Title	**Minimal Requirements for Product Certification with non-GMO characteristic/requirement**
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NOTE: The present document represents the English version of document under reference at the specified revision. In case of conflict, the Italian version will prevail. To identify the revised parts reference must be made to version in Italian language only.

Preparation	Approval	Authorization	Application date
The Director of Department	The Directive Council	The President	01-01-2018

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1. SCOPE AND FIELD OF APPLICATION

The scope of the present Regulation is to define the needed minimum requirements that conformity assessment schemes shall contain for the certification of products commonly defined as "non-GMO".

Considering the strong momentum of new GM species with EU approval, it is not considered suitable in the present document to present a positive list of species but rather to define as the field of application of the present Regulation the list of species of vegetables for use as foods or for livestock approved by the EU and available on the website http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

The products which, in their composition, do not contain raw materials with a GMO risk, or their derived products, as stated in the official list above cannot be certified under accreditation.

The present Regulation, in order to provide the broader level of sharing regarding the provisions in it contained, was prepared and updated by a special Working Group, coordinated by ACCREDIA's Department of Certification and Inspection (ACCREDIA-DC), consisting of representatives of accredited Certification Bodies – CBs – and the representatives of other relevant interested parties.

2. NORMATIVE REFERENCES

The normative references to be considered for the application of the present Regulation are:

- Reg. EC 1829 of Sept 22, 2003 for genetically modified food and feed;
- Reg. EC 1830 of Sept 22, 2003 regarding the traceability and labelling of genetically modified organisms and the traceability of food and feed obtained from genetically modified organisms, and modifying the Directive 2001/18/CE;
- Directive 2001/18/EC on the deliberated release into the environment of genetically modified organisms replacing the Directive 90/220/EC of the Council;
- The Ministerial Decree of 28/12/2001 Payments made in euro for verification of the deliberated release into the environment of genetically modified organisms;
- UNI CEI EN ISO/IEC 17065:2012 "General requirements for bodies certifying products, processes and services";
- UNI EN ISO 22005:2008 "Traceability in the food and feed chain – General principles and basic requirements for system design and implementation".

The present Regulation also makes reference, where applicable, to the following ACCREDIA-DC documents in the last version in force:

- RG-01 - Regulation for the accreditation of Certification, Inspection, Verification and Validation Bodies – General Requirements;
- RG-01-03 - Regulation for the accreditation of product/service Certification Bodies, and to the EA and IAF documents applicable to Product Certification Bodies.

3. TERMS AND DEFINITIONS

Raw material: Food matrix including ingredients, additives, aromas and technological adjuvants used for the preparation and processing of food products.

Cross contamination: Unforeseen event for which the analysis of the causes reveals fortuity and the unintentional presence of raw materials containing, consisting and deriving from GMO in the manufacture of the product.

GMO (Genetically Modified Organism): an organism whose genetic material has been modified differently from what occurs in nature with mating and / or natural genetics recombination.

Adjuvant technology: A substance which is not consumed as a food product in itself, that is intentionally used for processing raw materials, food products or their ingredients to respect a specific technological aim during processing, which may give rise to the presence – unintentional but technically inevitable – of residues of such substance or of its derived in the finished product, provided that these residues do not constitute a risk to health and do not have technological effects on the finished product.

Additive: Any substance, not normally consumed as a food as such and not used as a typical ingredient of aliments, irrespective of the fact that it has a nutritional value, added intentionally to food products for technological purposes during the production, processing, preparation, treatment, packaging, transport, or storage of foods, which could reasonably presume to become, itself or its derivatives, a component, directly or indirectly, of such foods.

Overall sampling: A set of elementary samples taken from the same sampled portion.

Elementary sampling: A quantity taken from a part of the sampled portion.

Set of samples: Raw material and/or finished product present in a company at the time of an audit.

Traceability: Capacity to follow the movement of a feed or food throughout a specific(s) phase or phases of production, processing and distribution.

CB: Certification Body.

