Commission Regulation (EU) No 619/2011 of 24 June 2011 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 authorisation of which has expired (Text with EEA relevance)

COMMISSION REGULATION (EU) No 619/2011

of 24 June 2011

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 authorisation of which has expired

(Text with EEA relevance)

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) Different international information exchange mechanisms providing information on the safety assessments performed by countries authorising the commercialisation of GMOs are in place. In accordance with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity of which all Member States are Parties, Parties to the Protocol have to inform the other Parties through the Biosafety Clearing House (BCH) on any final decision regarding domestic use, including placing on the market, of a GMO that may be subject to transboundary movement for direct use as food or feed or for processing. This information shall contain, inter alia, a risk assessment report. Countries which are not Parties to the Protocol may also provide such information on a voluntary

basis. International information exchange mechanisms regarding the authorisation of GMOs and their safety assessments are also provided by FAO and OECD.

(3) 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 cases where Member States apply different rules for official controls. It appears therefore appropriate to limit the scope of this Regulation to the feed sector which, in comparison with other sectors related to the production of foodstuffs, has a higher likelihood for GM presence.

(4) Regulation (EC) No 1829/2003 provides that the placing on the market of genetically modified feed is subject to an authorisation procedure. The authorisation procedure includes the publication of an EFSA opinion of which the main component is a safety assessment. In giving its opinion, EFSA consults Member States upon receipt of a valid application and Member States have 3 months to make their opinions known. The opinion of EFSA has also to include a method for detection validated by the European Union Reference Laboratory (EU-RL).

(5) In practice, the validation by the European Union Reference Laboratory (EU-RL) is carried out independently of the other elements provided for in the authorisation procedure. Generally the method is validated and published before all of the other elements are fulfilled for completing the EFSA opinion. These methods are published on the website of the EU-RL and are available to the competent authorities as well as to any interested parties.

(6) 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)].

(7) 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 testing procedures using qualitative methods require

other sampling schemes as they are otherwise associated with higher risks to provide diverging results regarding the presence or absence of genetically modified 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.

(8) Certified reference material should also be available to enable control laboratories to perform their analysis.

(9) Accordingly, the scope of this Regulation should cover the detection in feed of GM material authorised for commercialisation in a third country and for which an authorisation procedure is pending for more than 3 months under Regulation (EC) No 1829/2003 where the event-specific quantitative methods of analysis submitted by the applicant have been validated by the EU-RL and provided that the certified reference material is available.

(10) The scope of this Regulation should also cover GM material the authorisation of which has expired. It should therefore apply to feed containing, consisting of or produced from SYN-EV176-9 and MON-ØØØ21-9xMON-ØØ81Ø-6 maize and ACS-BNØØ4-7xACS-BNØØ1-4, ACS-BNØØ4-7xACS-BNØØ2-5 and ACS-BNØØ7-1 oilseed rape for which a quantitative method has been validated by the European Union Reference Laboratory provided that the certified 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[(6)], 2007/305/EC[(7)], 2007/306/EC[(8)], 2007/307/EC[(9)] and 2007/308/EC[(10)] 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 contain, consist of or are produced from SYN-EV176-9 and MON-ØØØ21-9xMON-ØØ81Ø-6 maize and ACS-BNØØ4-7xACS-BNØØ1-4, ACS-BNØØ4-7xACS-BNØØ2-5 and 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. It should also apply to any other GM material the authorisation of which is not renewed at the expiry of the authorisation due to the phasing out of the product.

(11) 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.

(12) 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.

(13) 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 conclusion is drawn from the same analytical results. 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.

(14) 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[(11)], it is 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.

(15) The methods validated by the EU-RL are specific to each transformation event irrespective of the fact that the transformation event is present in one or several GMOs containing one or several transformation events. The MRPL should thus apply to the whole GM material containing the measured transformation event.

