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Frequently Asked Questions: Guidance to Ensure Acceptable Validation of a Refining Process

The purpose of this document is to provide answers to frequently asked questions regarding the 'Guidance to Ensure Acceptable Validation of a Refining Process.'

1. Do I have to validate a refining process?

No, a regulated entity is not required to validate a refining process. Under the Standard, regulated entities must make a bioengineered food disclosure if they are using a food on the AMS List of Bioengineered Foods (the List), or a food produced from an item on the List unless they maintain records, in accordance with 7 CFR 66.9, to demonstrate that modified genetic material is undetectable. If regulated entities do not have the records described in 7 CFR 66.9 and do not want to create them, they must make a bioengineered food disclosure.

According to 7 CFR 66.9, a validated refining process is one possible way to demonstrate that modified genetic material is not detectable. Another way, as allowed by 7 CFR 66.9(a)(1), is to maintain records that demonstrate the food is sourced from a non-bioengineered crop or source. Such records may include organic certification; country of origin records that show the food is imported from a country that does not produce bioengineered crops; or affidavits from suppliers stating the food is sourced from non-bioengineered crops.

The final way to demonstrate that modified genetic material is not detectable, as allowed by 7 CFR 66.9(a)(3), is to maintain testing records that demonstrate the absence of modified genetic material. Such records may be, among other things, certificates of analysis showing that each batch or lot of a food or ingredient was tested and does not contain detectable modified genetic material. Guidance on appropriate testing methods can be found at <https://www.ams.usda.gov/rules-regulations/be/validation-process>.

2. Do I need to validate each step in the refining process?

Approaches to process validation may differ, but a regulated entity is not required to validate each key step in a process. Rather, they can identify and validate that by the time an ingredient produced from a bioengineered crop reaches a certain key step, that modified genetic material has been rendered undetectable. They do not need to identify the point at which the modified genetic material became undetectable.

If further process steps exist after the key step that is chosen, those additional steps must not introduce detectable modified genetic material back into the process.

3. Is end product testing allowed?

Yes, regulated entities may test the finished ingredient for detectable modified genetic material to validate that the refining process used to create that ingredient renders any modified genetic material undetectable.

4. If multiple ingredients are produced using a similar process, can I validate the common process used to produce each ingredient?

Yes, if a process is common to the production of multiple ingredients, a regulated entity may validate the part of the production process that is common to those ingredients.

5. Do I need to re-validate the entire process if minor changes are made?

No, minor changes do not require a regulated entity to re-validate an entire process. A regulated entity only needs to re-validate a process when they make significant changes to that process. Significant changes are changes to key steps that could impact or affect the process's ability to make modified genetic material undetectable (i.e. time, temperature, content level). If minor changes are made that do not hinder the process or the key step's ability to render the genetic material undetectable, then re-validating the entire process is not necessary.

6. If another facility has validated a refining process, does my facility also need to validate the same refining process?

No, validation refers to the process, not the facility in which the process occurs. As such, once a process is validated under the Standard and all recordkeeping requirements are followed, a regulated entity does not need to revalidate that process when completed in a different facility.

7. How often should I monitor my refining process?

Monitoring is the ongoing process of ensuring that the validated refining process is followed to ensure the modified genetic material is rendered undetectable. In most cases, the quality control procedures many regulated entities already have in place are sufficient for this purpose. USDA encourages regulated entities to establish their own monitoring protocols, such as observation of monitoring activities, review of records, and, in some cases, ongoing analytical tests.

8. What is the limit of detection for rDNA in a finished ingredient?

USDA does not have a specified threshold of minimal detection for rDNA. USDA recognizes that testing methodology may evolve so that a future test may have a lower limit of detection of rDNA than current tests. As such, USDA has not established a limit of detection to allow for new and emerging technologies to detect increasingly minimal levels of rDNA.

9. What constitutes a significant change in a validation process?

Significant changes are changes to the defined key steps that could impact or affect the process's ability to meet specified requirements of the Standard. Factors that could significantly alter key steps include, but are not limited to, changes in temperature or time.

10. Can in-house laboratories be used to validate a refining process that renders modified DNA undetectable?

USDA allows regulated entities to validate their own refining process. Laboratories that follow the National Bioengineered Food Disclosure Standard Guidance on Testing Methods may be internal or external laboratories.

11. Is there a zero tolerance for modified genetic material?

Section 7 CFR 66.5 of the Standard states that there is an allowance for inadvertent or technically unavoidable BE presence of up to 5% for each ingredient. As explained at 83 Fed. Reg. 65848-65849, this threshold exemption recognizes the complexities of the supply chain and acknowledges that bioengineered and non-bioengineered foods may be harvested by and processed on the same equipment. This exemption does not apply when a regulated entity intends to use a highly refined bioengineered food ingredient but does not refine it to the point where modified genetic material is no longer detectable.

12. What does “undetectable” mean?

Pursuant to 7 CFR 66.9(a), modified genetic material is undetectable if, pursuant to the recordkeeping requirements of § 66.302, the regulated entity responsible for making a BE food disclosure maintains:

- (1) Records to verify that the food is sourced from a non-bioengineered crop or source;
- (2) Records to verify that the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable; or
- (3) Certificates of analysis or other records of testing appropriate to the specific food that confirm the absence of modified genetic material.

USDA recognizes that testing methodology may evolve so that a future test may detect modified genetic material in a food or ingredient that current tests do not. If the modified genetic material in that food ingredient becomes detectable under 7 CFR 66.9 in the future, the food ingredient would be subject to BE disclosure.

13. If USDA is not establishing a limit of detection or further defining “undetectable,” does that mean undetectable is a “moving target”?

USDA recognizes that testing methodology may evolve so that a future test may detect modified genetic material in a highly refined food or ingredient that current tests do not. If the modified genetic material in that food ingredient becomes detectable under 7 CFR 66.9 in the future, the food ingredient would be subject to BE disclosure.

However, a process validated in conformance with the requirements of 7 CFR 66.9(a)(2) and 7 CFR 66.9(b) remains valid as long as a regulated entity does not make significant changes to that process. As such, a regulated entity can validate a process one time and as long as they do not make significant changes to that process, any foods or ingredients produced using that process would not require a bioengineered food disclosure as long as appropriate records are maintained. In this instance, the detectability of modified genetic material is determined at the time of validation and there is no “moving target.”

14. How long should records be maintained verifying a validated process?

Regulated entities should maintain records, such as validated process verifications, for at least two years beyond the date the food or food product is sold or distributed for retail sale. Regulated entities that choose to use a validated refining process to demonstrate that modified genetic material is not detectable would need to maintain appropriate records for the entire time they use the validated process, plus an additional two years beyond the date that any food or food product produced using that validated process is sold or distributed for retail sale.