EUROPEAN COMMISSION

Draft version

SCFCAH, 15/11/2010

**COMMISSION REGULATION (EU) No …/..**

**of […]**

**laying down the methods of sampling and analysis for the official control of feed as regards the presence of genetically modified material for which an authorisation procedure is pending or the authorization of which has expired**

Draft

**COMMISSION REGULATION (EU) No …/..**

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**laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorization of which has expired**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[1], and in particular Article 11(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed[2] does not provide for special rules for the control of material which contains, consists of or is produced from GMOs (GM material) for which an EU authorisation procedure is pending or GM material the authorisation of which has expired. Experience has shown that in the absence of such rules, the official laboratories and the competent authorities apply different methods of sampling and different rules for the interpretation of the results of the analytical tests. This may lead to different conclusions as regards the compliance of a product with Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[3]. As a result of the lack of harmonised rules, economic operators are faced with legal uncertainty and there is a risk that the functioning of the internal market will be affected.

(2) The EU imports significant quantities of commodities produced in third countries where GMO cultivation is widespread. While these imported commodities are used both in the production of food and feed, the majority of the commodities likely to contain GMOs are destined for the feed sector thereby entailing a higher risk of trade disruption for that sector in case where Member States apply different rules for official controls. It appears therefore appropriate to focus the scope of this Regulation to the

1 OJ L 165, 30.4.2004, p. 1.
2 OJ L 54, 26.2.2009, p.1.
3 OJ L 268, 18.10.2003, p 1.

feed sector which, in comparison with other sectors related to the production of foodstuffs, has a higher likelihood for GM presence.

(3) The validation of the method of analysis is one of the elements required by Regulation (EC) No 1829/2003 for the authorisation of a GM food and feed and for the placing on the market, use and processing of existing products within the meaning of Article 20 of that Regulation. In practice it is carried out by the European Union Reference Laboratory (EU-RL) independently of the other elements provided for in the authorisation procedure. Generally the method is validated before all of the other elements are fulfilled for a decision to be taken on the authorisation. These methods are published on the website of the EU-RL and are available to the competent authorities as well as to any interested part.

(4) A method may only be validated if it complies with the detailed rules for the fitness of the method set out in Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.[4] In addition, as required by that Regulation, common criteria for minimum performance requirements for analytical methods for GMO testing have been set[5].

(5) The methods of analysis validated by the EU-RL in the context of the authorisation procedure and for the placing on the market, use and processing of existing products within the meaning of Article 20 of Regulation (EC) No 1829/2003 are event-specific quantitative methods. They are validated through a collaborative trial in accordance with the principles of ISO 5725 International standard and/or the International Union of Pure and Applied Chemistry (IUPAC) protocol. As a matter of fact, the EU-RL is currently the sole laboratory in the world validating quantitative event specific methods in accordance with the above mentioned standards in the context of pre-marketing authorisation procedures. These quantitative methods are considered to be more appropriate than qualitative methods for the purpose of ensuring the harmonisation of the official controls. Indeed the robustness of qualitative methods is proportionate to the quantity of feed taken for sampling and these methods are less accurate on small amounts of material. It is therefore appropriate to use the methods of analysis validated by the EU-RL in the context of the authorisation procedure to prevent diverging analytical results amongst Member States.

(6) Reference material should also be available to enable control laboratories to perform their analysis.

(7) Accordingly, the scope of this Regulation should cover the detection in feed of non authorised GM material for which a valid application under Article 17 of Regulation (EC) No 1829/2003 has been lodged where the event-specific quantitative methods of analysis submitted by the applicant have been validated by the EU-RL and provided that the reference material is available.

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[4] OJ L 102, 7.4.2004, p. 14.

[5] http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requir_Analyt_methods_131008.pdf

