# Guideline

## for the control of

## GMOs in feed

Version 3

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# Guidance on monitoring the production, handling, use and placing on the market of feed related to genetically modified organisms (GMOs)

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**Outline:**

# 1 Legislation and other documents to be considered

## EU law

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the verification of the application of feed and food law, animal health and welfare rules, plant health and plant protection products, amending Regulations (EC) No. 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Regulations (EC) No. 1/2005 and (EC) No 1099/2009 of the Council, and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC of the Council and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEG, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Regulation on official controls), Official Journal L 95, 07.04.2017, p. 1-142.

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, Official Journal L 268, 18.10.2003, p. 1-23

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, Official Journal L 268, 18.10.2003, p. 24-28

Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms, Official Journal L 010, 16.01.2004, p. 5-10

Commission Regulation (EC) No 641/2004 of 6 April 2004 laying down detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for authorisation of new genetically modified food and feed, the notification of existing products and the adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation, Official Journal L 102, 07/04/2004, p. 14-25

Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the sampling methods and the methods of analysis for the official control of feedingstuffs, Official Journal L 54, 26/02/2009 p. 1, as amended by Commission Regulation (EC) No 691/2013 of 19 July 2013 amending Regulation (EC) No 152/2009 as regards the sampling methods and the methods of analysis, Official Journal L 197, 20/07/2013, p. 1-12

Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the sampling methods and the methods of analysis for the official control of genetically modified feed materials which are subject to an authorisation procedure or for which the authorisation is about to expire, Official Journal L 166, 25.06.2011, p. 9

Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 concerning applications for authorisation of genetically modified food and feed pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006, Official Journal L 157, 08.06.2013, p. 1-48

## Federal law

Act on the Implementation of Regulations of the European Community in the field of genetic engineering and on the labelling of food produced without the use of genetic engineering techniques (EG-Gentechnik-Durchführungsgesetz - EGGenTDurchfG) of 22 June 2004 (Federal Law Gazette I p. 1244), last amended by Article 58 of the Ordinance of 31 August 2015 (Federal Law Gazette I p. 1474)

**Further documents**

Concept for the analysis of genetically modified feed - Working Paper of the Working Group PCR-Analytics of the Expert Group Feed of the Association of German Testing and Research Institutes (VDLUFA), Version 3, Status: December 2018
Reference: https://www.vdlufa.de/Dokumente/Fachgruppen/FG6/GVO-Fumi_Konzept_Stand_11_18.pdf

Regulation (EU) 2017/625 establishes a uniform legal framework for carrying out official controls and for verifying compliance with food and feed law.

According to Regulation (EC) No. 1829/2003, food and feed containing, consisting of (e.g. reproductive maize grains) or produced from GMOs are subject to authorisation and must be labelled in accordance with Regulations (EC) No. 1829/2003 and 1830/2003. The labelling obligation also exists if the genetic modification is no longer directly detectable (e.g. in the case of vegetable oils).

Feed within the meaning of Regulation (EC) No 1829/2003 include, according to the definition of Art. 3 No. 4 of Regulation (EC) No 178/2002, certain feed additives within the meaning of Regulation (EC) No 1831/2003, Art. 2 (2 a), but not processing aids within the meaning of Regulation (EC) No 1831/2003, Art. 2 (2 h) and feedingstuff produced "with the aid" of GMOs (e.g. certain enzymes and vitamins).

With the Act amending the Genetic Engineering Act, amending the EC Genetic Engineering Implementation Act (EGGenTDurchfG) and amending the Novel Food and Food Ingredients Ordinance of 1 April 2008 (BGBI. IS. 499), special national regulations were created for voluntary labelling of food with the claim „Ohne Gentechnik“ (which may be translated with “without genetic engineering”). The requirements for such food labelling include, in the case of animal products, a legally regulated time limit on the use of feed consisting of, containing or produced from GMOs (for details see chapter 4.3).

According to the jurisdiction of the ECJ (Case C-528/2016, judgement of 25.07.2018), all organisms obtained by processes/methods of mutagenesis are GMOs. However, EU genetic engineering law does not apply to GMOs obtained by conventional processes/methods of mutagenesis, which have long been considered safe.

