THE SGS NO GE INGREDIENTS SUPPLY CHAIN PROCESS VERIFICATION STANDARD (US VERSION)

CONTENTS

Revision: V 1.1
Approval Date: 15 December 2015
Review Date: 15 December 2020
Revision Date: 15 March 2016
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INTRODUCTION

The SGS No GE Supply Chain Process Standard U.S. Version (the Standard) is a robust system to verify the process of preparing non-genetically engineered (non-GE) ingredients or (pet) food and beverage products for sale in the United States (U.S.). The Standard may be used by any entity in the supply chain (defined herein as an "operator"), including an ingredient or finished food manufacturer, vendor, or services provider like transport or storage facilities. The Standard 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 Standard was originally developed in accordance with EU legislative labeling requirements for GE ingredients (EU Regulations 1829/2003 and 1830/2003), but the Standard has a global application and can be adapted for country-specific markets.

This version of the Standard has been developed for the U.S. market, taking into consideration US federal and state guidance, proposed and passed laws, and subsequent regulations. These foundational materials are listed in Annex II, and if any of these foundational materials change, the corresponding details of the Standard may change.

Verification against the Standard consists of the independent third party assessment and approval by SGS of the management system of the applicant for the supply chain of non-GE product from the seed through cultivation and harvest, transportation, collection, storage and processing until it reaches the retail market. The product must maintain its original non-GE status, and it must be managed to avoid cross-contact or co-mingling with GE ingredients throughout the supply chain. The implementation of the requirements of the Standard and verification against the Standard does not substitute for the compliance with any applicable law or regulation in force.

The Standard is intended to be applied in combination with existing laws and regulations governing the labeling of food products. Verification of an operator's processes also includes the assessment and approval by SGS of the operator's process for developing and substantiating any statement regarding the non-GE status of the product to be used in product labeling.

1.1 SCOPE OF THE NO GE INGREDIENTS PROCESS VERIFICATION

The Standard can be applied to the processing of single ingredients or multi-ingredient products intended for human and pet consumption, including those ingredients that are derived from crops for which both GE and non-GE varieties are commercially available. For verification of facilities producing both GE and non-GE products, the impact of the GE products will need to be considered.

This Standard can be applied to any article of food intended for human and pet consumption. This Standard does not currently apply to animal feed.

The Standard is applicable to any of the operators in the supply chain – seed supplier, farmer, trader, and processor. The Standard is also applicable to operators providing services to the supply chain, such as storage, transport and sampling and analysis, as well as operators that are third party contractors of any other operator.

Specific requirements for operators in the supply chain and for service providers are described in Chapters 3 and Chapter 4, respectively.

1.2 DEFINITIONS

Action Threshold 0.45%: The threshold that triggers an investigation by the operator into the source of cross-contact or co-mingling. 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. The percentage shall be calculated on the total weight of the food, exclusive of added water or salt.

Audit Client: The auditee or any other organization that has the contractual right to request an audit.

Auditee: An operator being audited.

Auditor: A person with the necessary competence to conduct an audit.

Batch / Lot: A unit of products, produced within one single production plant, with uniform identifiable parameters.

Commodity Processor: Any entity that converts bulk and/or raw commodities into convenient, ready to use products. It refers to the operator responsible for undertaking the activities of manufacturing of the supplied products in order to produce intermediate or final products which are to be used by the final food processors. Typical examples for such companies are flour mills, refineries, sugar mills

Compliance Threshold 0.9%: The threshold above which any seed, raw agricultural commodity, ingredient or food is no longer in compliance with this Standard. The percentage shall be calculated on the total weight of the food, exclusive of added water or salt.

Farmer: Any entity that sows, grows, handles, harvests, stores and/or manages crops until they are sold or transferred to another entity

Feed: Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used as food for animals (except pets). This Standard does not apply to animal feed.

Finished Food Processor: Any entity that uses commodities and ingredients to produce a finished food product.

Flushing: A method to avoid the risk of cross-contact or co-mingling of non-GE products with GE products, by processing a defined quantity of non-GE products to eliminate the residues of GE products before starting the non-GE production.

Food: Any article of food intended for human and pet consumption, including dietary supplements. This Standard does not currently apply to animal feed.

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 Standard.

An organism or a product produced from this organism is not regarded as GE critical if:

- An organism or a product is not listed as GE critical in Annex I. This Annex is based on the Center for Environmental Risk Assessment (CERA) GM Crop Database.
- The product is derived from a conventional version of the crop and managed through a recognized IP program accepted by SGS.
- The product is derived from a certified organic version of the crop.

Genetic Engineering: The process by which the genetic material of an organism has been changed through the application of:

- In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) techniques and the direct injection of nucleic acid into cells or organelles; or
- Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells or protoplasts do not fall within the same taxonomic group, in a way that does not occur by natural multiplication or natural recombination
- Excluded from the definition of genetic engineering are traditional breeding methods, in vitro fertilization, natural breeding processes (conjugation, transduction, transformation) and polyploidy induction, provided the use of recombinant DNA or genetic engineering is not involved.

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..

Ingredient Processor: Any entity that produces food substances, including food additives, that are used in the manufacture or preparation of a food..

Labeling: A display of written, printed or graphic matter upon the immediate or shipping container of the food as well any related print or electronic advertising or promotional materials, brochures, websites, and social media.

Market Removal: Timely removal from the market of non-conforming products at any level of the supply chain that are not compliant with this Standard.

Market Removal Plan: A plan to facilitate the timely removal of non-conforming products from the marketplace and notification of all affected parties along the supply chain.

Non-Conforming Product: A product (seed, raw agricultural commodity, ingredient, or food) that is not in compliance with this Standard and requires corrective action.

Non-Conforming Product Plan: A plan to identify and segregate non-conforming products and to take corrective actions on any identified product.