(16) Measurement uncertainty should be determined by each official laboratory and confirmed as described in the guidance document on Measurement Uncertainty for GMO testing laboratories[(12)] developed by the Joint Research Centre of the Commission (JRC).

(17) 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.

(18) The rules established by this Regulation should not affect the possibility for the Commission, or where applicable for a Member State, to adopt emergency measures in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002.

(19) 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.

(20) 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) 'Precision — Relative Repeatability Standard Deviation (RSDr)'	:	The relative standard deviation of test results obtained under repeatability conditions. Repeatability conditions are conditions where test results are obtained with the same method, on identical test items, in the same laboratory, by the same operator, using the same equipment within short intervals of time;
(2) '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;
(3) '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 and in Annex I to Regulation (EC) No 152/2009 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 authorised for commercialisation in a third country and for which a valid application has been submitted under Article 17 of Regulation (EC) No 1829/2003 and for which the authorisation procedure has been pending for more than 3 months provided that:

  (i) it has not been identified by EFSA as susceptible to have adverse effects on health or the environment when present under the MRPL;

  (ii) the quantitative method requested under that Article has been validated and published by the European Union Reference Laboratory; and

  (iii) that the certified reference material fulfils the conditions set out in Article 3;

(b) after 25 April 2012, GM material notified under Article 20 of Regulation (EC) No 1829/2003 of which the authorisation has expired and for which a quantitative method has been validated and published by the European Union Reference Laboratory provided that certified reference material fulfils the conditions set out in Article 3; and

(c) GM material for which the authorisation has expired due to the fact that no application for renewal in accordance with Article 23 of Regulation (EC) No 1829/2003 has been submitted provided that certified reference material fulfils the conditions set out in Article 3.

Article 3

Certified reference material

1 Certified reference material must be available to Member States and any third party.

2 Certified reference material shall be produced and certified in accordance with ISO guides 30 to 35.

3 The information accompanying the certified reference material shall include information on the breeding of the plant which has been used for the production of the certified reference material and on the zygosity of the insert(s). The certified value of the GMO content shall be given in mass fraction and, where available, in copy number per haploid genome equivalent.

Article 4

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 5

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 6

Measures in case of detection of GM material referred to in Article 2

1 Where results of analytical tests indicate the presence of GM material referred to in Article 2 are at or above the MRPL as defined in accordance with the rules of interpretation set out in Annex II Part B, the feed shall be considered as non-compliant with Regulation (EC) No 1829/2003. Member States shall immediately notify this information through the RASFF in accordance with Article 50 of Regulation (EC) No 178/2002.

2 Where results of analytical tests indicate the presence of GM material referred to in Article 2 is below the MRPL as defined in accordance with the rules of interpretation set out in Annex II Part B, Member States shall record this information and notify the Commission and the other Member States by 30 June of each year. Recurrent findings over a period of time of 3 months shall be notified without delay.

3 The Commission shall or a Member State may, where appropriate, adopt emergency measures in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002.

Article 7

List of GM material referred to in Article 2

The Commission shall publish the list of GM material complying with the conditions set out in Article 2 on its website. The list shall include information as to the place where the certified reference material can be accessed as required by Article 17(3)(j) of Regulation (EC) No 1829/2003 and, if applicable, information on the measures adopted in accordance with paragraph 3 of Article 6 of this Regulation.

Article 8

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, bring forward proposals to review this Regulation.

Article 9

Entry into force

This Regulation shall enter into force on the 20th day following 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, 24 June 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX I

METHODS OF SAMPLING

1. For the purpose of applying Annex I to Regulation (EC) No 152/2009, GM material shall be considered as a substance likely to be distributed non-uniformly throughout the feed.

2. By derogation from points 5.B.3., 5.B.4 and 6.4 of Annex I to Regulation (EC) No 152/2009, the size of the aggregate samples for feed materials shall be not less than the weight corresponding to 35 000 grains/seeds and the final sample shall be not less than the weight corresponding to 10 000 grains/seeds.