# 2 Sources of information on genetically modified food and feed in the EU

The EU Commission maintains a Community register of genetically modified food and feed on the basis of Art. 28 of Regulation (EC) No. 1829/2003. The register ("EU Register of authorised GMOs") is available in English and can be viewed at the Internet address:

https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

The EUginius database provides information on genetically modified organisms, predominantly of plant origin, including data on the molecular characterisation of GMOs, their authorisation status and detection methods, as well as reference materials.

http://www.euginius.eu

Further information is available on the websites of the European Food Safety Authority (EFSA), the European Reference Laboratory for GMOs in Food and Feed (EURL GMFF), the Federal Institute for Risk Assessment (BfR) and the Federal Office of Consumer Protection and Food Safety (BVL):
http://www.efsa.europa.eu/de/topics/topic/gmo.htm
http://gmo-crl.jrc.ec.europa.eu/
http://bfr.bund.de/cd/2391
http://www.bvl.bund.de/DE/06_Gentechnik/gentechnik_node.html

# 3 Labelling of feed containing or produced from GMOs

In principle, there is a labelling obligation for feed authorised in the EU under Regulation (EC) No 1829/2003 that consists of, is produced from or contains GMOs. According to Art. 24 para. 2 of Regulation (EC) No. 1829/2003, an exemption from the labelling obligation only exists for feed with a GM content of 0.9% or below (labelling threshold), provided that this content is adventitious or technically unavoidable. For this purpose, the operator must be able to demonstrate to the competent authority that he has taken appropriate steps to avoid the presence of GMO-containing parts or parts consisting of or produced from GMO (see also chapter 5)[1].

[1] Where sector-specific guides to good manufacturing practice and to the labelling of feed containing, consisting of or produced from GMOs are used by an operator, the control authority may, in addition, evaluate that operator in the light of the guidelines and take that evaluation into account in its decision.

Tab.: 1:
"Definitions" according to Regulation (EC) No 1829/2003 and 1830/2003

| Labelling information | Example | Explanation |
|---|---|---|
| "genetically modified [name of organism]". | Whole GM soybean as feed material or whole GM maize kernels, if still capable of reproduction. | The feed **consists** of a genetically modified organism,<br>Indication of the unique identifier according to Art. 4 para. 1 to 3 of Regulation (EC) No. 1830/2003 |
| "genetically modified [name of organism]". | Mixed feed with whole GM grains, provided they are still capable of reproducing (e.g. bird feed). | The feed **contains** GM soybeans or whole, reproductive grains, e.g. maize,<br>Indication of the unique identifier according to Art. 4 para. 1 to 3 of Regulation (EC) No. 1830/2003 |
| "produced from genetically modified [name of organism]". | Soy oil from GM soybean<br>or compound feed containing soy extraction grist from GM soybeans, or<br>Compound feed containing ground GM maize grains | Labelling must be independent of detectability in the end product, as produced **from** GMOs; there is no information on the identification marker to the next customer. |

Unless the operator can prove to the competent authority that the GMO-containing or GMO-derived or GMO-produced components entered the feed adventitious or technically unavoidably, the labelling requirement also applies to a GM content of 0.9% or less. The determination of the authority is the result of a case-by-case assessment.

As soon as labelled products are further processed, all feed produced from them must also be labelled. This applies regardless of the place of production (EU/third countries).

Note:
The indication **„Ohne Gentechnik“** may only be used on **food of animal origin** if the animals from which the food was obtained have, during a specified period of time prior to the production of the food, not been fed feed which is labelled in accordance with Regulation (EC) No. 1829/2003 or Regulation (EC) No. 1830/2003, feed which is subject to a labelling obligation or, if placed on the market, would have to be labelled, or feed for which there is no authorisation to place on the market in accordance with Regulation No. 1829/2003 (§ 3a, Para. 4 in conjunction with Annex to § 3a Para. 4 Sentence 2 EGGenTDurchfG). This therefore also applies to livestock farmers who produce their own feed which is fed directly on their own farms. The „Ohne Gentechnik“ labelling of food of animal origin thus refers to the "genetic engineering labelling" of feed under Community law. This does not change the labelling regulations for feed.