Operator: Any entity that participates in the non-GE verification process in one or more of the roles of seed supplier, farmer, trader, and processor, as well as any entity providing services to the supply chain, such as storage, transport and sampling and analysis.

Organism: Any biological entity capable of replication, reproduction or transferring genetic material.

Packaged: Fully or partially enclosed in a container for use in the delivery or display of the product. This includes canning, jarring, or otherwise enclosing food in a container.

Pet food: Means any commercial feed prepared and distributed for consumption by dogs and cats. (Based on AAFCO definition in US)

Processing: Activities at any stage from raw agricultural commodity, to processed commodities, ingredients and finished food, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing and chilling.

Processing Aid:

- A substance that is added to a food during the processing of the food but that is removed in some manner from the food before the food is packaged in its finished form;
- A substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; or
- A substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at levels that do not have any technical or functional effect in that finished food.

Processed Food: Any food other than a raw agricultural commodity, including any food produced from a raw agricultural commodity, that has been subjected to processing such as canning, smoking, pressing, cooking, freezing, dehydration, fermentation, or milling.

Raw Agricultural Commodity: Any food in its raw or natural state, including any fruit or vegetable that is washed, colored, or otherwise treated in its unpeeled natural form prior to marketing.

Refined Derivative: An ingredient derived from a raw agricultural commodity which contains no detectable DNA or protein and, therefore, whose GE status cannot be measured analytically.

Risk Assessment System: A system to identify, evaluate and control potential cross-contact or co-mingling situations which could affect the non–GE status of any raw agricultural commodity, ingredient and food. It consists of, at a minimum, four steps: identification of the potential cross-contact or co-mingling, characterization of the potential cross-contact or co-mingling, exposure assessment and risk characterization.

Seed Supplier: Any entity that produces and packs the seeds to sell to the farmer.

Segregation: Measure(s) to avoid the cross-contact or co-mingling of non-GE ingredients and products with GE ingredients or products. It often consists in a physical separation between two kinds of products (e.g., separation of GE from non-GE seeds in an identity preservation (IP) program).

Service Provider: An entity that provides services to another operator such as transportation, storage, processing.

Supply Chain: The network of entities encompassing the steps it takes to get a product or service from a supplier to a customer. For this Standard, the supply chain includes the operators from seeds and raw agricultural commodities through commodity and ingredient processing to the processing of a finished packaged food.

Traceability: The ability to verify the history, location, or application of a product by means of documented recorded identification.

Trader: Any entity that buys and sells products (even without physically handling them)

1.3 INGREDIENTS

1.3.1 Ingredients That May Be Used in Products for which a "No GE Ingredients" Claim is Made:

- Agricultural crops for which there is no commercially available GE version and any of the derivatives of these crops. This includes, for example most fruits and vegetables like pumpkin, broccoli, pears, and bananas, as well as coffee and cacao, and some grains.
- Conventional versions of agricultural crops that have commercially available GE versions and any of the derivatives of these crops, such as identity preserved (IP) non-GE corn or certified organic soybeans.
- Meat, poultry, egg and milk ingredients, (and any of the derivatives of these ingredients) derived from animals whether or not they are fed GE feed or treated with GE medications/ growth hormones. The allowance for the use of these ingredients in products with GE absence claims is based on their exemption from mandatory GE labeling under current federal or state GE labeling legislation, provided the animal itself was not produced through genetic engineering.
- Ingredients permitted in organic products since genetic engineering is an excluded method under the National Organic Program (NOP) regulations, thereby prohibiting the use of GE ingredients in the production and handling of products bearing "organic" claims (e.g., "100% organic," "organic," or "made with organic [ingredients/ food groups]").
- Fermentation products produced from a GE or non-GE agricultural crop or a derivative through the use of GE or non-GE enzymes and microorganisms, provided

sufficient steps have been taken during the purification process to remove, denature or degrade any GE enzyme or microorganisms, and the identity of the agricultural crop or its derivative is unrecognizable in, the final ingredient. Examples are alcohol and citric acid.

- Insignificant ingredients, such as processing aids and incidental additives that are GE ingredients. Insignificant ingredients are added either directly or indirectly to a product often for their technical or functional effect during processing but that are present at insignificant amounts and have no technical or functional effect in the finished food.

  While these ingredients in products with GE absence claims are exempt from mandatory GE labeling under current and proposed federal and state GE labeling legislation, this Standard sets an upper limit for these ingredients in this Standard of 0.9% by weight in aggregate.

- Adventitious or technically unavoidable ingredients: Due to the prevalence of GE crops and ingredients derived from them in the US food supply and the corresponding potential for co-mingling in the supply chain, individual ingredients allowed in products bearing GE absence statements may contain GE material at a level no higher than 0.9% by weight considered individually only if the presence is adventitious or technically unavoidable.

1.3.2 Ingredients Not To Be Used in Products for which a "No GE Ingredients" Claim is Made:

- Agricultural crops grown from genetically engineered plants or seeds and the ingredients derived from these crops, unless exempted. Currently in the US the most common GE crops are corn, soybeans, sugar beets, canola, and cotton. Examples of GE crops and ingredients derived from these crops are:
  - GE corn > GE corn starch > GE corn syrup
  - GE soybeans > GE soy oil > GE soy mono/di-glycerides

There are other GE critical crops, namely genetically engineered crops being tested and pending approval or pending commercial production and common usage (e.g., potato). Therefore it is necessary to review regularly, at least annually, and update the list above as additional GE crops, and ingredients derived from them, come into commercial production and common usage. Annex I contains a list of GE critical organisms. This list is based on the CERA GM crop database http://cera-gmc.org. The CERA GM crop database is considered always to be more accurate than the annex in this Standard and will be the reference database. This database will be consulted in the framework of evaluating new GE crops.