4. OBJECT OF THE CERTIFICATION

There are three types of certification object against the present Regulation.

a) in the first typology, the object of certification is the use of raw materials not containing, not consisting and not produced starting with GM vegetable species as per § 1 above, the absence of cross contamination and/or with a concentration of GM material which is less than 0.1%. In particular, can be the object of certification:

   a.1) food products for human consumption containing raw materials at risk of GMO or their derived products as per the list referred to the § 1;
   a.2) additives and Adjuvant technologies containing raw materials at risk of GMO or their derived products as per the official list referred to the § 1;

b) in the second typology, the object of certification is the control activity carried out by economic operators for guaranteeing respect of the limit of 0.9% which is to be understood as a limit maximum technically inevitable and/or accidental in the processes of preparation of feed products for livestock. In particular, the control activity of preparation of feed products for livestock can be the object of certification if they contain raw materials at risk of GMO and/or their derived products in accordance with the official list referred to the § 1;

c) in the third typology, the object of certification regards products of animal origin provided by and deriving from animal fed with feed in compliance with point b).

In particular:

   c.1) control activity of livestock feed as per the above point used at breedings where animals are grown for human consumption and/or obtained products for subsequent processing;
   c.2) control activity of the production process of products supplied and deriving from animal fed with livestock feed in compliance with above point b).

It is advisable to mention that the principle of dilution for achieving the thresholds is not accepted.

5. IDENTIFICATION AND TRACEABILITY

Traceability shall be applied with regard to all raw materials at risk.

After identification of the raw material at risk, the production chain shall be controlled all the way to the DNA marker of the species being researched.

Traceability may have reduced extensions only if, in the re-construction of the production chain, products are encountered which derive from a certified company by accreditated CBs against the conformity assessment schemes in line with the present Technical Regulation.

Similarly, certificates issued against Reg. EC 834/07 only for feed and livestock of non-mixed producers (organic and non-organic product) are to be considered equal in conformity to the schemes predisposed in according to the present Regulation.

6. CONFORM DURATION OF ANIMAL FEEDING

Animals, their products and/or their derived products may be declared to be in conformity with the conformity assessment schemes obtained in accordance with the contents of the present Regulation only after guarantee that, for their entire life, they have been fed with feed in conformity with the above schemes.

In cases of a breeding undergoing certification or of the entrance of new animals from non-certified breedings, according to the conformity assessment schemes developed in accordance with the present Regulation, the operator may be authorized to declare conformity of the animals, of their products and/or their derived products, only if can provide evidence that these animals have been fed with products as per § 4 point b) for an uninterrupted period (of conforming feeding) at least equal to:

TABLE 1

Categories of Animals	Period (PC)
Ruminants for meat production	12 months and in any case at least ¾ of their life
Small Ruminants	6 months
Pigs	4 months
Animals for milk production	3 months
Broilers entered into breeding before 3 days old	10 weeks
Animals for egg production	6 weeks

For animals not given in the table, the period without interruption shall be at least three-quarters of life, determined in the final phase of the same.

7. NON-CONFORM PRODUCTS

If an animal has been fed for a period over 1% of its life cycle, excluding the conform duration of animal feeding referred to the point 6, with products containing GM species as per point 4, the animal, the products and derived products of this animal cannot be authorized to be declared in conformity during and/or after the conversion period.

The animal can return to be declared in conformity after a period the duration of which depends on the level of the non-conform feed consumed.

This period is determined by means of the following calculation method:

$$\text{Days for "reconversion"} = \sqrt{PC} * (X - U - 0{,}009) * t$$

PC = Specific period for the species in question (see Table 1) expressed in days
X = Result of the analytical outcome (expressed as an absolute value)
U = uncertainty of the method of analysis (expressed as an absolute value)
0,009 = maximum acceptable value for accidental contamination - see § 4 point b)
t = days of consumption of NC feed

At the end of the added period, fixed as set out above, the animal and its products (e.g. eggs) can be considered as having returned to conformity again.

8. SELF-CONTROL OF THE CERTIFIED OPERATOR AND QUALIFICATION CRIITERIA FOR ITS SUPPLIERS

Conformity assessment schemes predisposed in accordance with the present Regulation shall consider the following minimum requirements with regard to activities of self-control on the part of the certified operator and the qualification criteria for its suppliers of raw materials at risk.

