AOAC SMPR 2016.002

Standard Method Performance Requirements (SMPRs®) for Detection and Quantitation of Selected Food Allergens

Intended Use: Reference method for cGMP compliance

1 Purpose

AOAC SMPRs 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.

2 Applicability

Detection and quantitation of egg, milk, peanut, and hazelnut food allergens in finished food products and ingredients. Method(s) shall uniquely identify each allergen.

3 Analytical Technique

Mass spectrometry-based methods.

4 Definitions

Food allergens:

Hazelnut.—Any of the nuts deriving from species of the genus *Corylus*, especially the nuts of the species *Corylus avellana* (the common hazel tree).

Milk.—For the purposes of this SMPR, "milk" refers to pasteurized whole cow's (*Bos Taurus*) milk, and shall contain not less than 8 1/4% milk solids not fat and not less than 3 1/4% milkfat [*Code of Federal Regulations*, Title 21-Food and Drugs, § 131.110. Other internationally recognized definition may be applied.]

Peanut.—The seed of the *Arachis hypogaea* plant. For the purposes of this SMPR, includes both raw and roasted peanuts.

Whole egg.—A combination of pasteurized chicken (*Gallus gallus domesticus*) egg whites and egg yolks from the same production batch blended together in their entirety, in natural proportions [Introduction to Egg Products, U.S. Department of Agriculture-Food Safety and Inspection Service, http://www.fsis.usda.gov/wps/wcm/connect/c5c85914-5055-4f09-8098-1a179a1c6e14/EPT_Introduction.pdf?MOD=AJPERES, accessed 12/15/2015].

Method quantitation limit (MQL).—The minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result. MQL = average (blank) + 10 * s0 (blank) [*see* Table A3 in Appendix F: *Guidelines for Standard Method Performance Requirements*, *Official Methods of Analysis* (2016) 20th Ed., AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_f.pdf)].

Method detection limit (MDL).—The minimum concentration of a substance than can be measured and reported with 99% confidence that the analyte concentration is greater than zero. It is determined from analysis of a sample in a given matrix containing the analyte [Volume II—*Methods, Method Verification and Validation* ORA-LAB.5.4.5; Document No. IV-02; Version No.: 1.7; Section 2–*Microbiology*; Effective date: 10/01/03; Revised: 08/25/14; http://www.fda.gov/ScienceResearch/FieldScience/ucm171877.htm, accessed February 22, 2016].

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) [*see* Table A3 in Appendix F: *Guidelines for Standard Method Performance Requirements*, *Official Methods of Analysis* (2016) 20th Ed., AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_f.pdf)].

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) [*see* Table A3 in Appendix F: *Guidelines for Standard Method Performance Requirements*, *Official Methods of Analysis* (2016) 20th Ed., AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_f.pdf)].

Recovery.—The fraction or percentage of spiked analyte that is recovered when the test sample is analyzed using the entire method [*see* spiking method in Appendix M: *Validation Procedures for Quantitative Food Allergen ELISA Methods: Community Guidance and Best Practices* (2016) 20th Ed., AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_m.pdf)].

Table 1. Method performance requirements

	Target allergen			
Parameter	Whole egg	Milk	Peanut	Hazelnut
Analytical range, ppm	10–1000	10–1000	10–1000	10–1000
MQL[a], ppm[b]	≤5	≤10	≤10	≤10
MDL[a], ppm[b]	≤1.65	≤3	≤3	≤3
Recovery, %	60–120	60–120	60–120	60–120
RSD_r, %	≤20	≤20	≤20	≤20
RSD_R, %	≤30	≤30	≤30	≤30

[a] Definitions for MQL and MDL provided in section 4.
[b] Reported as ppm of the target allergen in food commodity, i.e., 25 ppm of "whole egg" in cookies.

5 Method Performance Requirements

See Table 1.

6 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.

7 Examples of Appropriate Reference Material(s)

Whole egg:
NIST 8445
LGC SAL-RSM-5 (check for characterization level)

Peanut:
NIST SRM 2387 (peanut butter)
LGC FAL-RFM1017-XXX

Hazelnut:
LGC FAL-RFM1015-50 or FAL-RFM1015-50Â or FAL-RFM1015-5

Additional materials can be found at the LGC and FAPAS websites:
LGC = http://www.lgcstandards.com/HK/en/search/?q=allergen:relevance:category:CEFP_77243
FAPAS = http://fapas.com/quality-control-materials/Available-quality-control-materials.cfm

Refer to Annex F: *Development and Use of In-House Reference Materials* in Appendix F: *Guidelines for Standard Method Performance Requirements*, *Official Methods of Analysis* (2016) 20th Ed., AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_f.pdf).

NIST = National Institute of Standards and Technology

LGC = Formerly the UK Laboratory of the Government Chemist, now simply "LGC Standards"

FAPAS = Formerly the Food Analysis Performance Assessment Scheme in the United Kingdom, now simply "FAPAS"

8 Validation Guidance

Method developers shall submit LOQ, MDL, recovery and precision data for the matrices in Table 2.

Appendix D: *Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis*, *Official Methods of Analysis* (2016) 20th Ed., AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_d.pdf)

Table 2. Priority allergen/matrix combinations

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)

Appendix F: *Guidelines for Standard Method Performance Requirements*, *Official Methods of Analysis* (2016) 20th Ed., AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_f.pdf)

9 Maximum Time-to-Result

None.

Approved by AOAC Stakeholder Panel on Strategic Food Analytical Methods (SPSFAM). Final Version Date: March 31, 2016. Effective Date: March 31, 2016.