- Ingredients derived from genetically engineered food animals. While currently there are no genetically engineered food animals with regulatory approval in commerce in the US, if GE animals eventually are in commerce, ingredients derived from them will not be allowed. This also includes ingredients such as meat or milk derived from animals genetically engineered to produce a pharmaceutical or industrial chemical.

1.4 PACKAGING & CLEANING AGENTS

1.4.1 Primary packaging is in direct contact with the final product. Therefore, primary packaging of biological origin (e.g., paper, cotton) needs to be assessed for its GE status.

Glass, metal and plastic primary packaging, as well as secondary packaging, which by definition is not in contact with the final products, is exempt from this consideration.

1.4.2 Cleaning agents will be approved for use based on evaluation of their components and production process for potential of cross-contact or co-mingling and/or presence of GE critical organisms.

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GENERAL REQUIREMENTS FOR THE SUPPLY CHAIN

This Chapter shall apply to all operators. The requirements in Chapter 2 are essential for developing and implementing an adequate system to control the non-GE status of a supply chain, which must be documented. An operator must have demonstrably implemented these elements in its operational management.

Each operator must establish a documented No GE ingredient management system including:

- An implemented and communicated non-GE company policy
- Quality control documentation, comprised of a physical and/ or electronic manual, compiling operating procedures, instructions, forms, etc., covering
    - Receipt, handling, storage, transfer, use, processing and disposal of non-GE and GE ingredients, semi-finished products and final products
    - Cleaning of facilities, equipment and transport, including CIP and COP, and appropriate records.
    - Training plan and training records for the above.
- A document review and record retention program. All relevant documents and records (sampling and analysis, traceability, etc.) shall be kept for a minimum of three years, as required by local legislation, or according to the retention policy of the operator, whichever is longest.
- Tasks, responsibilities and authorities must be defined, especially those with regard to this supply chain Standard. Records regarding experience, education and training for non-GE must be included in the Management system.
- An internal audit procedure and audit schedule. The procedure and schedule must include all relevant non-GE procedures and records and cover all locations in scope. Internal audits shall be performed by qualified people at least annually. The internal audit shall be documented.
- A notification procedure to inform clients and the certification body of any market removal due to a situation or change in circumstances that has the potential to compromise the non-GE status of the product or to affect its compliance with its certification status.
- A complaint procedure for dealing with consumer complaints relating to the non-GE status or identification of the supplied products and seeds. The actions taken and the response given to the customer or consumer must be documented.
- A corrective and precautionary measures procedure: Written procedures are drawn up for the implementation of corrective and precautionary measures with the purpose of eliminating any detected or observed non–conformity. Precautionary measures are taken in order to prevent problems or complaints.
- A documented risk assessment procedure to prevent potential cross-contact or co-mingling of non-GE products and seeds with GE products and seeds, including preventative measures, description of control points (CPs), Standards and tolerances, and monitoring program on CPs. HACCP principles shall by applied.

  The result will define company-specific risks relating to the cross-contact or co-mingling of non-GE product with GE product, the company specific analysis and the control of these hazards. This will result in a fully documented risk assessment. The risk assessment shall be reviewed at least annually or when changes occur that could affect the non-GE status of ingredients or products subject to the Standard.
- Contracts must be in place for the purchase of all non-GE products. These contracts shall clearly state the non-GE status of the purchased product.
- Order receipt and processing for confirming and recording the type, quantity and non-GE status of orders received must be demonstrated by an operator through appropriate methods.
- Packaging and delivery documents shall be clear and unambiguous. All relevant information required by local, national and/or international regulations shall be included.
- Non-conforming product plan to identify and segregate non-conforming products and to take corrective actions on any identified product. Actions include, but are not limited to, changing the identification of a non-conforming non-GE product to a GE product, re-labeling, additional testing, and market removal in accordance with the market removal plan. All corrective and preventative actions must be documented.
- A market removal plan to facilitate the timely removal of non-conforming products from the marketplace and notification of all affected parties along the supply chain if a significant issue regarding the GE status of a product arises. Removed products must be clearly identified, communicated to the impacted parties and subsequent corrective and preventative actions must be documented.
- A market removal plan shall contain the following elements, at a minimum:
    - The name of the person responsible for implementing the operator's market removal procedure.
    - The method of external communication.
    - An annual test to verify the plan's effectiveness. Such tests must be documented and recorded.
- Identification and traceability procedures must be established, including identification of all manual, paper and electronic tools used to control non-GE batches. Tracking of batch/lot numbers and labeling/ marking on packaging and containers shall be used as necessary to identify and segregate non-GE products from GE products.
- Appropriate resources, including staff and information, must be provided by the operator's management to assure effective implementation of the operator's No GE ingredient management system.
- An internal evaluation of the operator's No GE ingredient management system must be completed at least annually. These evaluations must be documented, including the implementation of any corrective or preventative action items identified during the evaluation.

3

SPECIFIC REQUIREMENTS FOR THE SUPPLY CHAIN

The requirements in Chapter 3 are applied to the specific roles of operators within the supply chain. An operator must have demonstrably implemented these elements appropriately to its role in the supply chain.

3.1. REQUIREMENTS FOR THE SEED SUPPLIER

3.1.1 Non-GE purchase procedure, which must contain the following elements:

a) Purchase of non-GE seeds must be performed against a product specification mutually agreed upon between the farmer and the seed supplier.

b) For GE critical products, the product specification must clearly describe the non-GE status of the products, including, where applicable, the non-GE verification scheme.

c) Incoming seeds must be checked against the product specification.

d) A monitoring, sampling and analysis program must be in place for incoming seeds based on a risk assessment of potential cross-contact or co-mingling with GE seeds.

e) An up-to-date and accurate lay-out and process description for receiving, storing, segregation and transport of non-GE and GE seeds must be available.