# 4 Control

The legal framework for carrying out official controls is Regulation (EU) 2017/625. Controls include verification of compliance with labelling requirements as well as sampling and testing of feed to verify whether it contains, consists of or is produced from GMOs authorised or not authorised in the EU.

## 4.1 Review of documents and traceability

In addition to analysis, the review of documens is an essential element in monitoring under Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003. This is particularly true for the control of feed produced from GMOs but which itself contains little or no detectable DNA or protein, such as oils, fats and starch.

The verification of the labelling shall be carried out taking into account the requirements laid down in Articles 24 and 25 of Regulation (EC) No 1829/2003.

The documentary check shall also include the control of the consistent labelling of feed containing or consisting of GMOs throughout the production chain as required by Article 4 (1) and (2) of Regulation (EC) No 1830/2003 and the systems and standardised procedures to ensure traceability to be set up in accordance with Article 4 (4) of Regulation (EC) No 1830/2003. However, the transfer of the unique identifier ends with the operator who processes the feed in such a way that the GMO is no longer capable of reproduction. Furthermore, in the case of feed produced from GMOs, the provisions on the traceability of feed produced from GMOs must be observed (Art. 5 para. 1 lit. b) and c) as well as para. 2 of Regulation (EC) No. 1830/2003).

The individual operator according to Art. 3 No. 5 of Regulation (EC) No. 1830/2003 is only obliged to document the immediate upstream and downstream stage - with the exception of the final consumer according to Art. 3 No. 6 of Regulation (EC) No. 1830/2003 - in order to ensure traceability.
The respective importer is also obliged to provide the above information to the purchaser of his feed.

Farmers who purchase or place on the market a feed consisting of or containing GMOs are also operators according to Art. 3 No. 5 of Regulation (EC) No. 1830/2003 and are thus subject to the provisions on traceability and labelling (Art. 4 and 5 of Regulation (EC) No. 1830/2003). This also includes cash sales of feed, i.e. traders and farmers must also set up traceability and documentation systems for cash sales.

Apart from that, reference is made to the "Guide to traceability in the feed sector (Leitfaden zur Rückverfolgbarkeit im Futtermittelsektor)"[2] . The information on the cash voucher must be suitable to enable the identification of the goods by the purchaser (e.g. name of the feed, quantity and date of purchase).

## 4.2 Sampling of feed

The official feed control shall take the following advice into account when deciding on the taking of samples:

- **Selection of feed to be sampled:**
  Feed must be labelled in accordance with the requirements of Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003. Feedstuffs that do not contain any references to the use of genetically modified organisms in their labelling must therefore comply with the requirements of the aforementioned regulations. Compliance with these requirements is also an essential prerequisite for the labelling of food of animal origin with the claim „Ohne Gentechnik“. When selecting the feedstuffs to

[2] https://www.bvl.bund.de/SharedDocs/Downloads/02_Futtermittel/fm_Leitfaden_Rueckverfolgbarkeit.html

be sampled, particular consideration should therefore be given to non-"GM-labelled" single-component feedstuffs of e.g. soybean, maize or rapeseed and their processed products.

The sampling and examination of compound feed containing, for example, these single-component feed materials is also possible, taking into account the composition, which must be examined in each individual case. In the case of detection of a GMO, the manufacturing process and the feed ingredients used must be examined, taking into account the production processes. It should be noted that GM contents are easier to analyse in low-processed single-component feed than in highly processed products.

The examination of feed can be divided into qualitative or quantitative GMO screening procedures and GMO-specific analyses. Positive results of a screening procedure require further specific evidence. For the quantitative determination of GM content in compound feed, the composition of the feed must be taken into account. If necessary, the individual components must be analysed separately. Further explanations, also on feed selection, can be found in the "Concept for the analysis of genetically modified feed (Konzept zur Analytik von gentechnisch veränderten Futtermitteln)" of the VDLUFA.

