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TECHNICAL SPECIFICATION FOR FOOD PRODUCTS
WITH NON-GENETICALLY ENGINEERED INGREDIENTS PROCESS VERIFIED

Revisions in this document

0 25/09/2016 **Creation**

1. SCOPE AND FIELD OF APPLICATION

This Technical Specification for Products (STP) aims to give a robust system to define the process of preparing Food products without non-genetically engineered (non-GE) ingredients.

The considered Food products are intended for sale in the United States (U.S.) and on the European market (EU).

The Technical Specification for Products may be used by a Food manufacturer (defined herein as an "operator). The Technical Specification is based primarily on product traceability with focus on the control of cross-contact or co-mingling between genetically engineered (GE) and non-GE ingredients at every level of the supply chain and manufacturing process, as well as an effective product market removal plan.

The STP is developed in accordance with EU legislative labeling requirements for GMos (EU Regulations 1829/2003 and 1830/2003) and with the U.S. market needs and specific approaches, taking into consideration US federal and State guidance, proposed and passed laws, and subsequent regulations related to GE.

This STP can be applied to the processing of single ingredients or multi-ingredient products intended for human consumption, when some ingredients may derive both from commercially available GE and non-GE crops. For management of facilities producing both GE and non-GE products, the impact of the GE products will need to be considered.

The products that can be the subject of certification[1] are:

Class 1 Products that are at risk of cross contamination; products whose "historic" composition provided for the use of raw materials that are at risk;

Class 2 Products that contain or that are composed of raw materials that are at risk

This specification does **NOT** apply to products in which the presence of GMOs is expressly forbidden by law.

2. REGULATORY AND NORMATIVE REFERENCES

- **Reg (CE) n. 1829/2003 -** 22 September 2003: relating to genetically modified food and feed http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0298&from=EN

- **Reg (CE) n. 1830/2003 -** 22 September 2003: concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R1830&from=EN

- **2015 – FDA - Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants** http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059098.htm

- Vermont Law No. 120. An act relating to the labeling of food produced with genetic engineering. http://ago.vermont.gov/assets/files/Consumer/GE_Food/ACT%20120%20As%20Enacted.pdf

- Vermont Annotated – Consumer Protection Rule 121 http://ago.vermont.gov/assets/files/Consumer/GE_Food/Guidance%20-%20Rule%20CP%20121%20Annotated.pdf

- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC http://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a8-4d20-86a8-0baaf0518d22.0004.02/DOC_1&format=PDF

- Center for Environmental Risk Assessment (CERA) GM Crop Database http://cera-gmc.org
- **UNI EN ISO 22005:2008**: Food Chain traceability
- **ACCREDIA (SINCERT) document RT-11 14/12/2004 version 01** "Minimum requisites for the certification of products having Non-GMO characteristics/requisites".

[1] Products whose composition does not include raw material at risk GMO, cannot be certified within the scope of this document, unless the company can prove that the formulation has been changed.

3. DEFINITIONS

The United States Department of Agriculture (USDA) defines these terms as follows:
–**Genetic Engineering (GE):** "Manipulation of an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques."
–**Genetic Modification (GM)**: "The production of heritable improvements in plants or animals for specific uses, via either genetic engineering or other more traditional methods. Some countries other than the United States use this term to refer specifically to genetic engineering."
–**Agricultural Biotechnology**: "A range of tools, including traditional breeding techniques, that alter living organisms, or parts of organisms, to make or modify products; improve plants or animals; or develop microorganisms for specific agricultural uses. Modern biotechnology today includes the tools of genetic engineering."

Genetically Modified organism (GMO): an organism, other than a human being, whose genetic material has been altered in a way that does not occur naturally by mating and / or genetic recombination.

Genetically Engineered (**GE) Critical:** An organism, or a product produced from this organism, which has commercially available GE versions.
A list of food-related GE critical organisms is enclosed in Annex I of the STP.
An organism or a product produced from this organism is not regarded as GE critical if it is not listed as GE critical in Annex I. This Annex is based on the Center for Environmental Risk Assessment (CERA) GM Crop Database.

Food: "food" means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

Ingredient: Any substance, including food or color additives, used in the manufacture or preparation of a food and still present in the finished food, even if in altered form.

Raw materials: food matrix including ingredients, additives, spices, technological aids used in the preparation and processing of food products.

Cross contact: In the context of Genetically Engineered ingredients prevention, "cross-contact" occurs when a residue or other trace amount of an GE food is unintentionally transferred into another food, despite good manufacturing practices (GMP).

Verification plan:
The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control or measure is or has been operating as intended.

4. PRODUCT CLASSIFICATION

Reference is made to the applicable product classification.

