



EUROPEAN COMMISSION

Draft version

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 EU authorisation procedure is pending or of obsolete products

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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 EU authorisation procedure is pending or of obsolete products

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 rules¹, and in particular Article 11(4) thereof,

Whereas:

- (1) Regulation (EC) No 882/2004 provides for general rules relevant for official control of material which contains, consists of or is produced from GMOs which are not covered by an EU authorisation, such as the need for official control laboratories to be accredited according to ISO 17025 and to participate in internationally recognised external quality control assessment and accreditation scheme. For official controls in feed, these rules have been implemented by 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 However, that Regulation does not provide for special rules or the control of as regards the presence of genetically modified (GM) material for which an EU authorisation procedure is pending or GM material the authorisation of which has expired.
- (2) Experience has shown that in the absence of such rules, the official laboratories and the competent authorities apply different methods of sampling for their detection and 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 feed³. 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.
- (3) Ensuring consistency in the interpretation of results is particularly relevant in the feed sector where the most important part of the imports is concentrated on commodities

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.

that may be derived from GMOs given, in particular, that an important part of these commodities are produced in third countries where the cultivation and use of GMOs is widespread. In addition, by contrast to the food industry, these commodities are an indispensable input for the livestock industry. These factors imply that potential trade disruptions would much more affect the feed sector than the food sector. It appears therefore appropriate to limit the scope of this Regulation to the methods of sampling and analysis, as well as the rules for the interpretation of results, to be used in official controls in feed.

- (4) Regulation (EC) No 882/2004 requires laboratories involved in the analysis of official samples to work in accordance with internationally approved procedures and performance standards and use methods of analysis that have, as far as possible, been validated.
- (5) 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 in the sense of Article 20 of that Regulation. In practice it is carried out by the by the European Union Reference Laboratory (EU-RL) independently of the other elements. 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.
- (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 Regulation (EC) No 641/2004, common criteria for minimum performance requirements for analytical methods for GMO testing have been set⁵.
- (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 in the sense of Article 20 of the Regulation (EC) No 1829/2003 are event-specific methods. Once available, these methods are considered the most appropriate for the detection of GM material in feed. In addition, they are the only methods available which are validated, as foreseen by Regulation (EC) No 882/2004. Given that this measure is intended to address a current legal uncertainty, and in particular the potential impact on the feed sector, the current analytical methods constitute the best that can be set, at European Union level, for the purpose of harmonising the interpretation of the results of controls of the presence in feed of GM material not yet covered by an EU authorisation between Member States.
- (8) Accordingly the scope of this Regulation should be limited to the detection in feed of GM material for which these methods have been validated EU-RL, namely GM material for which a valid application under Article 17 of Regulation (EC) No 1829/2003 has been lodged.

⁴ OJ L 102, 7.4.2004, p. 14–25

⁵ http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requr_Analyt_methods_131008.pdf

- (9) Feed containing, consisting of or produced from SYN-EV176-9 and MON-00021-9xMON-00810-6 maize and ACS-BN004-7xACS-BN001-4 and ACS-BN004-7xACS-BN002-5, ACS-BN007 oilseed rape have been lawfully 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 above mentioned products. 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 of the market of the respective products ('obsolete products'). These last decisions provide a tolerance for the presence in products of material which contains, consists of or is produced from them 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. Given that these GM materials have been authorised in the past and have not been withdrawn of the market for safety reasons, it is appropriate to ensure that at the expiry of the tolerance period set out in the above mentioned decisions this Regulation applies as well to the detection of these obsolete products in feed.
- (10) Harmonisation of the official controls in 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.
- (11) 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.
- (12) 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.
- (13) 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 materials.
- (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 safety⁶, 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

⁶ OJ L 31, 1.2.2002, p. 1.

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) A decision of non compliance of the feed should therefore only be taken when GM material falling under the scope of this Regulation is available is present at levels above the MRPL, measurement uncertainty being taken into account.
- (16) 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 laboratories⁷ developed by the Joint Research Centre of the Commission (JRC).
- (17) These implementing rules are based on the available scientific and technical knowledge and should be adapted if this becomes necessary to take account of new developments, in particular as regards new methods of analysis of GM material not covered by an EU authorisation.
- (18) 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 subplot;
 - (3) "aggregate sample": the combined total of all the incremental samples taken from the lot or subplot;
 - (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;
 - (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 http://www.irmm.jrc.be/html/reference_materials_catalogue/user_support/EUR22756EN.pdf

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 a quantitative method has been validated by the European Union Reference Laboratory (EU-RL) following the submission of a valid application under Article 17 of Regulation (EC) No 1829/2003 and for which the authorisation procedure is still pending, and
- (b) after the 25 April 2012, GM material notified under Article 20 of Regulation (EC) No 1829/2003 the authorisation of which has expired (obsolete products) and for which a quantitative method has been validated by the European Reference Laboratory (EU-RL).

Article 3

Methods of sampling

By derogation from the provisions of Regulation (EC) No 152/2009, samples for the official control of feed as regards the presence of material referred to in Article 2, shall comply with the methods of sampling, as set out in Annex I.

Article 4

Sample preparation and methods of analysis

By derogation from the provisions of Regulation (EC) No 152/2009, preparation of laboratory sample, methods of analysis and interpretation of results shall comply with the methods as set out in Annex II.

Article 5

Monitoring

The Commission shall monitor the evolution of the situation, in particular as regards new methods of analysis of material referred to in Article 4.