- **Selection of farms to be inspected:**
  Controls should start as early as possible in the production and distribution chain. The selection of the farms to be inspected is made taking into account the respective product ranges as well as the production processes. It makes sense to carry out controls in particular at the stage of import and trade in imported feed and, if necessary, at export. The distribution stages upstream or downstream of the manufacturing plants (e.g. trading companies, transport companies) should, to a limited extent, also be included in the monitoring (e.g. to check for carry-over/cross-contamination).

- **Modalities of sampling:**
  Official sampling for the testing of genetically modified feed and feed materials for which an authorisation procedure is pending or for which the authorisation expires shall be carried out in accordance with Regulation (EC) No 152/2009.

## *4.3 Tasks of the feed control in the examination of the labelling „Ohne Gentechnik“ in food of animal origin*

It is the task of the official food control authorities to check whether the labelling of a food of animal origin with the indication „Ohne Gentechnik“ is permissible according to § 3a EGGenTDurchfG. For the food sector, the "Guideline for the Control of Genetic Modifications in Food (Leitfaden zur Kontrolle gentechnischer Veränderungen in Lebensmitteln)" has been published[3] .

Controls by the feed control authorities may arise for the following reasons:

[3] ALS Opinion No. 2016/01 - Guidance on the control of genetic modification in food (https://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/ALS_ALTS/ALS_NEU/Leitfaden%20zur%20Kontrolle%20gentechnischer%20Ver%C3%A4nderungen%20in%20Lebensmitteln_Stand%2002.10.2019.pdf?__blob=publicationFile&v=2)

- The food control authorities can call on the support of the authorities responsible for official feed control (administrative assistance, e.g. to check the feed materials used at the compound feed manufacturer) when checking a „Ohne Gentechnik“ label.
- Special controls may also result from own findings of the authorities responsible for official feed control (concrete suspicious cases).
- Furthermore, the official feed control can carry out inspections of feed at manufacturers', traders' and farmers' premises (random sampling), irrespective of the use of a feed. In this context, it is initially irrelevant whether the results of these inspections can be linked to a food law „Ohne Gentechnik“ labelling.

In accordance with the requirements of Regulation (EC) No 852/2004[4], the food control authority on the animal holding can determine which feed has been fed. In doing so, it must be checked whether the animal from which the food originates was fed feed that was labelled according to Art. 24 and 25 of Regulation (EC) No. 1829/2003 or according to Art. 4 or 5 of Regulation (EC) No. 1830/2003 or, if it was placed on the market (= supplied to third parties), should have been labelled. If there are indications that make it necessary to trace the feed or to sample it, the official feed control must be involved. In such a control, the sampling of a delivery can take place and/or the origin of the feed can be traced back to the manufacturer. It is possible to check the documentation and the measures taken at all stages of production and distribution. According to the feed legislation, the farmer is not obliged to keep the declaration of the feed he has fed. However, according to Art. 4 para. 4 of Regulation (EC) No. 1830/2003, he must ensure the traceability of the feed with regard to GMOs for a period of 5 years by means of his documentation (e.g. delivery notes, invoices).

According to § 3b of the EGGenTDurchfG, anyone who markets or advertises foodstuffs with the claim „Ohne Gentechnik“ must provide evidence that the requirements prescribed for the use of the claim have been met, i.e. that no organisms developed by means of new procedures/methods of mutagenesis have been used, when preparing, processing or mixing the foodstuffs or when feeding the animals.

In the case of products of animal origin, appropriate means of proof are in particular

1. binding declarations by the upstream supplier that the requirements for labelling are met, or
2. in the case of feeding, labels or accompanying documents of the feed materials used.

Declarations from producers or suppliers (e.g. feed manufacturers) used as proof should be randomly checked for accuracy.

For the period prior to the production of the food within which the feeding of GM feed is not permissible, the animal species-specific time requirements listed in the following table are specified.

