



Agricultural Marketing Service

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National Bioengineered Food Disclosure Standard Instruction to Ensure Acceptable Validation of Refining Processes

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 instructions to validate a refining process. This document provides instructions for validating a refining process.

Among other things, the testing shall meet the following standards, as required by the regulations: (1) laboratory quality assurance must ensure the validity and reliability of test results; (2) 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, (3) the demonstration of testing validity must ensure consistent accurate analytical performance; and (4) method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

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 and provided that records are maintained to demonstrate that the refining process has been validated and that the validated refining process is followed. A validated process is not unique to a specific manufacturer; once a process has been validated in accordance with the regulations, that specific process does not need to be validated by others so long as that specific process is followed and appropriate records are maintained.

General Steps to Validate a Process^{1,2}

1. **Identify raw materials, ingredients, and product-contact materials.**
2. **Define characteristics and intended use of end product.**

For the National Bioengineered Food Disclosure Standard (the Standard), a defined characteristic of the end product would be that genetic material is not detectable.

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

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Management System or another form of monitoring system (e.g. Hazzard Analysis and Critical Control Points (HACCP)).

4. Identify all control measures (i.e., critical process steps) that may influence the end product’s characteristics and its ability to meet specified requirements.

A control measure is any action or activity that can influence (prevent, reduce, or eliminate) the ability to meet specified requirements. Determine the step(s) in the process that impacts the identified characteristics of the end product. To meet the NBFDS, determine the step(s) in the refining process that renders genetic material undetectable.

More than one control measure may be necessary to effectively manage or meet a specified requirement and the control measures may occur at different steps in the process.

5. Select critical control points (CCPs) where control measures can be evaluated for meeting the specified requirements.

CCPs must be measurable. Determine when and how the control measures (i.e., critical process steps) will be measured to validate genetic material is rendered undetectable.

Define the parameters (e.g., time, temperature, content level) and decision criteria (i.e., limit(s)) that will be used to determine that the process was effective.

6. Assemble relevant information to determine if control measures operate as intended to meet specified requirements, conducting studies as needed.

6a. Validation: Validation is the collection of evidence/data to demonstrate that defined, operational activities consistently and effectively meet specified requirements.

The assembly of validation information can be achieved through a range of approaches, depending on the product, processes, and specified requirements. Approaches include: reference to scientific or technical literature or previous validation studies; experimental data applicable to in-plant operations; applied data obtained during operational conditions; mathematical modelling; and surveys².

The information needed to validate a control measure (to meet the specified requirement) may be available from other sources so additional data may not be needed. Simply, maintain a copy of the validation study for records. If additional data is needed, determine the appropriate approach(es) to collect CCP data.

6b. Verification: Verification is the confirmation, through objective evidence, that the validated process meets or continues to meet the specified requirements. It is the application of tests or other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended. *Verification is the use of additional tools to*

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confirm control measures operate as intended to meet the specified requirement and to ensure control measures are being adhered to. Verification information occurs at initial validation and on an ongoing basis as a process check.

Example initial verification tool: analytical testing. The laboratory test selected is determined by the measurable characteristics of the end product or a measurable critical control point. Test methods should be appropriate for intended use, i.e., fit-for-purpose. Laboratory methods of analysis need to be carefully considered for ultra-refined processed foods (e.g., oils and sugars). Genetic material may be removed (absent) or difficult to detect and the chemical and physical characteristics of the matrix may cause interferences, potentially rendering classical polymerase chain reaction (PCR) techniques inappropriate. An indirect measurement may be more appropriate.

Examples of ongoing verification tools: observation of monitoring activities, review of records, and, in some cases, ongoing analytical tests (e.g., food safety testing).

6c. Monitoring: **Monitoring** is the conducting of planned observations or measurements to continually assess whether control measures are operating as intended and validated. *For on-going monitoring of a validated process, measurements will need to be continually recorded to demonstrate the control measures (i.e., critical process step) occurred as validated. Establish a system, including frequency, for monitoring control of the CCP.*

6d. Re-validation [as applicable]: *If significant changes are made to the validated process or process deviations occur, the control measures will need to be re-validated, as described above, to determine if the process, as changed, operates as intended to meet specified requirements. Significant changes are changes that could impact or affect the control measures and the ability to meet specified requirements.*

7. Document and analyze the validation data. Determine if the process will produce an end product that consistently meets specified requirements. Maintain record(s) of the validation.

Records should be auditable and traceable.

Useful Resources

¹ISO 22000:2005, Food safety management systems—Requirements for any organization in the food chain.

²CAC/GL 69-2008. Guidelines for the validation of food safety control measures.