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(Acts whose publication is not obligatory)

COMMISSION

COMMISSION RECOMMENDATION

of 4 October 2004

on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003

(Text with EEA relevance)

(2004/787/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, in particular the second indent of Article 211 thereof,

Whereas:

(1) 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 [1] sets up a system for the transmission and retention of information between operators at each stage of the placing on the market of products containing or consisting of genetically modified organisms, hereinafter "GMOs", or food and feed products produced from GMOs, but does not require operators to sample and test products at each stage of the placing of the market for presence of GMOs or material produced from GMOs.

(2) According to Article 9(1) of Regulation (EC) No 1830/2003, Member States are, however, required to ensure that inspections and other control measures including sample checks and testing (qualitative and quantitative), as appropriate, are carried out to ensure compliance with that Regulation.

(3) In order to facilitate a coordinated approach for those inspections and control measures, Article 9(2) of Regulation (EC) No 1830/2003 requires that technical guidance on sampling and testing for GMOs and food and feed material produced from GMOs in products should be established.

(4) This guidance should cover products that have received authorisations for their placing on the market but is without prejudice to Article 4(5) of Directive 2001/18/EC of the European Parliament and of the Council [2] with regard to GMOs which are not authorised in the European Union.

(5) The sampling and detection should be carried out using sound scientific and statistical protocols in order to achieve an appropriate level of confidence for detection of GMOs or material produced from GMOs.

(6) In developing the guidance, the Committee set up by Article 30 of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC has been consulted, and account has been taken of the work of the national competent authorities, the Standing Committee on the Food Chain and Animal Health and the Community Reference Laboratory.

[1] OJ L 268, 18.10.2003, p. 24.

[2] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003.

(7) Where lots of non-GM seed or other plant propagating material are required to comply with standards on adventitious or technically unavoidable presence of genetically modified seeds or other plant propagating material, a legally-binding protocol on sampling and testing for the presence of genetically modified seeds or other plant propagating material should be developed in the context of the specific legislation on seeds and other plant propagating material; whereby the elements provided in that protocol should also serve as a basis for sampling and testing of other GM crop species not covered by the abovementioned legislation, where appropriate,

HEREBY RECOMMENDS:

I. GENERAL PRINCIPLES

1. For the purpose of fulfilling the requirements set out in Article 9(1) of Regulation (EC) No 1830/2003, Member States should take account of:

(a) the past record of operators with respect to compliance with relevant legislation;

(b) the reliability of any controls that operators have already carried out;

(c) situations where non-compliance is suspected;

(d) using means proportionate to the desired specific objectives and particularly in the light of experience gained;

(e) the degree of heterogeneity and the point in the supply chain at which testing is being undertaken.

2. Official controls should be carried out without prior warning, except in cases where prior notification of an operator is necessary.

3. Official controls should be carried out at any stage of the production, processing, and storage, distribution of products that contain or may contain GMOs or food and feed produced from GMOs, including at the point of import [3].

4. Official controls should not differentiate between products intended for export outside the Community and products intended for placing on the market within the Community.

5. Operators whose products are subject to sampling and analysis should be entitled to appeal for a second opinion. Official bodies should collect a sufficient number of counter samples for enforcement and referee purposes in order to guarantee operators appeal right and have a second opinion, as required by national legislation.

6. Alternative sampling strategies to those recommended in this guidance may be applied.

7. Alternative testing strategies to those recommended in this guidance may be applied provided such methods are approved by the Community Reference Laboratory established under Regulation (EC) 1829/2003.

8. Without prejudice to specific requirements laid down in EU legislation concerning food, feed and other controls, and in particular Directive 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition, Directive 70/373/EEC on the introduction of Community methods of sampling and analysis for the official control of feeding stuffs, Directive 89/397/EEC on the official controls of foodstuffs and Directive 93/99/EEC on the subject of additional measures concerning the official control on foodstuffs, Member States should ensure that official controls are carried out, so as to achieve the objectives of Regulation (EC) No 1830/2003.