(8) The scope of this Regulation should also cover feed containing, consisting of or produced from SYN-EV176-9 and MON-ØØØ21-9xMON-ØØ81Ø-6 maize and ACS-BNØØ4-7xACS-BNØØ1-4 and ACS-BNØØ4-7xACS-BNØØ2-5, ACS-BNØØ7-1 oilseed rape for which a quantitative method has been validated by the European Union Reference Laboratory provided that the reference material is available**.** These GM materials were placed on the market before the application of Regulation (EC) No 1829/2003 and were notified as existing products under Article 20 of that Regulation. As the seeds were no more commercialised at global scale, the respective notifiers informed the Commission that they had no intention to submit an application for the renewal of the authorisation of the products concerned. As a consequence, the Commission adopted Decisions 2007/304/EC, 2007/305/EC, 2007/306/EC, 2007/307/EC and 2007/308/EC on the withdrawal from the market of the products concerned (obsolete products). These Decisions provide a tolerance for the presence in products of material which contains, consists of or is produced from SYN-EV176-9 and MON-ØØØ21-9xMON-ØØ81Ø-6 maize and ACS-BNØØ4-7xACS-BNØØ1-4 and ACS-BNØØ4-7xACS-BNØØ2-5, ACS-BNØØ7-1 oilseed rape provided that this presence is adventitious or technically unavoidable and in a proportion no higher than 0,9% for a limited period which expires on 25 April 2012. It is appropriate to ensure that at the time of the expiry of the tolerance period set out in Decisions 2007/304/EC, 2007/305/EC, 2007/306/EC, 2007/307/EC and 2007/308/EC this Regulation applies also to the detection of these obsolete products in feed.

(9) Harmonisation of the official controls of feed for the detection of GM material falling under the scope of this Regulation should also be ensured through the adoption of common methods of sampling.

(10) These methods should be based on recognised scientific and statistical protocols and, when available, on international standards and should cover the different steps of sampling, including the rules applicable to the sampling of the material, the precautions to be taken in the course of sampling and preparation of samples, the conditions to be applied for taking incremental samples and replicate laboratory samples, the handling of laboratory samples and the sealing and labelling of samples. To ensure adequate representativeness of the samples taken for official control purposes, specific conditions adapted to the fact that the lot of feed is presented in bulk agricultural commodities, pre-packaging or retail should also be adopted.

(11) It is also appropriate to harmonise the rules for the interpretation of the results of the analysis, to ensure that throughout the European Union the same results are obtained from the same products.

(12) In this context, it is also necessary to take into account the technical constraints associated with any method of analysis, in particular at trace levels since analytical uncertainty increases with decreasing levels of GM material.

(13) To take these constraints into account, as well as the need to ensure that controls are both feasible, robust and proportionate, as set out in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[6], it is

[6] OJ L 31, 1.2.2002, p. 1.

appropriate to set as a Minimum Required Performance Limit (MRPL) the lowest level of GM material which is considered by the EU-RL for the validation of quantitative methods. This level corresponds to 0.1% related to mass fraction of GM material in feed and is the lowest level where results are satisfactorily reproducible between official laboratories when appropriate sampling protocols and methods of analysis for measuring feed samples are applied.

(14) A decision of non compliance of the feed should therefore only be taken when GM material falling under the scope of this Regulation is present at levels equal or above the MRPL, measurement uncertainty being taken into account.

(15) Measurement uncertainty should be determined by each official laboratory on the basis of the results obtained during the validation by the EU-RL and confirmed by internal control data as described in the guidance document on Measurement Uncertainty for GMO testing laboratories[7] developed by the Joint Research Centre of the Commission (JRC).

(16) These implementing rules should be adapted if this becomes necessary to take account of new developments in particular as regards their impact on the internal market and on food and feed operators.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them.

HAS ADOPTED THIS REGULATION:

*Article 1*
*Definitions*

1. For the purposes of this Regulation, the following definitions apply:

(1) "lot": an identifiable quantity of a feed determined to have common characteristics, such as origin, variety, type of packing, packer, consignor or labeling; and in case of a production process a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together;

(2) "incremental sample": a quantity of material taken from a single place in the lot or sublot;

(3) "aggregate sample": the combined total of all the incremental samples taken from the lot or sublot;

(4) "laboratory sample": a sample intended for the laboratory;

(5) "Test sample": a sample, as prepared for testing or analysis, the whole quantity being used for analyte extraction at one time;

[7] http://www.irmm.jrc.be/html/reference_materials_catalogue/user_support/EUR22756EN.pdf

(6) "Minimum Required Performance Limit (MRPL)": the lowest amount or concentration of analyte in a sample that has to be reliably detected and confirmed by official laboratories.

(7) "GM material": material which contains, consists of or is produced from GMOs.2. The definitions set out in Article 2 of Regulation (EC) No 1829/2003 apply.