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 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 subplot. 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 24333:2009.

(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 and the file incremental samples 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 point (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.

(2) 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.

(3) Sampling at retail stage

Feed sampling at retail stage shall be done where possible in accordance with the provisions set out in paragraph 2.

Where that is not possible, an alternative method of sampling may be applied provided that it ensures that the aggregate sample is sufficiently 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 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 24276:2006, ISO 21570:2005, ISO 21569:2005 and ISO 21571:2005 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

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

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Feed sampling at retail stage shall be done where possible in accordance with the provisions set out in paragraph 2.

Where that is not possible, an alternative method of sampling may be applied provided that it ensures that the aggregate sample is sufficiently 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.

(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 ensure that the performance characteristics of the methods as stated in the common criteria set by the EU-RL and ENGL for minimum performance requirements for analytical methods for GMO testing⁸ are met. In particular 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 $x \pm U$ whereby x is the analytical result and U is the appropriate expanded measurement uncertainty.

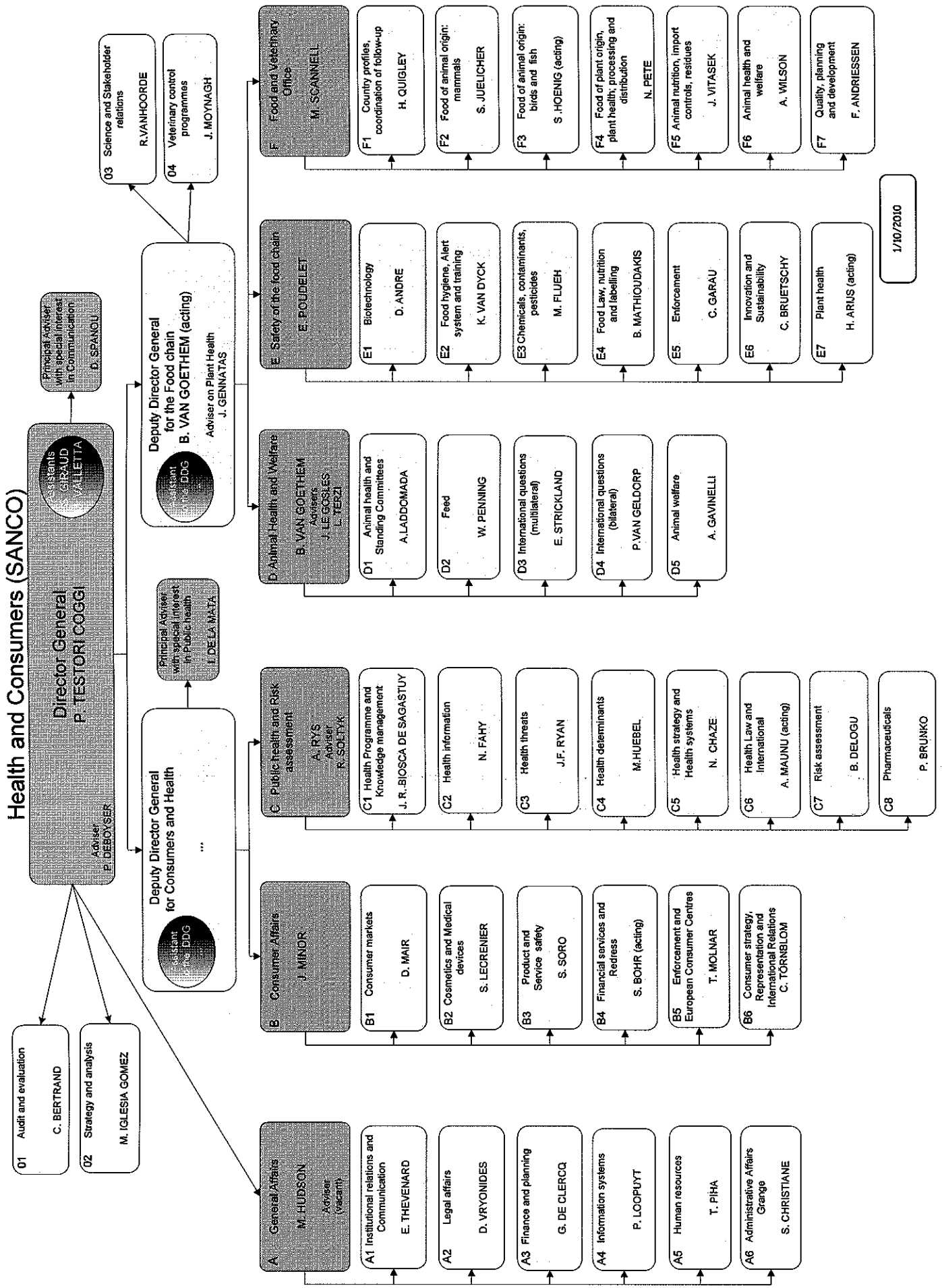
U shall be calculated on the basis of the results obtained during the validation by the EU-RL and confirmed by internal control data as described in the guidance document on Measurement Uncertainty for GMO testing laboratories⁹ developed JRC.

A feed shall be considered as non compliant 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. When the results are primarily expressed in haploid genome equivalents laboratories shall also indicate the corresponding level in mass fraction.

⁸ http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requir_Analyt_methods_131008.pdf

⁹ http://www.irmm.jrc.be/html/reference_materials_catalogue/user_support/EUR22756EN.pdf

Health and Consumers (SANCO)



1/10/2010