II. DEFINITIONS

(a) Lot is defined as a distinct and specified quantity of material.

The following definitions take account of the type of material forming a lot and are in line with ISTA, ISO standards 6644 and 13690 and FAO (International Standards for Phytosanitary Measures):

[3] In accordance with Article 9(3) of Regulation (EC) No 1830/2003 relevant information concerning GMOs which are not authorised in the EU should, where available, be placed on a central register.

seed lot: a specified quantity of seed, physically identifiable and uniform, not exceeding the maximum lot size as defined in the seeds Directives and forming the total or a part of a consignment;

other plant propagating material lot: a number of units of a single commodity identifiable by its homogeneity of composition, origin etc., not exceeding the maximum lot size as defined in the legislation on other plant propagating material, and forming the total or a part of a consignment;

food and feed products lot: quantity of product dispatched or received at one time and covered by a particular contract or shipping document.

(b) Increment sample: small equal quantity of product taken from each individual sampling point in the lot through the full depth of the lot (static sampling), or taken from the product stream during a stated portion of time (flowing commodities sampling).

(c) File increment sample: an increment sample that is retained for a specific period of time for further analysis.

(d) Bulk sample: quantity of product obtained by combining and mixing the increments taken from a specific lot.

(e) Laboratory sample: quantity of product taken from the bulk sample intended for laboratory inspection and testing.

(f) Analytical sample: homogenised laboratory sample, consisting either of the whole laboratory sample or a representative portion thereof.

(g) Counter sample: a sample retained for a specific period of time for enforcement or referee purposes.

(h) Percentage of GM DNA: the percentage of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes.

III. PRINCIPLES FOR SAMPLING PROTOCOLS

1. Member States should take account of the guidance on sampling protocols for products consisting of, containing or produced from GMOs when inspecting and controlling whether operators are complying with Articles 4 and 5 of Regulation (EC) No 1830/2003.

2. The Community Reference Laboratory established under Regulation (EC) No 1829/2003, and the nationally designated laboratories to the European Network of GMO Laboratories, hereinafter "ENGL", will provide further guidance and assistance on the methods of sampling falling within the scope of this Recommendation.

3. Harmonised sampling procedures should be utilised for the purpose of estimating the presence of GMOs. These procedures should apply to seed and other plant propagating material, food, feed and agricultural commodity lots.

4. The following sampling procedures are defined in order to ensure that the samples collected and analysed are representative of the different types of commodities under investigation. Whereas sampling protocols for the presence of GM seeds and other plant propagating material in seed lots should be developed according to the specific legislation on seeds or other propagating material, sampling strategies for bulk commodities and food and feed products are addressed in separate sections that take into account commodity-specific properties.

IV. SAMPLING PROTOCOLS

1. Sampling seed and other plant propagating material lots

This section deals with the detection of genetically modified seeds or other plant propagating material in lots of seed or other plant propagating material of non-GM varieties or clones and the detection of GM seeds or other plant propagating material arising from a transformation event other than that designated for a lot of seed or other plant propagating material of a GM variety or clone.

Samples should be drawn in accordance with current international methods and where appropriate from lot sizes as defined in Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 92/34/EEC, 98/56/EEC, 1999/105/EC,

2002/54/EC, 2002/55/EC, 2002/56/EC and 2002/57/EC. The general principles and methods of sampling of seeds and other plant propagating material should be in accordance with the International Seed Testing Association (ISTA) rules and the associated ISTA Handbook on Seed Sampling.

The sampling and testing schemes to be used for seeds or other plant propagating material should meet the requirements indicated in the specific legislation on seeds and other propagating material as regards statistical risks. Seed or other plant propagating material lot quality level and its associated statistical uncertainty are defined in relation to thresholds for GMOs and relate to the percentage of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes.

2. Sampling bulk agricultural commodities

The sampling protocol is based on a two-step procedure that allows, if necessary, to obtain estimates of GMO presence levels, together with their associated uncertainty expressed as Standard Deviation (SD), without imposing any assumption on the possible heterogeneity of the GMOs.