3.1.2 A non-GE monitoring, sampling and analysis program must be in place for incoming seeds and, if required based on the risk assessment, seeds in storage and outgoing seeds.

3.1.3 A specification must be available clearly describing the non-GE status of each product the seed supplier introduces into the non-GE supply chain.

3.2 REQUIREMENTS FOR THE FARMER

3.2.1 Non-GE purchase procedure, which must contain following elements:

a) Purchase of non-GE products (seeds) must be performed against a mutually agreed product specification and from a third party certified seed supplier of non-GE seeds.

b) Specifications must be available clearly describing the non-GE status of seeds.

c) A monitoring, sampling and analysis program must be in place for incoming seeds based on a risk assessment.

3.2.2 An up to date layout and process description for receiving storing and transport of non-GE and GE products must be available.

3.2.3 Records on planting, harvesting, storage and cleaning of equipment must be maintained.

3.2.4 The ground in which the seed is planted shall not have been used for a genetically engineered variety of the same crop in the previous year.

3.2.5 Farm plan/map shall be available for the farming operator's fields and identification of neighboring fields

a) Clear separation and identification of fields and establishment of "isolation distances" and "pollen barriers". Isolation distances are the minimum distances required between GM and non-GM cultivations for most of the GM pollen to fall to the ground before reaching non-GM plants. Pollen barriers attempt actively catch pollen, and can consist of hedges and trees which physically hinder pollen movement. Pollen barriers consisting of conventional crops of the same species as the GM crop have a special advantage, as the conventional plants not only physically limit the GM pollen flow, but also produce competitive, conventional pollen. During harvest, the buffer strip of conventional crops is considered part of the GM crop yield.

b) Suitable measures during cultivation are needed to prevent the mixing of GM and non-GM crops resulting from seed impurities, volunteers, and cross-pollination.

3.2.6 Procedures regarding cleaning and inspection of all equipment and storage facilities used for harvesting.

3.2.7 Non-GE monitoring, sampling and analysis program for incoming seeds, and based on risk analyses products in storage and outgoing products.

3.2.8 A specification must be available clearly describing the non-GE status of each raw agricultural commodity the farmer introduces into the non-GE supply chain.

3.2.9 Corrective action procedures, including control and market removal procedures for non-conforming product.

3.3. REQUIREMENTS FOR THE TRADER

3.3.1 A non-GE purchase procedure must be documented and implemented.

3.3.2 Suppliers to traders shall participate in third party non-GE certification schemes accepted by SGS.

3.3.3 If a supplier to a trader is not participating in a third party non-GE certification scheme, then:

a) The supplier shall make available to the trader the risk assessments and other information used to confirm the non-GE status of the product, or

b) if the supplier does not make this information available, the trader or another qualified entity identified by the trader, a so-called second party audit, shall assess the supplier to confirm the non-GE status of the supplier's products through on-site verification activities.

c) In either case, the trader will evaluate the GE status of the ingredient, taking into consideration the information provided by the supplier, the available historical data, performance details of the supplier, and the risk assessment. The trader shall determine the controls on incoming products (monitoring plan) and/or the controls on the processes/systems of the supplier (supplier audits) needed to ensure the non-GE status of the supplier's product. Alternatively, all incoming batches shall be sampled and analyzed according to requirements identified by the trader/SGS. If the analysis of these batches is not conclusive (i.e., no DNA can be detected), then that analysis cannot be taken into account in the assessment.

3.3.4 Specifications, agreed upon by the trader and his suppliers, that clearly describe the non-GE status of the raw agricultural commodities and other inputs received by the trader must be available.

3.3.5. Products used as inputs must be checked against the product specification upon arrival and receipt.

3.3.6 An up to date lay-out and process description for receiving storing and transport of non-GE and GE products must be available.

3.3.7 Procedure for identification and separation of non-GE and GE products.

3.3.8 Process control documents must prescribe clearly the non-GE status of the raw materials/ingredients/products to be traded. Batch/lot identification records must be kept at all stages of the processes.

3.3.9 For all outgoing traded raw materials and products agreed specifications must be available clearly describing the non-GE status of its ingredients, including, where applicable, the non-GE verification scheme.

3.3.10 Document/record of all inputs, segregation, cleaning and storage, training, internal audits, sampling and analysis and complaints regarding non-GE status must be retained according to the document retention program required in Chapter 2.

3.3.11 When a non-GE refined derivative is traded, no other derivative of that kind may be used in the same processing/ storage site unless the trader has established an effective control program to assure:

a) Commingling between non-GE and GE derivatives is prevented

b) Derivatives are clearly identified and segregated.

c) Correct use of derivatives is monitored by input/output balance.

3.3.12 A non-GE monitoring, sampling and analysis program must be in place for incoming, stored and outgoing products based on a risk assessment.

a) Monitoring for GE cross-contact or co-mingling against the action threshold, which, if exceeded, triggers the investigation for the cause of the cross-contact or co-mingling and correction of that cause when identified.

b) Corrective action procedures, including control and market removal procedures for non-conforming product, shall be applied.

3.3.13 A trader must create and make available a specification clearly describing the non-GE status of each product the trader introduces into the non-GE supply chain.

3.3.11 A trader must create and make available a specification clearly describing the non-GE status of each product the trader introduces into the non-GE supply chain.

3.3.14 A trader that owns and operates its own storage and/or transport functions shall apply the requirements for storage (4.1) and transport (4.2), respectively.

If transport and/or storage is performed through third party contractors, these contractors must meet the requirements in chapters 4.1 for storage and 4.2 for transport and be verified against the Standard or a non-GE auditing scheme accepted by SGS. If these contractors are not subject in a non-GE third party auditing scheme accepted by SGS, then the auditee must perform audits, at least annually, against the requirements of the Standard.