*Article 2*

*Scope*

This Regulation shall apply to the official control of feed with respect to the presence of the following material:

(a) GM material for which valid application has been submitted under Article 17 of Regulation (EC) No 1829/2003 and for which the authorisation procedure is pending provided that the quantitative method requested under that Article has been validated by the European Union Reference Laboratory and that the reference material is available, and

(b) after 25 April 2012, GM material notified under Article 20 of Regulation (EC) quantitative No 1829/2003 the authorisation of which has expired and for which a method has been validated by the European Union Reference Laboratory provided that reference material is available.

The Commission shall publish the list of GM material complying with the conditions set out in this Article on its website and it updated. The list shall include information as to the place where the reference material can be accessed as required by Article 17(2)(j) of Regulation (EC) No 1829/2003.

*Article 3*

*Methods of sampling*

Samples for the official control of feed as regards the presence of the GM material referred to in Article 2, shall comply with the methods of sampling, as set out in Annex I.

*Article 4*

*Sample preparation, methods of analysis and interpretation of results*

The preparation of laboratory samples, the methods of analysis and the interpretation of results shall comply with the requirements set out in Annex II.

*Article 5*

*Review*

The Commission shall monitor the application of this Regulation and its impact on the internal market as well as on feed, livestock and other operators, and, if necessary, will bring forward proposals to review this Regulation.

*Article 6*

*Entry into force*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*
*[…]*
*Member of the Commission*

## ANNEX I

## METHODS OF SAMPLING

Incremental samples intended for official control of the presence in feed of the GM material referred to in Article 2 shall be taken according to the methods of sampling set out in this Annex. Aggregate samples thus obtained shall be considered as representative of the lots.

### (A) GENERAL REQUIREMENTS FOR SAMPLING

Sampling shall be performed by an authorised person designated by the Member State.

#### 1 Material to be sampled

Each lot which is to be examined shall be sampled separately.

#### 2 Precautions to be taken

In the course of sampling, preparation and transportation of the samples, precautions shall be taken to avoid any changes which would:

- affect the content of the genetically modified material;

- adversely affect the analytical determination;

- make the aggregate samples unrepresentative;

- affect the feed safety of the lots to be sampled.

All measures necessary to ensure the safety of the persons taking the samples shall be taken.

#### 3 Incremental samples

As far as possible incremental samples shall be taken at various places distributed throughout the lot or sublot. Departure from such procedure shall be recorded.

The weight of the incremental sample shall be about 500 grams.

#### 4 Replicate laboratory samples

In accordance with Article 11(5) and (6) of Regulation (EC) No 882/2004, the competent authorities shall establish adequate procedures in order to guarantee the right of operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion. Two replicate laboratory samples used for this purpose shall be taken from the homogenised aggregate sample.

### 5 Sealing and labelling of laboratory samples

Each laboratory sample taken for official use shall be sealed at the place of sampling and identified following the rules applicable in the Member State concerned.

A record of each sampling shall be kept, permitting each lot to be identified unambiguously and giving the date and place of sampling. Any other information likely to be of assistance to the analyst shall be reported.

## (B) SPECIFIC REQUIREMENTS FOR SAMPLING

### 1 Sampling lots of bulk agricultural commodities

#### (a) General conditions

Sampling of bulk commodities shall take place in accordance with the general principles and methods of sampling described in ISO standard 24333:2009.

In case of flowing commodities, the sampling period shall be defined according to ISO standard 6644 as: total off-loading/total number of increments.

In case of static sampling, increments shall be collected at specific sampling points. Such sampling points shall be uniformly distributed throughout the lot volume, according to the principles described in ISO 24333.

#### (b) Number of incremental samples or sampling points

The number of incremental samples or sampling points (where the incremental samples for creating the aggregate sample are taken) is defined depending on the lot size in accordance with Table 1:

Table 1. Number of incremental samples to be taken from the lot

| Lot size in tonnes | Size of the aggregate sample in kg | Number of incremental samples |
|---|---|---|
| < 50 | 5 | 10 |
| 100 | 10 | 20 |
| 250 | 25 | 50 |
| > 500 | 50 | 100 |

In case of lots from 50 to 500 tonnes, the size of the aggregate sample shall be 0.01% of the total lot size. In case of lots smaller than 50 tonnes, the size of the aggregate sample shall be 5 kg. In case of lots larger than 500 tonnes, the size of the aggregate sample shall be 50 kg.