5. BASIC QUALITATIVE REQUISITES

The Food products must maintain its original non-GE status, and it must be managed to avoid cross-contact or co-mingling with GMO raw materials and ingredients throughout the supply chain. The implementation of the requirements of the STP does not substitute for the compliance with any applicable law or regulation in force.
The STP is intended to be applied in combination with existing laws and regulations governing the labeling of food products.

5.1. Analysis of risks

An analysis of risks must be performed for the purpose of identifying the products / ingredients/ raw materials of interest.
To this end, the raw materials and ingredients that are at risk must be classified as follows:
Class A Raw materials and Ingredients that contain detectable DNA
Class B Raw materials and Ingredients that do not contain DNA, but that may originate from products that are genetically modified
The risk of cross contamination, however, must be taken into consideration in the above classification.

DNA-FREE Raw materials and Ingredients (Class B)
When the production processes include a material that is DNA-free or whose DNA cannot, in any case, be amplified (e.g. maize glucose, maize oil), the analytical tests to verify the GMO-free origin are carried out in the preceding phases of the production chain; said phases are chosen on the basis of significance of the analytical test. (The analytical test results must indicate the presence of amplifiable DNA of the species that is the subject of the research).

5.2. Process and product control

5.2.1. Flow of operations

The phases within the production process that are potentially at risk must be identified and operational methods of control must be defined.
The analysis of risks must be reviewed periodically to ensure its adequacy and it must always be reviewed when new products are introduced.
Transportation conditions of ingredients shall be agreed and appropriate documentation shall accompany all supplies clearly identifying the product, lot number, quantity, source and destination in order to avoid any accidental contamination of G.E.

The packaging shall be clean, original, undamaged, labelled, within the best-before-date if applicable and in full compliance with the supply contract.
All the procedures, GMP (good manufacturing practices) shall be recorded and used as part of the risk analysis mentioned above, in the food manufacturing process taking into consideration:

- All points that are potentially subject to G.E contamination e.g. areas shared for warehousing, production, packaging, equipment facilities, etc.
- All activities aimed at minimizing the risk of G.E contamination.

The ingredients are subject to sampling; the finished product is subject to sampling as well only when the analysis of risks points out potential cross-contamination.
The operator shall develop a sampling and analysis program to validate the non-GE status of the supply chain.
The sampling frequency shall be based on a risk assessment for each ingredient, taking into consideration the source material and its GE risk and the nature of the ingredient (e.g., primary material, derivative).
A statistically valid sampling and testing plan shall reflect the level of monitoring appropriate for the risks inherent in the production/handling system, as well as industry standards.

Due to the heterogeneous nature of GE materials, the operator shall follow sampling procedures that meet legal requirements and good sampling practices to ensure representative samples are obtained.

Analyses of the samples shall be performed by a laboratory that is ISO 17025 accredited for GE genetics based testing using the real time PCR analyses for the crops and inputs in question. In the analysis report, sampling methods, detection limits, and methods shall be specified.
If no DNA is detected in the sample and therefore not "testable" through PCR, the non-GE status of the sample must be verified by batch-specific traceability back to testable inputs to the ingredient or product.

If one non-conformity is found, the product must be promptly identified and segregated. Should NON-conformity be detected when the finished product is already on the market, the company shall immediately inform DNV GL and agree upon appropriate actions.

5.2.2. Supplier requisites

The company must prepare technical specifications relative to raw materials and ingredients that rule out GMO contamination; said specifications must be officially shared with suppliers.

The following criteria must be applied in the selection of suppliers of materials at risk:
1. Certification of the product for the "non-GE" requisite or the ability to supply guarantees on the lot furnished. (Certificate of the product purchased and certificate of the analysis of the lots);
2. Contractual relationship defined between the parties;
3. Plan of the controls and audits of the supplier.

If the analytical test results performed on samples received from the supplier prove to be insignificant, the sampling should be carried out during audits on the supplier facilities.

The audits to be performed at the suppliers' must have the following two objectives:
- to carry out sampling (see Point 2: disposition to include into the contractual document) of the individual ingredients/raw materials having A and B criticality.
- to verify the management of the non-GMO requisite (analytical plans, declarations, audits of suppliers, etc.) for the products that are supplied to the company and that are considered to have A and B criticality.

Points 1 and 2 are also to be applied for any spot purchases.

5.3. Characteristics of the Food product

Absence of all GMOs is the target for all Non-GE Food products concerned by this STP.

The actual analytical method detection limit is currently done at about 0.01 %.

The acceptable limit for the presence of GMOs is:
= 0.9 % transgenic DNA on species specific DNA.
Considering the EC regulations and the lack of formal content definition into the U.S.

For values between the method detection limit 0.01 % and 0.9 %, the accidental nature of the event must nonetheless be demonstrated by the applicant/licensee.

The threshold that triggers an investigation by the operator into the source of cross-contact or co-mingling is defined as the method detection limit.

Information from the investigation, such as sampling protocol, geographical origin, supplier status etc., shall be recorded and applied to prevent future cross-contact or co-mingling.