[4] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

**Tab. 2:**
Period of time prior to the production of the food within which the feeding of genetically modified feed is not permitted for the „Ohne Gentechnik“ labelling of foodstuffs.

| No. | Animal species | Period |
|---|---|---|
| 1 | in equidae and cattle (including Bubalus and Bison species) for meat production | twelve months and in any case at least three quarters of their life |
| 2 | in small ruminants | six months |
| 3 | for pigs | four months |
| 4 | in milk-producing animals | three months |
| 5 | in the case of poultry for meat production, housed before they were three days old | Ten weeks |
| 6 | in poultry for egg production | Six weeks |

For other animal species, e.g. fish, the entire lifetime applies.

# 5 Assessment and procedure in case of GMO detection

## *5.1 Preliminary remarks*

In principle, there is a labelling requirement for feed authorised in the EU under Regulation (EC) No 1829/2003 that consists of, is produced from or contains GMOs. Feed additives, such as vitamins or enzymes, are not covered by Regulation (EC) No 1829/2003 if they have been produced with the aid of genetically modified microorganisms, whereby the GM microorganisms or their components must not be contained in the additive.

### Authorised GMOs

Feedstuffs whose content of **GMOs authorised in** the EU or products derived thereof does not exceed a value of 0.9% (Art. 24 para. 2 of Regulation (EC) No. 1829/2003) are exempt from the labelling obligation, **provided that** this GM content is adventitious or technically unavoidable. This labelling threshold also applies to exemptions from the obligation to transmit data for traceability (Art. 4 (7) and (8) and Art. 5 (4) of Regulation (EC) No. 1830/2003). The burden of proof for this lies with the trader.

The labelling obligation taking into account the labelling threshold according to Regulation (EC) No 1829/2003 shall apply to feed materials and compound feed.

The labelling threshold only applies to GMOs authorised in the EU and products derived from them.

### Stacked Events

In addition to GM plant lines that only have one specific GMO trait (single events), so-called **"stacked events"** are increasingly being approved. These stacked events result from the crossing of several GM plant lines, each of which has a transgenic trait and thus combines several transgenic traits in one plant line. These stacked event plant lines also fall under Regulations (EC) No. 1829/2003 and No. 1830/2003 and must also undergo the EU approval procedure in this form.

Due to the lack of analytical detection methods, however, these stacked events cannot be clearly identified as such. The respective transgenic characteristics of the original individual events can be detected, as they are also detectable in the stacked event. However, in the case of a positive analytical detection of certain transgenic characteristics in a feedstuff, it is currently not possible to distinguish between the presence of the individual GM plant line and the stacked events resulting from crossing. This is particularly problematic when testing for the presence of stacked events, for example, which are not authorised in the EU. A quantitative statement on the GMO content for the 0.9% threshold test in the case of the possible presence of analysis results that can be attributed to both individual events and stacked events is currently not possible. Until suitable analytical methods are available for the detection of stacked events, the GMO content detected must be added together for the purpose of checking compliance with the labelling threshold, unless the feed business operator can prove in individual cases that stacked events are involved.

The EUginius database application (www.euginius.eu) provides information on the approval status of stack sub-combinations (substacks) that are subject to EU approval procedures.

**Non-authorised GMOs**

GMOs and products derived thereof which are **not authorised** in the **EU in** accordance with Art. 16 (2) of Regulation (EC) No. 1829/2003 may not be placed on the market, used or processed. Appropriate analytical methods must be used to verify whether such GMOs and products derived thereof are contained in feed.

**Exeptions for feed according to Regulation (EC) No 619/2011**

For **certain feed materials for** which an authorisation procedure is pending or whose authorisation expires, a **minimum performance limit (MRPL)**[5] of 0.1 % (based on mass fraction) for the detection of GMOs has been established under Regulation (EC) No 619/2011.
Art. 2 of this regulation contains the conditions for the application of the MRPL to these feeds, among others according to the following criteria:

- Approval for trade in a third country,
- the existence of a valid application according to Art. 17 of Regulation (EC) No 1829/2003 (authorisation procedure has been pending for more than three months),
- EFSA has found that no adverse health or environmental effects are expected under the MRPL,
- quantitative methods from the European Union Reference Laboratory that are validated and published are available; and
- certified reference material is available.

