AOAC SMPR® 2016.016

Standard Method Performance Requirements (SMPRs) for Identification of Non-Animal-Derived Proteins in Dietary Supplements

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 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 methods 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

Methods must identify one or more non-animal-derived proteins and their corresponding sources (Table 1) in the presence of potential adulterants (Table 2) in ingredients and finished dietary supplements.

3 Analytical Technique

Any analytical technique is acceptable.

Table 1. One or more recommended non-animal-derived proteins from these sources
Algae
Canola
Flax
Hemp
Pea
Potato
Pumpkin
Quinoa
Rice
Soy
Wheat

Table 2. Examples of nonprotein ingredients including nonprotein ingredients and adulterants
Melamine
Urea
Free amino acids
Creatine
Caffeine
Taurine
Surfactants
Peptides (less than 10 000 daltons)
Nontarget proteins

Table 3. Method performance requirements

	Study	Parameter	Parameter requirement	Target test concn, %	Minimum acceptable results
Single-laboratory validation	Matrix study	POI at low concentration	Minimum of 33 replicates representing all target analytes in Table 2	0.1	90% POI[a] of the pooled data for all target compounds and matrices.
		POI at high concentration	Minimum of 5 replicates per matrix type spiked at 10x the designated low level target test concentration	10	100% correct analyses are expected[b]
		POI at 0 concentration	Minimum of 5 replicates per matrix type	0	
	Selectivity	False-positive rate	Evaluate samples containing nonprotein ingredients and adulterants listed in Table 3	10	≤5%
Multi-laboratory validation	Matrix study[c]	LPOI	Use Appendix N: *ISPAM Guidelines for Validation of Qualitative Binary Chemistry Methods*	0.1	≥0.85[a]
				10	≥0.95[a]
		$LPOI_{(0)}$		0	≤0.05[a]

[a] 95% confidence interval.

[b] 100% correct analyses are expected. Some aberrations may be acceptable if the aberrations are investigated, and acceptable explanations can be determined and communicated to method users.

[c] Multilaboratory validation matrix study (LPOI and $LPOI_{(0)}$) are not required for First Action *Official Methods of Analysis* approval.

4 Definitions

Protein.—Naturally occurring and synthetic polypeptides having molecular weights greater than about 10000 daltons (the limit is not precise) (IUPAC definition).

Probability of identification (POI).—Proportion of positive analytical outcomes for an identification method for a given matrix at a given analyte level or concentration. LPOI is the Laboratory Probability of Identification.

5 Method Performance Requirements

See Table 3.

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 Potential Reference Material(s)

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 of AOAC INTERNATIONAL* (current edition), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_f.pdf)

8 Validation Guidance

Data demonstrating method performance for the non-animal-derived proteins listed in Table 1 in the presence of the potential nonprotein ingredients, including adulterants listed in Table 2, is recommended.

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

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

Appendix K: *Guidelines for Dietary Supplements and Botanicals*, *Official Methods of Analysis of AOAC INTERNATIONAL* (current edition), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_k.pdf)

9 Maximum Time-to-Result

None.

Approved by the AOAC Stakeholder Panel on Dietary Supplements (SPDS). Final Version Date: September 16, 2016.