The mass equivalent of 10 000 grains/seeds is provided in Table 1 below.

TABLE 1

Mass equivalent of 10 000 grains/seeds for different plants

Plant	**Mass, in grams, corresponding to 10 000 grain/seed**
Barley, Millet, Oat, Rice, Rye, Wheat	400
Maize	3 000
Soybean	2 000
Rape seed	40

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. PREPARATION OF SAMPLES FOR ANALYSIS

In addition to the requirements of Annex II Part A to Regulation (EC) No 152/2009, the following provisions shall apply.

1. **Treatment of the final samples**

Official laboratories shall use the standard EN ISO 24276, ISO 21570, ISO 21569 and ISO 21571 that indicate strategies for the homogenisation of the final sample (also designated as the ‘laboratory sample’ in the ISO standards), the reduction of the final sample to the sample for analysis, the preparation of the test sample and the extraction and the analysis of target analyte.

2. **Size of the sample for analysis**

The sample for analysis 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 %.

B. APPLICATION OF METHODS OF ANALYSIS AND EXPRESSION OF THE RESULTS

By derogation from Part C of Annex II to Regulation (EC) No 152/2009, the following rules for the application of methods of analysis and expression of results shall apply.

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 at the level of 0,1 % related to mass fraction of GM material in feed with an adequate precision (relative repeatability standard deviation less than or equal to 25 %).

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 for one measured transformation event and *U* is the appropriate expanded measurement uncertainty.

U shall be specified by the official laboratory for the whole analytical method and confirmed as described in the guidance document on Measurement Uncertainty for GMO testing laboratories[(13)] developed by JRC.

A feed material, feed additive or, in the case of compound feed each of the feed material and feed additive of which it is composed shall be considered as non-compliant with Regulation (EC) No 1829/2003 when the analytical result (x) for one measured transformation event minus the expanded measurement uncertainty (*U*) equals or exceeds the level of 0,1 % related to mass fraction of GM material. When results are primarily expressed as GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes, they shall be translated into mass fraction in accordance with the information provided in each validation report of the EU-RL.

(**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.

(**4**) OJ L 102, 7.4.2004, p. 14.

(**5**) http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requirements_Analytical_methods.pdf

(**6**) OJ L 117, 5.5.2007, p. 14.

(**7**) OJ L 117, 5.5.2007, p. 17.

(**8**) OJ L 117, 5.5.2007, p. 20.

(**9**) OJ L 117, 5.5.2007, p. 23.

(**10**) OJ L 117, 5.5.2007, p. 25.

(**11**) OJ L 31, 1.2.2002, p. 1.

(**12**) http://www.irmm.jrc.be/html/reference_materials_catalogue/user_support/EUR22756EN.pdf

(**13**) http://www.irmm.jrc.be/html/reference_materials_catalogue/user_support/EUR22756EN.pdf

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EU) No 619/2011. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Art. 2 words substituted by S.I. 2019/654 reg. 126(a)
- Art. 2 words substituted by S.I. 2019/654 reg. 126(b)
- Art. 3(1) words substituted by S.I. 2019/654 reg. 127
- Art. 6 substituted by S.I. 2019/654 reg. 128
- Art. 7 substituted by S.I. 2019/654 reg. 129
- Art. 8 substituted by S.I. 2019/654 reg. 130

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2019/654 reg. 131
- Annex 2 Pt. B point 1 word omitted by S.I. 2019/654 reg. 132(a)(ii)
- Annex 2 Pt. B point 1 words omitted by S.I. 2019/654 reg. 132(a)(i)
- Annex 2 Pt. B point 2 words substituted by S.I. 2019/654 reg. 132(b)
- Art. 1.1(4) words inserted by S.I. 2019/654 reg. 125
- Art. 2(b) words inserted by S.I. 2022/1351 reg. 19