Also included in the scope are GM feed materials whose authorisation has expired, provided that certified reference material is available in accordance with Article 3 of Regulation (EC) No 619/2011.

[5] "Minimum Performance Limit (MRPL)": Lowest amount or concentration of analyte in a sample that must be detected and confirmed by official laboratories.

GM feed with a content of these GMOs ≥ 0.1 % (based on mass fraction) is not marketable and must be notified directly via the European Rapid Alert System for Food and Feed (RASFF) in accordance with Art. 50 of Regulation (EC) No. 178/2002.

A list of GM feed materials falling within the scope of Regulation (EC) No 619/2011 is published by the EU Commission at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

**Mutagenesis**

According to the jurisdiction of the ECJ (Case C-528/2016, judgement of 25.07.2018), all organisms obtained by processes/methods of mutagenesis are GMOs. As a consequence, the controls of the feed monitoring authorities must also include organisms developed by new processes/methods of mutagenesis.

However, EU GMO legislation does not apply to GMOs obtained by conventional processes/methods of mutagenesis, which have long been considered safe.

In order to ensure enforcement of the ECJ's jurisdiction, sampling and analysis must be carried out as a matter of principle. In cases where no reliable detection methods exist, the feed monitoring authorities can only carry out a documentary check. In this case, the documents to be submitted by the operator must fully document that the legal requirements have been complied with (see chapter 4.1).

## *5.2 Single-component feed*

The labelling threshold according to Regulation (EC) No 1829/2003 applies to the feed material. Single-component feeding stuffs may contain several authorised genetically modified lines. If different lines are contained in a feed material, the GM content of the individual GMO lines must be added together to check compliance with the labelling threshold.

## *5.3 Compound feed*

According to Regulation (EC) No 1829/2003, Art. 24 (2), in the context of Regulation (EC) No 641/2004, Art. 19 (2), the legally established labelling threshold applies to the feed and each feed ingredient (e.g. feed material) of which it consists. This means that in addition to the compound feed, the individual feed ingredients of a compound feed are subject to the requirements of the above-mentioned Regulation with regard to labelling thresholds and labelling.

## *5.4 What does "adventitious or technically unavoidable" mean?*

The exemption from the labelling requirement depends on two conditions:

- the labelling threshold of 0.9 % GM content must not be exceeded, and
- the presence of the GM component must be "adventitious or technically unavoidable".

The assessment of whether the detected contamination is adventitious or technically unavoidable should always be preceded by a case-by-case examination.

The following criteria are to be checked depending on the individual case:

According to Art. 24 para. 3 of Regulation (EC) No. 1829/2003, the operator must have demonstrably taken appropriate steps to avoid the presence of GM ingredients (according to Art. 24 para. 2 of Regulation (EC) No. 1829/2003). The burden of proof for this vis-à-vis the authorities lies with the operator.

If an operator has taken contractual precautions to avoid the presence of GM material (for example, through an IP system = Identity Preservation System), the presence of GM material at a concentration not exceeding 0.9% should be considered adventitious or technically unavoidable.
A feed business operator who produces, uses or handles both GM-containing and GM-free feed must separate the two product lines spatially or temporally in order to avoid mixing. In the case of temporal separation, he must prevent the entry of GMOs or products made from them as far as possible, e.g. by rinsing batches and/or by appropriate cleaning of the facilities. It is the responsibility of the operator to provide evidence of the suitability and implementation of the measures, in particular through self-monitoring.