Sampling of materials larger than grains (such as fruits, rhizomes, potatoes), shall be carried out according to ISO standard 2859. Sampling of oilseed rape shall be carried out according to ISO standard 542.

**(c) Preparation of the aggregate samples**

The incremental samples collected in accordance with points (a) and (b) shall be combined and mixed thoroughly, according to the procedures described in ISO standards 13690 and 6644, to form a homogeneous aggregate sample**.**

**1 Sampling lots of pre-packaged feed products**

This paragraph shall apply to pre-packed units of raw materials, such as kernels, flours, of up to 50 kg.

The number of incremental samples shall be defined, depending on the lot size, in accordance with Table 1.

The total weight of a lot or consignment shall be calculated as follows: weight per pack x number of packs x lot or consignment.

Incremental samples shall be taken from different parts, for example top, middle and bottom, of all the pre-packed units, by means of a sack/bag spear.

If pre-packed units up to 0.5 kg are sampled, the number of units has to be increased in order to reach the size of the aggregate sample given in Table 1. The required pre-packed units shall be randomly sampled from the consignment.

The aggregate sample shall be created by thoroughly mixing the incremental samples in order to ensure maximum homogenization.

**2 Sampling at retail stage**

Feed sampling at retail stage shall be done where possible in accordance with point 2.

Where that is not possible, an alternative method of sampling may be applied provided that it ensures that the aggregate sample is representative of the sampled lot and on condition that it is fully described and documented. In any case, the aggregate sample shall be at least 1 kg.

## ANNEX II

## CRITERIA FOR SAMPLE PREPARATION AND METHODS OF ANALYSIS

In order to detect the presence in feed of the GM material referred to in Article 2, the official laboratories shall use the methods of analysis and control requirements described in this Annex.

### A. LABORATORY SAMPLE PREPARATION

#### 1 Introduction

Laboratory samples shall be obtained from the aggregate samples taken according to the methods described in Annex I.

#### 2 Precautions

As the distribution of GM material may not be homogeneous, laboratory samples shall be prepared, and especially homogenised, with care.

#### 3 Treatment of the laboratory samples

Official laboratories shall use the standard EN ISO 24276, ISO 21570, ISO 21569 and ISO 21571 that indicate strategies for the homogenization of the laboratory sample, the reduction of the laboratory sample to the analytical sample, the preparation of the test sample and the extraction and the analysis of target analyte.

#### 4 Size of the laboratory sample

The laboratory sample shall be of a size which ensures the quantification of GM material at a presence corresponding to the MRPL with a statistical degree of confidence of 95 %.When expressed in grains, the size of the laboratory sample shall be 3000.

The weight equivalent of 10 000 grain/seed is provided in Table 2 below.

Table 2

| Plant | Weight, in grams, corresponding to 10 000 grain/seed |
|---|---|
| Barley, Millet, Oat, Rice, Rye, Wheat | 400 |
| Corn | 3000 |
| Soybean | 2000 |
| Rape seed | 40 |

(Data source ISO 21568)

## B. METHODS OF ANALYSIS TO BE USED BY THE OFFICIAL LABORATORY AND RULES FOR INTERPRETATION OF RESULTS

### 1 General conditions

Official laboratories shall comply with the requirements of ISO 17025 and use quantitative methods of analysis that have been validated by the European Union Reference Laboratory in collaboration with the European Network of GMO Laboratories. They shall ensure that, considering the whole analytical method starting with the treatment of the laboratory sample of feed, they are in position to carry out the analysis with an adequate relative reproducibility standard deviation.

### 2 Rules for interpretation of results

To ensure a level of confidence of approximately 95 %, the outcome of the analysis shall be reported as x +/– *U* whereby x is the analytical result and *U* is the appropriate expanded measurement uncertainty.

*U* shall be estimated on the basis of the results obtained during the validation by the European Union Reference Laboratory and shall be specified by the official laboratory for the whole analytical method using internal control data as described in the guidance document on Measurement Uncertainty for GMO testing laboratories[8] developed JRC.

A feed shall be considered as non compliant with Regulation (EC) No 1829/2003 when the analytical result (x) minus the expanded measurement uncertainty (U) equals or exceeds the level of 0.1 % related to mass fraction of GM material in feed.

8 http://www.irmm.jrc.be/html/reference_materials_catalogue/user_support/EUR22756EN.pdf