for method being considered for *Performance Tested*
14   *Methods* or AOAC *Official Methods of Analysis*, and can be used as acceptance criteria for
15   verification at user laboratories.
16
17 **2. Applicability**:
18   Detection and quantitation of egg, milk, peanut, and hazelnut food allergens in finished food
19   products and ingredients.   Method(s) shall uniquely identify each allergen.
20
21 **3. Analytical Technique**:
22   Mass spectrometry based methods.
23
24 **4. Definitions**:
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26 **Food Allergens**
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28   **Hazelnut**
29   Any of the nuts deriving from species of the genus *Corylus*, especially the nuts of the
30   species *Corylus avellana* (the common hazel tree). It is also known as cobnut or filbert
31   nut according to species. For the purposes of this SMPR, includes both raw and
32   processed nuts.
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34   **Milk**
35   For the purposes of this SMPR "milk" refers to pasteurized cow's milk.
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37   **Peanut**
38   The seed of the *Arachis hypogaea* plant. For the purposes of this SMPR, includes both
39   raw and roasted peanuts.
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41   **Whole Egg**
42   A combination of pasteurized [chicken] egg whites and egg yolks from the same
43   production batch blended together in their entirety, in natural proportions.[1]

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[1] Introduction to Egg Products, USDA Food Safety and Inspection Service, website: http://www.fsis.usda.gov/wps/wcm/connect/c5c85914-5055-4f09-8098-1a179a1c6e14/EPT_Introduction.pdf?MOD=AJPERES, accessed 12/15/2015.

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46   **Limit of Quantitation (LOQ)**
47   The minimum concentration or mass of analyte in a given matrix that can be reported as a
48   quantitative result.
49
50   **Method detection limit (MDL)**
51   The minimum concentration of a substance that can be measured (detected) and reported
52   with 99% confidence that the analyte concentration is greater than zero and is determined
53   from analysis of a sample in a given matrix containing the analyte using at least two ion
54   MS/MS transitions.[2]
55
56   **Repeatability**
57   Variation arising when all efforts are made to keep conditions constant by using the same
58   instrument and operator and repeating during a short time period. Expressed as the
59   repeatability standard deviation (SD_r); or % repeatability relative standard deviation
60   ($\%RSD_r$).
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62   **Reproducibility**
63   The standard deviation or relative standard deviation calculated from among-laboratory
64   data. Expressed as the reproducibility standard deviation (SD_R); or % reproducibility relative
65   standard deviation ($\% RSD_R$).
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67   **Recovery**
68   The fraction or percentage of spiked analyte that is recovered when the test sample is
69   analyzed using the entire method.
70
71 **5. Method Performance Requirements**:
72   See table 1.
73
74 **6. System suitability tests and/or analytical quality control:**
75   Suitable methods will include blank check samples, and check standards at the lowest point
76   and midrange point of the analytical range.
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78 **7. Reference Material(s):**
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80   Refer to Annex F: *Development and Use of In-House Reference Materials* in Appendix F:
81   *Guidelines for Standard Method Performance Requirements*, 19th Edition of the AOAC
82   INTERNATIONAL Official Methods of Analysis (2012). Available at:
83   http://www.eoma.aoac.org/app_f.pdf
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85   Whole Egg
86   •   NIST 8445
87   •   LGC SAL-RSM-5 (Check for characterization level)
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[2] 40 CFR Part 136, Appendix B to Part 136 - Definition and Procedure for the Determination of the Method
Detection Limit-Revision 1.11

91   Nonfat Milk Powder
92   • NIST SRM 1549 (nonfat milk powder)
93   • NIST SRM 1549a (whole milk powder)
94
95   Peanut
96   • NIST SRM 2387 (peanut butter)
97
98   Hazelnut
99   • No known reference material available.
100
101 **8. Validation Guidance**:
102
103   Method developers shall submit data evaluating the matrices in Table 2.
104
105   Appendix D: Guidelines for Collaborative Study Procedures To Validate Characteristics of a
106   Method of Analysis; 19th Edition of the AOAC INTERNATIONAL Official Methods of Analysis
107   (2012). Available at: http://www.eoma.aoac.org/app_d.pdf
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109   Appendix F: Guidelines for Standard Method Performance Requirements; 19th Edition of the
110   AOAC INTERNATIONAL Official Methods of Analysis (2012). Available at:
111   http://www.eoma.aoac.org/app_f.pdf
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113 **9. Maximum Time-To-Result:** None
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116   **Table 1: Method performance requirements.**

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Parameter	Target allergen			
	whole egg	**milk**	**peanut**	**hazelnut**
Analytical Range (ppm)	10-1000	10-1000	10-1000	10-1000
LOQ (ppm)	5	10	10	10
MDL (ppm)	10	10	10	10
Recovery (%)	60-120%	60-120%	60-120%	60-120%
% RSD_r	≤20 %	≤20 %	≤20 %	≤20 %
% RSD_R	≤ 30%	≤ 30%	≤ 30%	≤ 30%

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139 **Table 2: Priority Allergen/Matrix Combinations**
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whole egg	cookies bread dough salad dressing wine
milk	cookies, baked goods infant formula wine dark chocolate (optional matrix for methods that claim a chocolate matrix)
peanut	cookies ice cream breakfast cereal milk chocolate (optional matrix for methods that claim a chocolate matrix)
hazelnut	cookies ice cream breakfast cereal milk chocolate (optional matrix for methods that claim a chocolate matrix)

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