For feed deliveries within the EU, Regulation (EC) No. 1829/2003 and Regulation (EC) No.1830/2003 regulate the labelling obligation for feed with GM contents.
In the case of feed deliveries from third countries where no comparable labelling system exists, the requirements must be contractually agreed by the operator and secured by certificates and self-monitoring. The available documents must be examined in their entirety and evaluated in relation to the individual case.
If a feed in which GM content cannot be ruled out is delivered in relevant quantities, it is reasonable and necessary to enquire with the supplier whether and what protective measures have been taken to prevent the carry-over of GM content.
If repeated inspections in a company regularly reveal GM contents in a certain range below the labelling threshold, this does not generally entitle the feed company to conclude that the contamination is adventitious or technically unavoidable and that labelling can therefore be dispensed with in any case. Reasonable duties of care in the own area of responsibility of enterprises are e.g. measures to avoid carry-over, the inspection of delivered goods and the obligation of upstream suppliers. This is to be examined by the competent authority in each individual case.

If it has been established that a feed contains up to 0.9% GM content by chance or technically unavoidable and therefore does not have to be labelled, this classification remains applicable with regard to labelling for all further feed produced from this batch, provided that in the further flow of goods the measures to prevent other inputs of GM content are sufficient and the labelling threshold of 0.9% is not exceeded.

## *5.5 GM content in feed due to carry-over*

An entry of GMOs and products made from them can also result from a carry-over in the feed chain (e.g. from components or via the mixing technique) with the consequence of cross-contamination. If the operator's examination of the individual components leads to the result that the proportion of GMOs in relation to the individual components does not exceed the labelling threshold of 0.9%, there is no labelling obligation for any of these individual components. If the proportion of GMOs in relation to the compound feed exceeds 0.9 %, labelling is required (cf. Annex 1 No. 4b and 5).
However, Regulation (EC) No. 1829/2003 does not provide for a prescribed wording for this case, as the components from the carry-over are not declared. Therefore, an analogous application of Art. 25 para. 2b of Regulation (EC) No. 1829/2003 can be

considered (as a labelling behind the name of the feed is not possible due to the non-declaration, the labelling is done separately). If one rejects this way, however, the minimum requirement for labelling from the provision of Art. 5 (1) (b) of Regulation (EC) No 1830/2003 remains.
Such a finding should, after examination of the individual case, lead the company to take further measures to avoid the entry of GMOs and products made from them, e.g. via incoming goods, the manufacturing process or loading.

## *5.6 GM content in feed by entry as botanical impurities*

According to Annex I No. 2 of Regulation (EC) No. 767/2009[6] the botanical purity of single-component feeding stuffs must be at least 95 %, unless a different percentage is specified in the catalogue according to Art. 24. Botanical impurities include impurities with plant material without harmful effects on the animals, e.g. straw and seeds from other crops or from weeds. By way of derogation, the percentage of botanical impurities, such as residues of other oilseeds or oil fruits resulting from a previous production process, shall not exceed 0.5 % for each type of oilseed or oil fruit.

**Single-component feed**
In the case of single-component feeding stuffs with botanical impurities of other plant species, which in turn contain GM fractions, compliance with the labelling threshold of 0.9 % in relation to the single-component feeding stuff as such (= 100 %) shall be determined (cf. Annex 1 No. 2).

**Compound feed**

Compound feeds may contain feed materials with botanical impurities of other plant species, which in turn may contain GM ingredients.
In such a case, the operator should check each feed material as a component of the compound feed to determine whether there is an adventitious or technically unavoidable GM content of another plant species in one or more of the feed materials contained. He is responsible for the correct labelling of his products.
The calculation of compliance with the labelling threshold shall be made on the basis of the respective feed material in which GM content has been detected. If the labelling threshold is exceeded in a feed material which is a component of a compound feed, this feed material must be indicated on the compound feed declaration as "genetically modified [name of organism]" or as "produced from genetically modified [name of organism]".

As it is usually not known at first during the official examination of a compound feed whether a contained feed material is botanically contaminated or which feed material shows this botanical contamination, the following must be observed:

> If GM content is detected in a compound feed by PCR, it should be checked whether it can be determined that this is due to botanical contamination of a single-component feed contained therein.

[6] Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending Regulation (EC) No. 1831/2003 of the European Parliament and of the Council and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directive 82/471/EEC, Council Directive 83/228/EEC, Council Directive 93/74/EEC, Council Directive 93/113/EC, Council Directive 96/25/EC and Commission Decision 2004/217/EC, Official Journal L 229, 01.09.2009, p. 1-28.

