AOAC SMPR 2020.XXX; Draft AOAC Standard Method Performance Requirements (SMPRs) for Non-Targeted Testing (NTT) of Ingredients for Food Authenticity/Fraud Evaluation of Honey; version 4; February 18, 2020

Intended Use

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 MethodsSM* or AOAC *Official Methods of Analysis*^{SM}, and can be used as acceptance criteria for verification at user laboratories.

1. Applicability

This document contains assessment parameters on the performance of Non-Targeted Testing methods to monitor honey for the probable presence of Economically Motivated Adulterants (EMA).

This SMPR was designed to evaluate Non-Targeted Testing (NTT) methods developed to assess potential economic adulteration in defined commodities. The SMPR was purposely designed with general descriptions to be applicable to a broad range of innovative analytical platforms and chemometric approaches. Binary analytical results of "Authentic" or "Not Authentic" on defined samples from the performance of the method will be used to perform the evaluations by the Expert Review Panel.

Complete documentation of the collection and use of authentic samples is to be supplied by the method authors. The scope of authentic samples will be the applicable scope of the NTT method and expansion of the scope is possible with the inclusion of additional authentic samples into the baseline calibration, and validation using the protocol listed in this SMPR.

2. Analytical Technique

A non-targeted method to be used to evaluate foods and ingredients for possible EMAs. Any method generating a baseline fingerprint of the authentic material and comparing test sample fingerprints to assess differences will be considered. The final binary result identifies test samples as either authentic or potentially adulterated. This method demonstrates reliability using the requirements listed in this SMPR.

For single lab validation studies, the method will be evaluated using prescribed adulterated materials as shown in Table 1. Methods approved at this level will proceed to a second level of evaluation (i.e., multi-laboratory validation) where blinded samples containing unknown adulterants will be sent to laboratories participating in the ensuing multi-laboratory validation.

The scope of the NTT method will be defined by the authentic samples used in generating the baseline fingerprint.

3. Definitions

Applicability Statement – a general statement about the intended purpose and scope of the method entailing key aspects of expected achievements for the specific situation and circumstances. Key points to cover are the intended matrix, the purpose, and an indication of sensitivity, specificity, and significance (USP Appendix XVIII).

Authentic Samples – Samples representative of the genuine commodity. These samples should represent the food's or ingredient's variability seen naturally in the commodity. The authentic samples used to generate the product baseline fingerprint will be used to properly define the NTT method testing scope. Documentation for authentic honey samples must contain any feeding protocols used in the production of the honey to properly authenticate the material.

Baseline Fingerprint – A food-specific model created by software evaluation of collected analytical data.

Economically Motivated Adulteration – The fraudulent addition of non-authentic substances or removal or replacement of authentic substances without the purchaser's knowledge for economic gain of the seller (USP Appendix XVIII).

False Origin – Honeys containing mislabeled geographic and botanical sources.

Authentic Honey – The type(s) of honey used to generate the baseline fingerprint. The method's scope of authenticity is defined by the honey(s) used in generating the baseline fingerprint.

Single Laboratory Validation – Demonstration by one laboratory of method performance on the validation samples described in Table 1.

Multilaboratory Validation – Demonstration between laboratories using adulterated samples created by a third-party group and supplied blindly to the participating laboratories.

Sugars – The intentionally-added sugars to be included in a method's evaluation include high fructose corn syrup, sucrose, fructose, glucose, beet sugar, cane sugar, and invert sugar.

4. Method Performance Requirements

(Table 1: Method Performance Requirements)

Test	Adulterant	%Adulterant in Test Materials	Number of Samples to be Tested[1]	Number of Test Results Qualified as Adulterated
Baseline	None (Authentic Honey)	0%	Establish Baseline Fingerprint[2]	
Validation using Authentic Samples[3]	None	0%	30	0
Validation[4]	Sugars	5%	30	30
Validation[4]	Molasses	5%	30	30

1. Multiple samples from the same batch of adulterated material can be used for method evaluation.
2. Full details on protocol used to establish an authentic fingerprint must be supplied.
3. Method validation using authentic samples shall cover the entire scope used in creating the baseline fingerprint.
4. Method validation using adulterated samples shall cover the entire scope used in creating the baseline fingerprint.

5. System Suitability Tests and/or Analytical Quality Control

Suitable methods will include authentic and adulterated material check standards.

6. Reference Materials

A detailed description of the process used to obtain and evaluate authentic samples, and of the test protocol establishing the baseline fingerprint must be supplied.

7. Validation Guidance

a) Data demonstrating method performance is required.

b) Available guidance documents:

a. AOAC INTERNATIONAL Guidelines for Validation of Botanical Identification Methods, Journal of AOAC International Vol. 95, No. 1, 2012.

b. Statistical analysis of interlaboratory studies. LII. Sample size needed to meet performance requirement on proportion. http://lcfltd.com/AOAC/tr347-SAIS-LII-sample-size-needed-for-PR-for-proportion.pdf

c. United States Pharmacopeia (USP). Appendix XVIII: Guidance on Developing and Validating Non-targeted Methods for Adulteration Detection. Food Chemicals Codex, 3rd supplement to 11th ed.; USP: Rockville, MD, 2019

8. Maximum Time-to-Results

None