Certified operators shall give evidence of having validated the implemented activities/ procedures to ensure the absence of eventual cross contaminations in their final products.

The minimum criteria required for the qualification of suppliers of raw materials at GMO risk are the following:

1. Supplier certified against conformity assessment schemes as per the present Technical Regulation and in conformity with paragraph 5 of Reg. EC 834/07:

    - definition of a contract between the parties ensuring the supply of products in conformity with the conformity assessment scheme and the possibility by the CB to perform audits and samplings at supplier's location;
    - monitoring of the continuous validity of the certification and/or of the respect of the contractual obligations including the periodical analytical confirmation by the certified operator;
    - assessment of the risk of contamination from GMO risk raw materials and related identification of a monitoring system;
    - assessment of the risk of botanical contamination and relative identification of a monitoring system and definition of the measures to be taken in cases of negative evidences of the above point;
    - definition of a sampling plan the significance of which is a task which regards the certified operator.

2. Non-certified supplier:

    - definition of a contract between the parties ensuring the supply of products in conformity with the conformity assessment scheme and the possibility by the CB to perform audits and samplings at supplier's location;
    - monitoring of the respect of the contractual obligations including the periodical analytical confirmation by the certified operator;
    - assessment of the risk of contamination from GMO risk raw materials and identification of a monitoring system;
    - assessment of the risk of botanical contamination and relative identification of a monitoring system and definition of the measures to be taken in cases of negative evidence of the above point;
    - analytical guarantee of every batch, which may take place by means of tests performed directly by the operator or its supplier. Anyhow, the analysis cannot be based only on the analysis of the supplier. If the guarantee is provided by means of analytical tests conducted by the supplier or if the supplier demonstrates the geographical origin of seeds where GMO production is illegal, a sampling plan will nevertheless be drawn up

(periodical analytical confirmation) prepared by the certified operator who retains responsibility for its meaningfulness.

If the sampling on the products obtained from suppliers is not analytically meaningful to the search for the expected, the sampling shall be conducted on sub-suppliers[1], and the certified operator retains responsibility for its meaningfulness. The sub-suppliers shall be audited and submitted to samplings by the CB over the three-years period in accordance with the frequencies defined in § 10.2 and § 11. In these cases, a contract shall be prepared for the certified operator, the supplier and the sub-supplier, which includes and guarantees the supply of products which are in conformity with the conformity assessment scheme as well as the possibility that the CB performs audits and samplings at the sub-suppliers location.

The validation of the qualification procedures for suppliers and the frequency of monitoring shall also take into account of the provisions at the following point 10.2.

9. SAMPLING

The samplings are made taking into consideration characteristics of the products and respecting the sampling schemes (number, modalities and quantities) for food and feed for animal and human consumption, as indicated below.

Batches accompanied by a test report issued by a laboratory in accordance with point 10.1 and certified products under accreditation for conformity assessment schemes drawn up in accordance with the present Regulation shall be excluded from sampling.

The overall samples taken must be divided into three aliquots or final samplings.

[1] This principle may be derogated in the following cases: 1) aromas/additives as ingredients of a complex product, whilst respecting the obligation to obtain evidence regarding its conformity 2) case of a sub-supplier undergoes a traceability test which provides analytical guarantees for the tested batch or certified against the conformity assessment schemes as per the present Technical Regulation and in compliance with Reg. EC 834/07, paragraph 5.

9.1. SAMPLING OF FEED

On the basis also of the Official National Control Plan for animal feed (PNAA) and the applicable legislation, the sampling plan adopted for feed is as follows:

1. FOR FEED WITH ANALYTE DISTRIBUTED IN A NON-UNIFORM WAY (SIMPLE FEED IN GRAIN AND SILAGE REQUIRING GRINDING AND HOMOGENIZATION)