6. PACKAGING AND MARKING

Sample label statements consistent with this STP, and which may be associated with an operator-owned logo or mark, are:

FOR FDA-REGULATED PRODUCTS: For products where the ingredients do not include poultry or meat

- No GMO Ingredients Process Verified

No prior label approval is required

FOR USDA-REGULATED PRODUCTS: For products where ingredients include meat or poultry in the multi-ingredient final product

- No GE Ingredients Process Verified

In this case, the label must be pre-approved by USDA/FSIS.

7. CRITERIA FOR LOT ACCEPTANCE

Lots can be accepted if:

- there are quality registrations that demonstrate the observance of traceability requisites and of process control;
- the samples analyses show clear conformance to non-GE contamination, within the limits of acceptability as expressed in the sampling plan.

8. SAMPLING

The sampling methods depending the materials (solids, liquids, powders…) shall use the best practices as defined into:

- CODEX ALIMENTARIUS General Guidelines on sampling -CAC/GL 50-2004.
- CODEX ALIMENTARIUS Recommended methods of sampling - CAC/GL 33-1999G
- CODEX ALIMENTARIUS Principles for the Use of Sampling and Testing in International Food Trade - CAC/GL 83-2013

The ingredients are subject to sampling; the food products are subject to sampling as well only when the analysis of risks points out potential cross-contamination. The sampling shall be representative of the batch lot.

The sampling plan will at a minimum consider:

- For Liquid products refer to the ISO 5555 standard.
- For other products, the minimum number of incremental samples to be taken from the lot shall be as given in Table 1.

Table 1: Minimum number of incremental samples to be taken from the lot

Weight of lot	Minimum number of incremental samples to be taken (kg)
< 50	3
50 to 500	5
> 500	10

If the lot consists of individual packages, then the number of packages which shall be taken to form the aggregate sample is given in Table 2.

Table 2: Number of packages (incremental samples) which shall be taken to form the aggregate sample if the lot consists of individual packages

Number of packages or units in the lot	Number of packages or units to be taken
1 to 25	1 package or unit
26 to 100	About 5 %, at least 2 packages or units
> 100	About 5 %, at maximum 10 packages or units

9. EVALUATION OF QUALITATIVE REQUISITES

All raw materials and ingredients that are at risk, and when cross-contamination is a possibility, also the finished product.

10. METHOD OF ANALYSIS

The analytical method used to determine the presence of genetically modified organisms must have a detection limit equal to at least 0.01% for all qualitative and quantitative analyses, and must demonstrate the presence of amplifiable DNA of the species being tested.

This STP takes into account the requirements of the international standards:

- Guidelines on performance criteria and validation of methods for detection, identification and quantification of specific DNA sequences and specific proteins in foods. Codex Alimentarius, 2010 (CAC/GL 74-2010). http://www.codexalimentarius.org/standards/en/
- International standard (ISO) 24276:2006/Amd 1:2013, Foodstuffs. Methods of analysis for the detection of genetically modified organisms and derived products – General requirements. International Organization for Standardization, Geneva, Switzerland.
- International standard (ISO) 21569:2005/Amd 1:2013, Foodstuffs. Methods of analysis for the detection of genetically modified organisms and derived products – Qualitative nucleic acid based methods. International Organization for Standardization, Geneva, Switzerland.
- International standard (ISO) 21570:2005/Amd 1:2013, Foodstuffs. Methods of analysis for the detection of genetically modified organisms and derived products – Quantitative nucleic acid based methods. International Organization for Standardization, Geneva, Switzerland.
- International standard (ISO) 21571:2005/Amd 1:2013, Foodstuffs. Methods of analysis for the detection of genetically modified organisms and derived products – Nucleic acid extraction. International Organization for Standardization, Geneva, Switzerland.

ANNEX 1:

1. PLANT-RELATED GE CRITICAL ORGANISMS

This reference list of GE critical organisms is the CERA GM Crop Database.
http://www.cera-gmc.org/GMCropDatabase

All risk assessments for and ingredient evaluations shall be completed in reference to the CERA GM Crop Database and with a clear understanding of which species have been commercialized within the supply chain from which they are sourced.

At the date of writing of this STP, the actual GE recorded into the CERA GM Crop Database are:

1.Alfafa
2.Apple
3.Argentine Canola
4.Carnation
5.Chicory
6.Common bean
7.Cotton
8.Creeping bent grass
9.Flax/Linseed
10.Lentil
11.Maize
12.Melon
13.Papaya
14.Plum
15. Polish Canola
16.Potato
17.Rice
18.Rose
19.Soybean
20.Squash
21.Sugar beet
22. Sunflower
23.Tobacco
24.Tomato
25.Wheat

2. NON PLANT-RELATED GE CRITICAL ORGANISMS

1.Bacteria
2.Salmon
3.Virus