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National Bioengineered Food Disclosure Standard
Guidance to Ensure Acceptable Validation of a Refining Process

The regulations implementing the National Bioengineered Food Disclosure Standard (the Standard) identify the requirements for a validated refining process at 7 CFR 66.9(b)-(c). In the final rule, AMS indicated it would provide industry stakeholders further guidance to validate a refining process. As described at 7 CFR 66.9(a), there are three ways to show modified genetic material is not detectable: (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. This guidance pertains to 7 CFR 66.9(a)(2) and 7 CFR 66.9(b) on how to ensure acceptable validation of a refinement process. For more guidance on detectability testing, 7 CFR 66.9(c) Standards of performance for detectability testing, see National Bioengineered Food Disclosure Standard Guidance on Testing Methods.

As explained at 7 CFR 66.9(b)(2), once a refining process has been validated, additional testing is not necessary to confirm the absence of detectable modified genetic material in food subsequently refined through that process, provided that no significant changes are made to the validated process, that records are maintained to demonstrate that the refining process has been validated, and that the validated refining process is followed. Also, a process only has to be validated in accordance with the regulations once, and may be applicable to multiple facilities or manufacturers so long as that specific process is followed and appropriate records are maintained.

General Steps to Validate a Refinement Process

1. **Identify raw materials, ingredients, and product-contact materials**.

2. **Define characteristics and intended use of end product.**
   For the Standard, a defined characteristic of the end product would be that modified genetic material is undetectable.

3. **Define the sequence and interaction of all processing steps used to arrive at the end product.**
   Utilize process map(s), written procedure(s), and/or other means to document processes step-by-step, beginning to end. Some of these items may already exist as a part of a Quality Management System or another form of existing monitoring system.

4. **Identify key step or steps in the refinement process that may influence the end product's characteristics and its ability to meet specified requirements.**
   A key step is any action or activity that can influence (prevent, reduce, or eliminate) the ability to meet specified requirements. For the Standard, determine the step(s) in the refining process that renders modified genetic material undetectable, or the series of steps in the process (which may include the entire process) after which modified genetic material is undetectable.

   Define the parameters (e.g., time, temperature, content level) and decision criteria (i.e., limit(s)) that make it a key step. It is important to identify parameters that can be measured. These parameters are what is studied during validation to determine if the intended end product characteristics, such as making modified genetic material undetectable, is achieved. If minor changes are made in the future, the refinement process would not need to be revalidated if the key parameters are not affected.

5. **Assemble relevant validation information that demonstrates the refinement process operates as intended to meet specified requirements (end product characteristics), conducting studies as needed.**

   Validation is the collection of evidence/data to demonstrate that a key step(s) consistently and effectively meets specified requirements, such as making modified genetic material undetectable.

   The collection of evidence/data, may be achieved through a variety of approaches depending on the product, processes/steps, and specified requirements. Approaches include testing, reference to scientific or technical literature or previous validation studies, experimental data applicable to in-plant operations, or applied data obtained during operational conditions.

   The evidence/data needed to validate a key step (to meet the specified requirement) may be available from other sources, so additional data may not be needed. If so, regulated entities should maintain a copy of the other source's evidence/data for their records. Also, the evidence/data may be applicable to multiple facilities and/or manufacturers; each would

simply need to maintain copies as records.

Ultimately, evidence/data is needed to demonstrate that the key step(s) renders modified genetic material undetectable. If other data sources do not exist, testing is often a means to collect evidence and demonstrate modified genetic material is undetectable.[1]

Note, non-key steps are documented within procedures and maps. It is important to ensure and document that steps that occur after key steps do not alter the intended end product characteristics, for example, do not introduce modified genetic material.

6. **Continually verify the refinement process is operating as validated**

   Verification is the confirmation, through objective, recorded evidence, that the validated process continues to meet the specified requirements. It requires monitoring that identified parameters of the key step(s) are operating as intended and validated. Measurements are to be recorded to demonstrate the key step(s) occurred as validated. Regulated entities should establish a system, including frequency, for monitoring the parameters of the key step(s).

7. **Revalidate the refinement process, as applicable, if significant changes are made to the process.**

   If significant changes are made to the validated refinement process, especially the key step(s), it will need to be revalidated, as described above, to determine if the process/step, as changed, operates as intended to meet specified requirements. Significant changes are changes to the defined key step(s) that could impact or affect the process's ability to meet specified requirements.

8. **Maintain record(s) of the validation and ongoing verification.**

   Regulated entities must maintain records to demonstrate that the refining process has been validated and that the validated refining process is verified/followed pursuant to 7 CFR 66.9(b)(2).

   In accordance with 7 CFR 66.300 *et. seq.*, customary or reasonable records must be maintained to demonstrate compliance with the Standard. Regulated entities must maintain

[1] Testing in this instance is conducted one-time as part of the validation process. This is not to be confused with ongoing end-product testing, allowed by 7 CFR 66.9(a)(3), which is used in lieu of validating the refinement process.

records for at least two years beyond the date the food or food product is sold or distributed for retail sale. Some of the examples of customary or reasonable records that could be used to demonstrate compliance with the disclosure requirements of this part include, but are not limited to, third party certifications, laboratory testing results, validated process verification, and other records generated or maintained by the regulated entity in the normal course of business.