In order to allow the estimation of SD, in the first instance, a bulk sample should be produced and the derived analytical sample analysed for the presence of GM materials. Where the obtained analytical result is close to the established threshold (± 50 % of its value), the analysis of the individual file increment samples is recommended to provide a measure of the associated uncertainty.

The following documents should be taken into account:

(a) ISO standard 6644 (2002);

(b) ISO standard 13690 (1999);

(c) ISO standard 5725 (1994);

(d) ISO standard 2859 (1985);

(e) ISO standard 542 (1990).

2.1. Protocol for sampling lots of bulk agricultural commodities

It is recommended that sampling of bulk commodities (grains, oilseeds) takes place in accordance with the general principles and methods of sampling described in ISO standards 6644 and 13690. In case of flowing commodities, the sampling period should be defined, according to ISO standard 6644, as: total off-loading time/total number of increments. In case of static sampling, increments should be collected at specific sampling points. Such sampling points should be uniformly distributed throughout the lot volume, according to the principles described in ISO 13690. The number of increments or sampling points (where the increment samples for creating the bulk sample and the file increment samples are taken) is defined according to lot size, as follows:

+++++ TABLE +++++

In case of lots from 50 to 500 tonnes, the size of the bulk sample should be 0,01 % of the total lot size. In case of lots smaller than 50 tonnes, the size of the bulk sample should be 5 kg. In case of lots larger than 500 tonnes, the size of the bulk sample should be 50 kg. At each sampling interval (systematic sampling) or sampling point (static sampling) an increment of 1kg should be collected and split into two portions of 0,5 kg: one to be used as an increment for the production of the bulk sample, the other to be stored as a file increment sample.

Sampling of materials larger than grains (e.g. fruits, rhizomes, potatoes) should be carried out according to ISO standard 2859. Sampling of oilseed should be carried out according to ISO standard 542.

2.2. Protocol for the preparation of the analytical samples

A multiple-step protocol is recommended in order to minimise costs and maximise statistical power according to pre-defined acceptance levels.

Initially, the increment samples collected according to sub-section 2.1 are combined and mixed thoroughly, according to the procedures described in ISO standards 13690 and 6644, to form a bulk sample.

The bulk sample is used to create an analytical sample, according to the procedures described in ISO standards 13690 and 6644, and analysed for the presence of GMOs according to "analytical test protocols/testing methods", as outlined in section V. If the result of the analysis is close to the established threshold (threshold ± 50 % of its value), an estimation of the associated uncertainty may be necessary (a protocol for estimating this uncertainty is foreseen in Article 2.3).

2.3. Protocol for estimating uncertainty

If there are 20 or fewer file increment samples, as in the case of smaller lots, all samples should be analysed individually and a decision as to labelling should be taken.

If there are more than 20 file increment samples, 20 samples should be randomly selected and individually analysed for the presence of GMOs. Analytical results from these 20 samples are used to estimate the GMO content of the lot and its associated uncertainty expressed as standard deviation (SD). If this uncertainty associated to the analysis of the 20 samples is acceptable, no additional analysis of the remaining file increment samples is necessary. If, instead, the level of associated uncertainty is not acceptable, additional analysis of the remaining file increment samples should be carried out.

The number of additional samples to be analysed should be established on a case-by-case basis, depending upon the level of uncertainty estimated from the initial 20 samples.

The sequential analytical process should stop when either or both of the following is the case:

- the estimated lot GMO content (mean GMO content of the analysed file increment samples) is above or below the established threshold ± 50 % of its value,

- the uncertainty associated to the measured lot GMO content reaches an acceptable level (± 50 % of the mean analytical result).

Where all samples have been tested a decision as to labelling should be taken.

2.4. Protocol for sampling lots of food and feed products

Sampling of pre-packaged food and feed products should be carried out according to the procedures described in ISO 2859.

Sampling of non pre-packaged food and feed products should be carried out according to the protocol described in sub-section 2.1.