In case transport and/or storage are performed by the trader they must be part of the No GE ingredient management system and will be audited by SGS in the framework of this Standard.

3.4 REQUIREMENTS FOR PROCESSORS

3.4.1 Commodity Processor

3.4.1.1 A non-GE purchase procedure must be established.

3.4.1.2 Suppliers to a Commodity Processor shall participate in third party non-GE certification schemes accepted by SGS.

3.4.1.3 If a Supplier to a Commodity Processor of a non-GE critical ingredient is not participating in third party non-GE certification scheme then:

a) The supplier shall make available to the commodity processor the risk assessments and other information used to confirm the non-GE status of the product, or

b) if the supplier does not make this information available, the commodity processor or another qualified entity identified by the commodity processor, a so-called second party audit, shall assess the supplier to confirm the non-GE status of the supplier's products through on-site verification activities.

c) In either case, the commodity processor will evaluate the GE status of the ingredient, taking into consideration the information provided by the supplier, the available historical data, performance details of the supplier, and the risk assessment. The commodity processor shall determine the controls on incoming products (monitoring plan) and/or the controls on the processes/systems of the supplier (supplier audits) needed to ensure the non-GE status of the supplier's product. Alternatively, all incoming batches shall be sampled and analyzed according to requirements identified by the trader/SGS. If the analysis of these batches is not conclusive (i.e., no DNA can be detected), then that analysis cannot be taken into account in the assessment.

3.4.1.4 If a supplier to a Commodity Processor of a GE critical ingredient is not participating in a third party non-GE certification scheme then an exception to the third party certification requirements can be granted on a case by case basis, PROVIDED the ingredient supplier can demonstrate the appropriate controls are in place, including but not limited to the criteria specified in 3.4.1.3, to assure the non-GE source of the raw materials used to make the ingredient.

3.4.1.5 Specifications, agreed upon by the commodity processor and his suppliers, that clearly describe the non-GE status of the raw agricultural commodities and other inputs received by the commodity processor must be available.

3.4.1.6 Products used as inputs must be checked against the product specification upon arrival and receipt.

3.4.1.7 An up to date lay-out and process description for receiving storing, processing, and transport of non-GE and GE products must be available.

3.4.1.8 A documented and validated cleaning or flushing program, including materials, cleaning processes, inspections, tasks and responsibilities for use of all materials, handling and processing equipment, storage (e.g. silos/tanks) and transportation facilities, used for both GE and non-GE products must be in place.

In practice a defined quantity of non-GE products (this quantity is defined according to analysis results and risk assessment) has to be processed to eliminate the residues of GE products in the flow before starting the non-GE production. The quantity used as flushing material is identified as GE contaminated products.

3.4.1.9 A procedure for identification and segregation of non-GE and GE products must be documented and implemented.

a) When a non-GE refined derivative is used or produced, no other derivative of that kind may be used or produced in the same processing/storage site unless the commodity processor has established an effective control program to assure:
   i) Commingling between non-GE and GE derivatives is prevented
   ii) Derivatives are clearly identified and segregated.
   iii) Correct use of derivatives is monitored by input/output balance.

b) Where non-GE batches are mixed in e.g. silos, where the silo is not emptied between the batches, all incoming batches shall be recorded and be traceable to all outgoing batches. Of every produced batch, it should be clear from which incoming batch it has been produced and vice versa.

c) Physical segregation is mandatory for bulk products. Packed products can be stored in the same warehouse(s) as long as they are clearly identified and cross-contact or co-mingling is avoided at all times.

d) In case of an identified cross-contact or co-mingling to the batches with GE positive material, all batches in the silo and the batches produced from the silo shall be identified, and degraded to GE positive batches

e) A root cause analysis must be conducted, and agreed upon corrective actions and timeline must be implemented and their effectiveness must be verified.

3.4.1.10 Process control documents must prescribe clearly the status of the raw materials/ingredients/products to be traded with regard to their non-GE status. Batch/lot identification records must be kept at all stages of the processes.

3.4.1.11.A commodity processor must create and make available a specification clearly describing the non-GE status of each product the commodity processor introduces into the non-GE supply chain.

3.4.1.12 Document/record keeping of all inputs, segregation, cleaning and storage, training, internal audits, sampling and analysis and complaints regarding non-GE.

3.4.1.13 A non-GE monitoring, sampling and analysis program must be in place for incoming, stored and outgoing products based on a risk assessment.

a) Monitoring for GE cross-contact or co-mingling against an Action Threshold, which, if exceeded, triggers the investigation for the cause of the cross-contact or co-mingling and correction of that cause when identified.

b) Corrective action procedures, including control and market removal procedures for non-conforming product, shall be applied

3.4.1.14 A commodity processor that owns and operates its own storage facilities and/or transport shall apply the specific requirements for storage facilities (4.1) and transport (4.2)

3.4.2 Ingredient Processor

3.4.2.1 A non-GE purchase procedure must be established that is performed against a mutually agreed product specification.

3.4.2.2 Suppliers to ingredient processors shall participate in a third party non-GE certification scheme accepted by SGS,

3.4.2.3 If a Supplier to an Ingredient Processor of a non-GE critical ingredient is not participating in third party non-GE certification scheme then:

a) The supplier shall make available to the ingredient processor the risk assessments and other information used to confirm the non-GE status of the product, or

b) if the supplier does not make this information available, the ingredient processor or another qualified entity identified by the ingredient processor, a so-called second party audit, shall assess the supplier to confirm the non-GE status of the supplier's products through on-site verification activities.

c) In either case, the ingredient processor will evaluate the GE status of the ingredient, taking into consideration the information provided by the supplier, the available historical data, performance details of the supplier, and the risk assessment. The ingredient processor shall determine the controls on incoming products (monitoring plan) and/or the controls on the processes/systems of the supplier (supplier audits) needed to ensure the non-GE status of the supplier's product. Alternatively, all incoming batches shall be sampled and analyzed according to requirements identified by the ingredient processor /SGS. If the analysis of these batches is not conclusive (i.e., no DNA can be detected), then that analysis cannot be taken into account in the assessment.