<table>
<tr><th colspan="3">Size of the sampled batch</th><th>Minimum number of elementary samples (*)</th><th>Overall sample</th><th>Final sample</th></tr>
<tr><td rowspan="8">< 80 tons</td><td rowspan="2">Solid feed in bulk</td><td>≤ 2,5 ton</td><td>2,5 × 7 = 18</td><td rowspan="2">4 kg</td><td rowspan="2">500 g</td></tr>
<tr><td>> 2,5 t < 80 tons</td><td>2,5 x √ of (20 × n° tons) (up to maximum of 100 elementary samples)</td></tr>
<tr><td rowspan="2">Liquid feed in bulk (**)</td><td>≤ 2,5 tons or ≤ 2500 litres</td><td>2,5 × 4 = 10</td><td rowspan="2">4 litres</td><td rowspan="2">500 ml</td></tr>
<tr><td>> 2,5 tons or > 2500 litres</td><td>2,5 × 7 = 18</td></tr>
<tr><td rowspan="4">Packaged feed (***) (iii)</td><td>From 1 to 20 packs (i)</td><td>2,5 × 1 = 3</td><td rowspan="4">4 kg</td><td rowspan="4">500 g</td></tr>
<tr><td>From 21 to 150 packs (i)</td><td>2,5 × 3 = 8</td></tr>
<tr><td>From 151 to 400 packs (i)</td><td>2,5 × 5 = 13</td></tr>
<tr><td>> 400 packs (i)</td><td>2,5 × ¼ of √ of n° units (up to maximum of 40 units)</td></tr>
<tr><td>80 tons ≤ x ≤ 500 tons</td><td></td><td></td><td>100</td></tr>
<tr><td>> 500 tons</td><td></td><td></td><td>100 + √ n° tons</td></tr>
</table>

2. FOR FEED WITH ANALYTE DISTRIBUTED IN A UNIFORM WAY (COMPLETE AND COMPLEMENTARY FEED)

<table>
<tr><th colspan="3">Size of the sampled batch</th><th>Minimum number of elementary samples (*)</th><th>Overall sample</th><th>Final sample</th></tr>
<tr><td rowspan="8">Up to 500 tons</td><td rowspan="2">Solid feed in bulk</td><td>≤ 2,5 tons</td><td>7</td><td rowspan="2">4 kg</td><td rowspan="2">500 g</td></tr>
<tr><td>> 2,5 tons</td><td>√of (20 × n° tons) (up to maximum of 40 elementary samples)</td></tr>
<tr><td rowspan="2">Liquid feed in bulk</td><td>≤ 2,5 tons or ≤ 2500 litres</td><td>4 (**)</td><td rowspan="2">4 litres</td><td rowspan="2">500 ml</td></tr>
<tr><td>> 2,5 ton or > 2500 litres</td><td>7 (**)</td></tr>
<tr><td rowspan="4">Packaged feed (iii)</td><td>Da 1 a 20 packs</td><td>1 (***) (i)</td><td rowspan="4">4 kg (ii)</td><td rowspan="4">500 g</td></tr>
<tr><td>From 21 to 150 packs</td><td>3 (***) (i)</td></tr>
<tr><td>From 151 to 400 packs</td><td>5 (***) (i)</td></tr>
<tr><td>> 400 packs</td><td>¼ of √ of n° of units (up to maximum of 40 units)</td></tr>
<tr><td>>500 tons</td><td>Solid and liquid feed in bulk</td><td></td><td>40 + √ n° tons which constitute the sampled portion</td></tr>
</table>

(*) If the result of the calculation is a decimal number, it rounds up to the higher whole number.

(**) If it is not possible to make the liquid homogeneous, the number of elementary samples must be increased.

(***) For packs containing not more than 1 kg or 1 litre, the elementary sample is constituted by the contents of an original pack.

(i) If the opening of the pack can alter the results of the analysis (e.g. in cases of perishable wet feed), the elementary sample is constituted by an unopened pack.

(ii) In cases of packaged feed, it is possible that the size of each unit does not permit taking 4 kg for the overall sample.

(iii) Large packages (sacks, stems, cans) with contents equal to or more than 500 litres or kilos must be sampled as required for solid or liquid feed in bulk.

For feed in packages of >500 tons the sampling is undertaken on the basis of the rules for bulk feed.

