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Frequently Asked Questions: Guidance on Testing Methods

The purpose of this document is to provide answers to frequently asked questions regarding 'Guidance on Testing Methods.'

1. What does the USDA consider as the limit of detection (LOD) minimum when selecting a testing method?

Section 7 CFR 66.9(c)(4) of the Standard states that method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements. LOD is the lowest amount or concentration of analyte in a sample which can be reliably detected. As such, entities should use their best discretion when selecting a test method to ensure appropriate sensitivity.

2. What does USDA consider a “fit for purpose” method?

Section 7 CFR 66.9(c)(2) of the Standard states that analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing. Regulated entities should ensure that the method selected is appropriate for their specific analyte of interest and validated for the product. Additionally, the method is fit for purpose if it has appropriate accuracy, precision, robustness, reliability, reproducibility, and range for the entity’s testing needs.

3. In what instances could a method not be “fit for purpose”?

USDA recognizes that not all methods are appropriate for each target analyte or each product. As such, regulated entities should understand how their product may possess inherently interfering compounds to various methods and use discretion when selecting a method that is fit for purpose. For example, highly refined foods may contain lipids that interfere with a PCR reaction. Regulated entities must follow appropriate procedures such as ISO guidelines (ISO 21568) or other acceptable methods to remove PCR inhibiting compounds in the sample extraction process.

4. What are highly refined foods or ingredients?

USDA has not defined highly refined food or ingredient but uses the phrase to refer to food and ingredients that have been processed to a degree that they may no longer contain detectable modified genetic material. If a regulated entity does not want to make a bioengineered food disclosure for a highly refined ingredient, they must comply with the requirements of 7 CFR 66.9.

5. Which type of analytical testing method does the USDA prefer, qualitative or quantitative?

USDA does not prescribe a particular method, as long as the method selected is fit for purpose and otherwise meets the regulatory requirements.

6. Where can I find literature about testing method selection?

When referencing outside sources for selecting a testing method, USDA recommends referencing the International Organization for Standardization's (ISO) International Standard 24276 *Foodstuffs -Methods of analysis for detection of genetically modified organisms and derived products- General requirements and definitions*, Codex Alimentarius Commission document CAC/GL 74-2010 *Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods*, or AOAC Official Methods of Analysis.

7. What should my sample size be?

USDA does not have a sample size requirement. Regulated entities should follow recommendations for performance and validation criteria which can be found in Codex Alimentarius Commission document CAC/GL 74-2010 *Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods*.

8. Can regulated entities validate their own testing method?

Yes, regulated entities can validate their own testing methods. Regulated entities should follow internationally accepted method validation protocols and ensure that their laboratory's quality assurance is suitable for testing, consistent with the requirements of 7 CFR 66.9(c).

9. Will somebody filing a complaint that a bioengineered food was not properly disclosed be required to provide evidence that their testing methods meet the criteria in the regulations and associated guidance documents?

As noted at 7 CFR 66.402, compliance with the Standard is based on recordkeeping and AMS will look at a regulated entity's records to determine whether they complied with the disclosure requirements of the Standard. AMS will not be testing foods to determine compliance with the Standard and will not rely solely on test results submitted by people making a complaint.