3.4.2.4 If a supplier to an Ingredient Processor of a GE critical ingredient is not participating in a third party non-GE certification scheme then an exception to the third party certification requirements can be granted on a case by case basis, PROVIDED the ingredient supplier can demonstrate the appropriate controls are in place, including but not limited to the criteria specified in 3.4.2.3, to assure the non-GE source of the raw materials used to make the ingredient.

3.4.2.5 Specifications, agreed upon by the ingredient processor and his suppliers, that clearly describe the non-GE status of the products and other inputs received by the ingredient processor must be available.

3.4.2.6 Products used as inputs must be checked against the product specification upon arrival and receipt.

3.4.2.7 An up to date lay-out and process description for receiving, storing, processing and transport of non-GE and GE products must be available.

3.4.2.8 A documented and validated cleaning or flushing program, including materials, cleaning processes, inspections, tasks and responsibilities for use of all materials, handling and processing equipment, storage (e.g. silos/tanks) and transportation facilities, used for both GE and non-GE products must be in place.

In practice a defined quantity of non-GE products (this quantity is defined according to analysis results and risk assessment) has to be processed to eliminate the residues of GE products in the flow before starting the non-GE production. The quantity used as flushing material is identified as GE contaminated products.

3.4.2.9 Procedure for identification and separation of non-GE and GE products.

a) When a non-GE refined derivative is used or produced, no other derivative of that kind may be used or produced in the same processing/storage site unless the ingredient processor has established an effective control program to assure:
    i) Commingling between non-GE and GE derivatives is prevented
    ii) Derivatives are clearly identified and segregated.
    iii) Correct use of derivatives is monitored by input/output balance.
b) Where non-GE batches are mixed in e.g. silos, where the silo is not emptied between the batches, all incoming batches shall be recorded and be traceable to all outgoing batches. Of every produced batch, it should be clear from which incoming batch it has been produced and vice versa.
c) Physical segregation is mandatory for bulk products. Packed products can be stored in the same warehouse(s) as long as they are clearly identified and cross-contact or co-mingling n is avoided at all times.
d) In case of an identified cross-contact or co-mingling to the batches with GE positive material, all batches in the silo and the batches produced from the silo shall be identified, and degraded to GE positive batches
e) A root cause analysis must be conducted, and agreed upon corrective actions and timeline must be implemented and their effectiveness must be verified.

3.4.2.9.10 Process control documents must prescribe clearly the status of the raw materials/ingredients/products to be traded with regard to their non-GE status. Batch/lot identification records must be kept at all stages of the processes.

3.4.2.11 An ingredient processor must create and make available a specification clearly describing the non-GE status of each product the ingredient processor introduces into the non-GE supply chain.

3.4.2.12 Document/record keeping of all inputs, segregation, cleaning and storage, training, internal audits, sampling and analysis and complaints regarding non-GE.

3.4.2.13 A non-GE monitoring, sampling and analysis program must be in place for incoming, stored and outgoing products based on a risk assessment.

a) Monitoring for GE cross-contact or co-mingling against an Action Threshold, which, if exceeded, triggers the investigation for the cause of the cross-contact or co-mingling and correction of that cause when identified.
b) Corrective action procedures, including control and market removal procedures for non-conforming product, shall be applied

3.4.2.14 An ingredient producer that owns and operates its own storage facilities and/or transport shall apply the specific requirements for storage facilities (4.1) and transport (4.2)

If transport and/or storage is performed through third party contractors, these contractors must meet the requirements in chapters 4.1 for storage and 4.2 for transport and be verified against the Standard or a non-GE auditing scheme accepted by SGS. If these contractors are not subject in a non-GE third party auditing scheme accepted by SGS, then the auditee must perform audits, at least yearly, against the requirements of this Standard.

In case transport and/or storage are performed by the ingredient processor they must be part of the No GE ingredient management system and will be audited by SGS in the framework of this Standard.

3.4.3 Food Processor

3.4.3.1 A non-GE purchase procedure must be established that is performed against a mutually agreed product specification.

3.4.3.2 Suppliers to a food processor shall participate in a third party non-GE certification scheme accepted by SGS,

3.4.3.3 If a supplier to a Food Processor of a non-GE critical ingredient is not participating in third party non-GE certification scheme then:

a) The supplier shall make available to the food processor the risk assessments and other information used to confirm the non-GE status of the product, or
b) if the supplier does not make this information available, the food processor or another qualified entity identified by the food processor, a so-called second party audit, shall assess the supplier to confirm the non-GE status of the supplier's products through on-site verification activities.
c) In either case, the food processor will evaluate the GE status of the ingredient, taking into consideration the information provided by the supplier, the available historical data, performance details of the supplier, and the risk assessment. The food processor shall determine the controls on incoming products (monitoring plan) and/or the controls on the processes/systems of the supplier (supplier audits) needed to ensure the non-GE status of the supplier's product. Alternatively,

all incoming batches shall be sampled and analyzed according to requirements identified by the trader/SGS. If the analysis of these batches is not conclusive (i.e., no DNA can be detected), then that analysis cannot be taken into account in the assessment.

3.4.3.4 If a supplier to a Food Processor of a GE critical ingredient is not participating in a third party non-GE certification scheme then an exception to the third party certification requirements can be granted on a case by case basis, PROVIDED the ingredient supplier can demonstrate the appropriate controls are in place, including but not limited to the criteria specified in 3.4.3.3, to assure the non-GE source of the raw materials used to make the ingredient.