9.2. SAMPLING OF FOOD

On the basis also of the Official National Control Plan on the Presence of GMOs in Food, from the technical note UNI CEN/TS 15568 "Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Sampling strategies" and from the provisions shown in the law in force, the sampling plan adopted for foods is as follows:

TABLE 1: ***Bulk or packaged products, batches/lots of ≥ 50 tons***

Size of batch / lot (tons)	Weight or number of sub-batches	Number of elementary samples / packages	Weight of the overall sample (kg)
≥1500	500 tons	100	10
> 300 and < 1500	3 sub-batches	100	10
≥50 and ≤ 300	100 tons	100	10

(An elementary sample weighs about 100 grams)

TABLE 2: ***Bulk products or marketed in packaging, single sacks or packages, bulk or packaged products, batches/lots of ≤ 50 tons (Regulation EC/401/2006)***

Size of batch / lot	Number of elementary samples / packages	Weight of the overall sample (kg)
≤ 50 kg	3	1
>50 and <500 kg	5	1
>500 and < 1000 kg	10	1
>1 and < 3 t	20	2
> 3 and < 10 t	40	4
> 10 and < 20 t	60	6
> 20 and < 50 t	100	10

TABLE 3: ***Packaged products – alternative method (UNI CEN/TS 15568)***

Number of units constituting the Batch / Lot	Number of units for sampling
Up to 10	Every unit
From 10 to 100	10 units taken at regular intervals
> 100	√ of the total number of units, sampled at regular intervals

VERIFY IF THE SAMPLE FALLS WITHIN THE MATRICES FOR GRINDING AND/OR HOMOGENIZATION IN ACCORDANCE WITH THE SCHEME BELOW

Main food groups	Examples	Homogeneous distribution of GMOs in the product	Non-homogeneous distribution of GMOs in the product. Products requiring grinding and homogenization
Grains, mixed corn creams and flours	corn for popcorn, corn and mixed flours	corn and mixed flours	grain, corn for popcorn, sweet corn (corn grain)
Pasta, noodles	corn vermicelli, gnocchi, etc.	corn vermicelli, gnocchi, etc.	
Pastry, bakery and biscuit products	cereal flakes, bread, crackers, corn cakes, mixed and corn biscuits, cereal balls bars, pancakes, muesli	bread, crackers, corn cakes, mixed corn biscuits, bars, pancakes, cereal flakes, muesli, cereal balls	
Vegetables and derived products classification according to Reg. 178/2006 - pesticides	cooked and tinned sweet corn and soy, also in mixed salads, corn on the cobs		cooked and tinned sweet corn and soy, also in mixed salads, corn on the cobs
Legumes and oleaginous seeds	Grain and soy flour, rape seeds, cotton seeds	soy flour	soy grains, rapeseed, cotton seeds

Vegetable milk and derived products	Milk/Soy drink, soy cheese, bechamel, soya yogurt, tofu	Milk/Soy drink, soy cheese, bechamel, soya yogurt, tofu	
Products for infants and babies	Liquid or powder vegetable milk, cereal-based foods, biscuits, pasta, homogenized products	Liquid or powder vegetable milk, cereal-based foods, biscuits, pasta, homogenized products	
Food supplements	soy or corn based diet bars	soya or corn based diet bars	
Gastronomic preparations	soy hamburgers, soy stew, nuggets, sauces and dressings	soya hamburgers, soy stew, nuggets, sauces and dressings	
Snacks, desserts and other foods	tortilla chips, potato chips, cereal puffs, popcorn, ice-creams and sorbets, desserts, puddings, creams, sweet creams	tortilla chips, potato chips, cereal puffs, ice-creams and sorbets, desserts, puddings, creams, sweet creams	popcorn

10. TESTS, CONTROLS AND TESTING METHODS

10.1. LABORATORIES

The Laboratories authorized to perform analysis shall carry out tests covered by accreditation against the standard ISO/IEC 17025 by Accreditation Body signatory of the international agreements of mutual recognition. The list of the signatory bodies is available at http://www.european-accreditation.org/.

Considering that the EU has identified, as reference Laboratory, the EUROPEAN COMMISSION - Joint Research Center (JRC) - Directorate F, Unit F.5 - EURL GMFF, the testing methods used by Laboratories shall be those validated by the JRC (the methods are available at the above link regarding authorized species) or internal methods developed on the basis of them, whose minimum performances shall be in accordance with the document (in the current edition) *"Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing"* available at http://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm.