V. ANALYTICAL TEST PROTOCOLS/TESTING METHODS

The Community Reference Laboratory established under Regulation (EC) No 1829/2003, and the nationally designated laboratories to the ENGL, will provide further guidance and assistance on the methods of testing falling within the scope of this Recommendation.

2. Laboratory requirements

Member States' laboratories carrying out the analyses in accordance with this Recommendation should be accredited according to EN ISO/IEC 17025/1999 or certified according to an appropriate scheme, and should regularly participate in proficiency testing schemes organised or co-ordinated by nationally or internationally recognised laboratories and/or by national, international organisations.

Foodstuffs submitted for analysis in accordance with this Recommendation should be submitted to laboratories complying with the provisions of Article 3 of Directive 93/99/EEC.

The analytical investigation of the samples should be carried out in accordance with the general laboratory and procedural requirements from the draft European standard prEN ISO 24276:2002.

3. Analytical sample preparation

When taking samples, the aim is to obtain a representative and homogeneous laboratory sample without introducing secondary contamination. Member States should use the draft European standard prEN ISO 24276:2002 and prEN ISO 21571:2002 that indicate strategies for the homogenisation of the laboratory sample, the reduction of the laboratory sample to the test sample, the preparation of the test sample and the extraction of target analyte.

Obtaining samples of seeds should be done according to the ISTA International Rules for Seed Testing. Obtaining plant-propagating material samples should be done according to current international methods, in so far such methods exist.

4. Analytical testing

The current scientific knowledge does not allow for the detection and quantification of all GMOs or food and feed material produced from GMOs that have been approved for the placing on the market by using a single method.

Several testing approaches are likely to provide equally reliable results. These may include one or a combination of the following:

(a) qualitative methods, that may be event-specific, construct-specific or genetic element-specific;

(b) quantitative methods, that may be event-specific, construct-specific or genetic element-specific.

It may be appropriate to start with a screening method to test whether GMOs are present or not. If a positive result is obtained, specific methods for a genetic construct and/or transformation event should be carried out. If different GMOs containing the same genetic construct are present on the market, an event specific method is strongly recommended. The results of quantitative analysis should be expressed as the percentage of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes. Whenever possible, laboratories should use a method validated according to internationally recognised criteria (e.g. ISO 5725/1994 or IUPAC harmonised protocol), and include the use of certified reference material.

An up-dated list of validated methods, including validated methods reported to Codex Alimentarius, is available in (http://biotech.jrc.it).

5. Absence of validated methods

If a situation arises where no validated method exists, for instance to test whether GMOs are present or not, Member States' laboratories should carry out an in-house validation of the method according to internationally recognised criteria. If no validated method is available for the matrix under analysis, it is recommended to select from the database available on http://biotech.jrc.it a method that has been validated on a similar matrix or raw material. Before adoption, the performance of such method should be tested on the matrix of interest.

6. Expression and interpretation of the results of the analyses

In case of qualitative methods, the limit of detection (LOD) is the lowest level of analyte that can be reliably detected, given a known number of target taxon genome copies.

In case of quantitative methods, the limit of quantification (LOQ) is the lowest level of analyte that can be reliable quantified, given a known number of target taxon genome copies. Results of quantitative analysis should be expressed as GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes. If the GM target sequence content is below the limit of quantification (LOQ), the results shall only be expressed qualitatively.

It is recommended to interpret the results according to the instructions given in the draft European standard prEN ISO 24276:2002.

VI. FINAL PROVISIONS

Sampling and detection methodology, including relevant protocols and documents, should continue to be developed and up-graded taking account of any change in thresholds and threshold values established under Articles 12, 24 and 47 of Regulation (EC) No 1829/2003, Article 21(2) and (3) of Directive 2001/18/EC and under other Community legislation, the report under Article 12 of Regulation (EC) No 1830/2003 concerning the implementation of that regulation, advances in technology and developments in international fora.

Done at Brussels, 4 October 2004.

For the Commission

Margot Wallström

Member of the Commission