3.4.3.5 Specifications, agreed upon by the food processor and his suppliers, that clearly describe the non-GE status of the products and other inputs received by the food processor must be available.

3.4.3.. Products used as inputs must be checked against the product specification upon arrival and receipt.

3.4.3.7 An up to date lay-out and process description for receiving, storing, processing and transport of non-GE and GE products must be available.

3.4.3.8 A documented and validated cleaning or flushing program, including materials, cleaning processes, inspections, tasks and responsibilities for use of all materials, handling and processing equipment, intake, transfer, storage (e.g. silos/tanks) and transportation facilities, used for both GE and non-GE products must be in place to remove sources of GE cross contact or comingling. Validation of cleaning and flushing programs can use a similar approach to that for food allergens.

In practice, a quantity of non-GE product is defined according to analysis results and risk assessment. The defined quantity of non-GE products must be processed to eliminate the residues of GE products in the flow before starting the non-GE production. The resulting flushed material is identified as GE co-mingled product, and is treated as non-conforming product

3.4.3.9 Procedure for identification and separation of non-GE and GE products.

a) When a non-GE refined derivative is used, no other derivative of that kind may be used in the same processing/storage site unless the food processor has established an effective control program to assure:
   i) Commingling between non-GE and GE derivatives is prevented
   ii) Derivatives are clearly identified and segregated.
   iii) Correct use of derivatives is monitored by input/output balance.

b) Where non-GE batches are mixed in e.g. silos, where the silo is not emptied between the batches, all incoming batches shall be recorded and be traceable to all outgoing batches. Of every produced batch, it should be clear from which incoming batch it has been produced and vice versa.

c) Physical segregation is mandatory for bulk products. Packed products can be stored in the same warehouse(s) as long as they are clearly identified and cross-contact or co-mingling is avoided at all times.

d) In case of an identified cross-contact or co-mingling n to the batches with GE positive material, all batches in the silo and the batches produced from the silo must be identified with a sequence and time analysis, and degraded to GE positive batches. If there are doubts due to, e.g., information gaps, the entire production must be degraded.

e) A root cause analysis must be conducted, and agreed upon corrective actions and timeline must be implemented and their effectiveness must be verified.

3.4.3.10 Process control documents must prescribe clearly the status of the raw materials/ingredients/products to be traded with regard to their non-GE status. Batch/lot identification records must be kept at all stages of the processes.

3.4.3.11 A food processor must create and make available a specification or other documentation clearly describing the non-GE status of each product the food processor introduces into the non-GE supply chain.

3.4.3.12 Document/record keeping of all inputs, segregation, cleaning and storage, training, internal audits, sampling and analysis and complaints regarding non-GE.

3.4.3.13 A non-GE monitoring, sampling and analysis program must be in place for incoming, stored and outgoing products based on a risk assessment.

a) Monitoring for GE cross-contact or co-mingling against an Action Threshold, which, if exceeded, triggers the investigation for the cause of the cross-contact or co-mingling and correction of that cause when identified.

b) Corrective action procedures, including control and market removal procedures for non-conforming product, shall be applied

3.4.3.14 A food manufacturer that owns and operates its own storage facilities and/or transport shall apply the specific requirements for storage facilities (4.1) and transport (4.2)

If transport and/or storage is performed through third party contractors, these contractors must meet the requirements in chapters 4.1 for storage and 4.2 for transport and be verified against the Standard or a non-GE auditing scheme accepted by SGS. If these contractors are not subject in a non-GE third party auditing scheme accepted by SGS, then the auditee must perform audits, at least yearly, against the requirements of this Standard.

In case transport and/or storage are performed by the ingredient processor they must be part of the No GE ingredient management system and will be audited by SGS in the framework of this Standard.

4

REQUIREMENTS FOR SUPPORT SERVICES TO THE SUPPLY CHAIN

4.1 STORAGE OF NON-GE PRODUCTS

A specification must be received from the owner of the product being stored that clearly identifies its non-GE status in order to assure traceability and to assure the storage operator is informed and therefore handles the product appropriately.

An operator that stores non-GE seeds, raw agricultural commodities, ingredients or finished foods must have a non-GE acceptance procedure containing the following elements:

- A procedure for checking the incoming products against the product specifications
- An accurate diagram of the storage operator's facility and process description for receiving, handling, storing and transport of non-GE and GE products must documented.
- Documented cleaning, validated flushing and inspection procedures including materials, cleaning processes, inspections, tasks and responsibilities for use of all materials, handling and processing equipment, storage (e.g. silos), and records for silos and other storage facilities in use for GE and non-GE batches must be in place.
- When non-GE batches are mixed, storage records for the container (e.g., silo, tanks, etc.) must identify all constituent batches and their amounts. Each incoming batch shall be traceable to all outgoing batch(es) in which it is used, and each outgoing batch shall be traceable to all incoming batches from which it was made.
- In case of an identified cross-contact or co-mingling (other than adventitious presence) of a batch with GE material, all batches in the storage container and the batches produced from the storage container shall be identified, separated and reserved for use only in GE positive batches. The owner of the material shall be notified.
- Records on the origin of all product inputs (including GE status), on traceability (lot ID), cleaning of transport elements, separation of conventional, non-GE and GE products must be maintained.
- Silos/warehouses shall be adequately identified.
- Procedures regarding cleaning and/or a validated flushing program and inspection of all equipment and storage facilities shall be established.

4.2 TRANSPORT OF NON-GE PRODUCTS

A specification must be received from the owner of the product being transported that clearly identifies its non-GE status in order to assure traceability and to assure the transport operator is informed and therefore handles the product appropriately.