The methods shall guarantee the following performances:

- Limit of Quantification (LOQ) 0,1%;
- Limit of Detectability (LOD) less than or equal to 0,045%.

The LOD and LOQ shall be explained within the Testing Report issued by the laboratory for certification in accordance with the present Regulation.

The tests shall be carried out for research of all the events associated with a species.

10.2. NUMEROSITY OF ANALYTICAL TESTS PERFORMED BY THE CB

Irrespective of the object of the certification, the CB has the task of evaluating the conformity of the certified organization and therefore of its reliability. It is advisable to signal that the number of tests performed by the CB cannot be statistically meaningful because the principle objective is to validate the activities of the certified operator in its self-control system.

According to the sampling modalities set out in § 9, granted that the test is carried out in such a way as to be meaningful (in which it is possible to find the presence of the DNA marker of the species of origin in the ingredient)[2]:

- for typologies a.1, a.2 and b: during the certification phase, the CB shall sample 60% of the Raw Materials at risk which are present in the plant at the time of the audit. During the first, second and third years of surveillance 30% of the number of Raw Materials shall be sampled, chosen on the basis of a risk analysis undertaken by the CB taking into account Raw Materials previously sampled;
- for typology c.1: the sampling is performed at the breeder's location. The CB shall take and analyze (in the certification phase and then in each surveillance) a sample of livestock food deriving from every supplier of feed;
- for typology c.2: the sampling is performed at the location of the breeder supplying the certified operator. The CB shall perform the sampling of sub-suppliers (feed producers) of the certified operator using the criterion of one livestock food sampling deriving from every sub-supplier, during the certification phase and at every surveillance.

The analytics research is carried out by the CB for all approved species as per the list mentioned in § 1 taking into consideration only the raw materials present in the product, without considering any possible botanical contamination.

To guard the botanical contaminations the CB shall evaluate how the operator can manage and prevent these contaminations.

11. NUMEROSITY OF AUDITS PERFORMED BY THE CB

The number of sites to audit shall be determined as follows:

- During the initial certification it is necessary to audit a number of sites at least equal to the sum of $\sqrt{Ni}$, where Ni is the number of sites attributable to the i-th group of similar sites included in the certificate (e.g. number of production plants, suppliers of raw materials or ingredients, agricultural producers, etc.);
- During the annual surveillance, it is necessary to audit at least 60% of the sites included in the initial certification determined as above. This number may increase or decrease over time and shall be determined annually.

[2] This principle may be derogated in cases of aromas/additives as ingredients of a complex product, whilst respecting the obligation to obtain evidence concerning its conformity.

The number of sites may also be determined, as an alternative and at the discretion of the CB, by means of the following calculation:

$$n = \left[1 - (1 - a)^{1/D}\right]\left(N - \frac{D-1}{2}\right)$$

where:

N = the total number of (similar) primary production sites included in the chain
D = 0.1N
a = level of trust
N ≥ 1000 a = 0.95
501 < N < 999 a = 0.85N ≤ 500 a = 0.75

12. USE OF THE SCOPE OF CERTIFICATION

Certified products:

- cannot state on primary and/or secondary packaging the generic wording "GMO-free product";
- if the certification object falls within the typology a) of paragraph 4, the products may state the generic wording "NO GMOs AND DERIVED PRODUCTS";
- if the object of certification falls within typology b) of paragraph 4, the products shall make explicit reference to the details of the certification (standard, certificate number, CB);
- if the object of certification falls within typology c.1) of paragraph 4, the products can state the general diction "ANIMALS FED WITH GMO-FREE FEEDS AND DERIVED PRODUCTS", or by means of a synonymous declaration;
- if the object of certification falls within typology c.2) of paragraph 4, the products may state the general diction "PRODUCTS OBTAINED FROM ANIMALS FED WITH GMO-FREE FEEDS AND DERIVED PRODUCTS", or by means of a synonymous declaration.

Packaging shall contain the following minimum information:

- the reference technical document;
- the number of the certificate and/or the order number.