Furthermore, it must be checked whether the proportion of this botanical impurity can be quantified microscopically[7] . Then the GM content of the botanical impurity can be quantitatively related to the compound feed and the compliance with the labelling threshold in the compound feed can be checked. If this exceeds 0.9% of the feed (due to the botanical contamination), labelling would be required.

If several quantifiable genetic modifications are detected, these are to be added together in accordance with Art. 24 para. 2 of Regulation (EC) No. 1829/2003 in order to check compliance with the labelling threshold.

Proof of the origin of the genetically modified botanical impurity is the responsibility of the operator.

[7] VDLUFA method: Identification and estimation of constituents in feeds

# 6 Appendix

Appendix 1: GMO labelling - examples

| **Findings** (reference value mass percentage[8] (m/m%)) | **Labelling** |
|---|---|
| 1. GM maize in maize, GM content ≤ 0.9 %,<br>adventitious or technically unavoidable | No labelling of GM maize |
| 2. GM soy in maize, proportion of soy < 5 % =<br>botanical contamination. | - the soy content does not have to be declared as a component,<br>- the proportion of GM soy in the total amount of maize must therefore be determined and, if necessary, labelled (see 2b): |
| a. Proportion of GM soy in maize ≤ 0.9 %, adventitious or technically unavoidable: | - no labelling of GM soy * |
| b. Proportion of GM soy in maize > 0.9 %: | - GM soy labelling * |
| 3. GM soy in maize, soy content > 5 % = component to be declared: | - the soy content must be indicated in the composition,<br>- the proportion of GM soy in the total quantity of soy must be determined and, if necessary, labelled (see 3b): |
| a. Proportion of GM soy in soy ≤ 0.9 %, adventitious or technically unavoidable: | - No labelling of GM soy |
| b. Proportion of GM soy in the soy > 0.9 %: | - GM soy labelling |
| 4. GM soy in compound feed, soy is listed as a component in the compound feed: | the proportion of GM soy in the total amount of soy is determined and may have to be labelled: |
| a. Proportion of GM soy in soy ≤ 0.9 %, adventitious or technically unavoidable: | - No labelling of GM soy |

[8] m = mass

| **Findings** (reference value mass percentage[8] (m/m%)) | **Labelling** |
|---|---|
| b. Proportion of GM soy in the soy > 0.9 %: | - GM soy <u>labelling</u><br><br>No GM labelling requirement for the individual components in the compound feed if none of the individual components is subject to labelling. |
| 5. GM soy in compound feed, soy is not listed as a component, proportion of soy < 5 % = botanical impurity: | - the soy content does not have to be indicated in the composition;<br>- the proportion of GM soy in the total quantity of the compound feed must be determined and, if necessary, labelled. * |

* Calculation examples see appendix 2

Sources:
Working Document SANCO, Section on GM Food, Feed and Environmental Risk of 19.10.2009
2nd BTSF Training: Better Training for Safer Food -Training Course on Food Law, November 2009, Barcelona

Appendix 2: GMO labelling - calculation examples for Appendix 1

| **Findings from table in appendix 1** | **Example of findings and calculation** |
|---|---|
| to 2.a. | 2 % Soy in maize<br>25 % GM soy based on soy content<br>= 0.5 % GM in relation to single-component feeding stuffs Maize |
| to 2.b. | 2 % Soy in maize<br>100 % GM soy based on soy content<br>= 2 % GM in relation to single-component feeding stuffs Maize |
| to 5. | 2 % Soy (undeclared) in compound feed<br>25 % GM soy based on soy content<br>= 0.5 % GM in relation to the compound feed<br>No labelling requirement<br>----------<br>2 % Soy (undeclared) in compound feed<br>80 % GM soy based on soy content<br>= 1.6 % GM in relation to the compound feed<br>Compulsory labelling |

Examples of 2.a. and 2.b. from: Working Document SANCO, Section on GM Food, Feed and Environmental Risk of 19.10.2009