An operator that transports non-GE seeds, raw agricultural commodities, ingredients or unpackaged finished foods must have a non-GE acceptance procedure containing the following elements:

- A procedure for checking the incoming products against the product specifications
- An accurate description of the transport operator's processes for receiving and transport of non-GE and GE products must be available.
- Records on cleaning of the transport elements (e.g., trucks, rail cars, containers, vessels, barges) must be maintained.
- Records on the origin of all product inputs (including GE status) on traceability (lot ID), cleaning, separation of conventional and GE products must be maintained.
- Transport elements shall be adequately identified.
- Cleaning and inspection procedures and records for transport elements between usage for GE and Non-GE batches must be established.
- Procedures and records on identification, traceability, separation of conventional and Non-GE products must be maintained and documented.
- Delivery documentation and product labeling shall adequately describe the non-GE status of the product in order to assure traceability and to assure the transport operator is informed and therefore handles the product appropriately.

5

REQUIREMENTS FOR SAMPLING AND ANALYSIS

5.1 SAMPLING

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).

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.

5.2 ANALYSIS

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.

The operator will determine root cause and take corrective action when the 0.45% action threshold is exceeded.

The operator will implement his non-conforming goods procedure, including market removal if appropriate, when the 0.9% compliance threshold is exceeded.

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6

LABELING OF PRODUCTS

As defined above, labeling includes a display of written, printed or graphic matter upon the immediate or shipping container of the food as well any related print or electronic advertising or promotional materials, brochures, websites, and social media.

The use of labeling covers all products in the supply chain covered by this Standard, namely, seeds, raw agricultural commodities, processed commodities, ingredients and finished packaged foods.

SGS has not created a logo or other mark that represents this Standard or an operator's compliance with this Standard.

Any reference to SGS, the verification of the operator's process(es) by SGS, or this Standard in product labeling must be approved by SGS in writing before use.

An example of an acceptable reference statement is "SGS verified the [Operator] process for manufacturing this product with no GMO ingredients."

Any "No GE" or similar statement used by an operator used in product labeling must comply with any relevant regulations and must be truthful and not misleading.

Sample label statements not consistent with this Standard and therefore not acceptable include, but are not limited to, "zero GMOs", GMO-free", "GE-free".

Any "No GE" or similar statement, logo or mark created and owned by an operator and used in product labeling must comply with any relevant regulations and must be truthful and not misleading.

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

FOR FDA-REGULATED PRODUCTS:

No GMO Ingredients*

*SGS verified the [Operator] process for manufacturing this product with no GMO ingredients.
www.sgs.com/no-gmo

No GMO Ingredients Process Verified*

*SGS verified the [Operator] process for manufacturing this product with no GMO ingredients.
www.sgs.com/no-gmo

FOR USDA-REGULATED PRODUCTS:

No GE Ingredients*

SGS verified the [Operator] process for manufacturing this product with no genetically engineered (GE) ingredients.
www.sgs.com/no-gmo

No GE Ingredients Process Verified*

SGS verified the [Operator] process for manufacturing this product with no genetically engineered (GE) ingredients.
www.sgs.com/no-gmo

SGS is not responsible for any costs incurred by an operator

- for the preparation of any printed or electronic examples of product labeling that include statements referring to SGS or this Standard without the written approval of SGS, or
- for the operator's inability to use any printed or electronic examples of product labeling due to the operator's non-compliance with regulatory labeling laws, regulations or guidelines, or
- for the operator's inability to use any printed or electronic examples of product labeling due to the operator's non-compliance with any part of this Standard.

7

INITIAL AND ANNUAL PROCESS VERIFICATION AUDITS

Compliance with the Standard of the operator's process to manufacture non-GE ingredients or foods and beverages will be confirmed through a process verification audit. The operator's process needs to be re-verified annually through a surveillance audit. All audit requirements are described in the process verification rules, which are described in a companion document to the Standard (add title/link).

Audits can be conducted to verify specific components of the operator's process at different locations, as appropriate. For example, the operator may implement certain sub-processes at a headquarters location and other sub-processes at one or more manufacturing locations. In any event, documentation of a successful SGS process verification audit applies to the operator's entire process, regardless of location, provided it was encompassed by the audit process.

Further details about the process verification scope and flow are described in the Process Verification Rules, which support this Standard. The Process Verification Rules describe the requirements imposed on certification bodies and on their auditors, as well as the way in which participants in this system should be evaluated, and the way in which the actual issuance of certificates takes place. The regulation also includes the specific rights and obligations of the participant.

This Standard and the Process Verification Rules are companion documents, integral to each other, and must be used together during the initial and annual process verification audits.

ANNEX I

1. PLANT-RELATED GE CRITICAL ORGANISMS

This list of GE critical organisms is for the purpose of reference only. 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.

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

2. NON PLANT-RELATED GE CRITICAL ORGANISMS

1. Bacteria
2. Salmon
3. Virus

ANNEX II

REFERENCES

The Standard was originally developed in accordance with EU legislative labeling requirements for GE ingredients (EU Regulations 1829/2003 and 1830/2003), but the Standard has a global application and can be adapted for country-specific markets.

This version of the Standard has been developed for the U.S. market, taking into consideration US and state guidance, proposed and passed laws, and subsequent regulations.

Other relevant references are included here as well.

2015 Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants

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

Commission Declaration

http://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a8-4d20-86a8-0baaf0518d22.0004.02/DOC_2&format=PDF

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed http://ec.europa.eu/food/food/animalnutrition/labelling/Reg_1829_2003_en.pdf

As amended by:

Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1981&from=EN

Regulation (EC) No 298/2008 of the European Parliament and of the Council of 11 March 2008 amending Regulation (EC) No 1829/2003 on genetically modified food and feed, as regards the implementing powers conferred on the Commission

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0298&from=EN

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling 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

Center for Environmental Risk Assessment (CERA) GM Crop Database http://cera-gmc.org

ISO 19011:2011 Guidelines for auditing management systems

WWW.SGS.COM

WHEN YOU NEED TO BE SURE

SGS