



Bundesministerium für
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Verbraucherschutz und
Lebensmittelsicherheit



Guideline

for Monitoring GMOs in Feed

(last revised in November 2011)

Monitoring the production, processing, use and placing on the market of feed in connection with genetically modified organisms (GMOs)

Orientation framework for the application of legal regulations

Elaborated by the PG GMOs in Feeds of the Working Group of the Federal States on Consumer Protection (Länderarbeitsgemeinschaft Verbraucherschutz, LAV) Working Group Feed with involvement of the German Federal Administration and the Association of German Agricultural Analytic and Research Institutes (Verband Deutscher Landwirtschaftlicher Untersuchungs- und Forschungsanstalten, VDLUFA)

1 Legal regulations and other documents to be considered

The orientation frame is based on the following legal regulations and documents:

EU law

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed

Amtsblatt No. L 268 of 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

Amtsblatt No. L 268 of 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

Amtsblatt No. L 010 of 16/01/2004, p. 5-10

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

Amtsblatt No. L 102 of 07/04/2004, p. 14-25

Commission Recommendation of October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003, (2004/787/EC)

Amtsblatt No. L 348 of 24/11/2004, p. 18 – 26

Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed

Amtsblatt No. L 54 of 26/02/2009, p. 1

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

Amtsblatt No. L 166 of 25/06/2011, p. 9

Federal law

Act implementing the Regulations of the European Community or of the European Union in the field of genetic engineering and on labelling of food manufactured without using genetic engineering procedures (EC Genetic Engineering Implementation Act) from June 22, 2004 (BGBl I p. 1244), most recently amended by Article 2 of the law from April 1, 2008 (BGBl I p. 499)

German Feed Sampling and Analysis Regulation (Futtermittel-Probenahme- und Analyse-Verordnung) in the version of its publication on March 15, 2000 (BGBl I p. 226), most recently amended by Article 2 of the regulation from March 14, 2007 (BGBl I p. 335)

other documents

Concept for the analysis of genetically modified feeds (Konzept zur Analytik von gentechnisch veränderten Futtermitteln), work paper of the Working Group PCR Analysis of the Section Feedstuff Analysis of the Association of the German Analytic and Research Institutes, last revised in February 2011.

Source: http://www.vdlufa.de/joomla/Dokumente/Fachgruppen/FG6/VI-O-32_GVO-Fumi_Konzept_Februar_2011.pdf

Sampling of feeds for the analysis of amounts of GMO authorized in the EU in the frame of control of labeling requirements,

Position of the working group PCR analytics of the expert group feeds of the VDLUFA, (Juli 2010),

Source: http://www.vdlufa.de/joomla/Dokumente/Fachgruppen/FG6/Probenahme_Futtermittel_GVO_ueberarb_10-9-10.pdf

Pursuant to the EU Regulations (EC) No. 1829/2003 and (EC) No. 1830/2003 food and feed containing or consisting of GMOs (e.g. reproducible maize kernels), or produced therefrom, must be labelled. This labeling requirement exists also when the genetic modification can no longer be directly evidenced (e.g. in vegetable oils).

Feeds in the sense of these representations include, according to the definition of Art. 3 No. 4 of the Regulation (EC) No.178/2002, certain feed additives in the sense of Regulation (EC) No. 1831/2003, Art. 2 (2 a), however, not processing aids in the sense of Regulation (EC) No. 1831/2003, Art. 2 (2 h) and feeds produced "with the aid of" GMOs (e.g. certain enzymes and vitamins).

With the act to revise the Genetic Engineering Act, to revise the EGGenTDurchfG, and to revise the Novel Food and Food Ingredients Regulation from April 1, 2008 (BGBl I, 2008, p. 499) special national provisions were created for the voluntary labeling of food produced without applying techniques of genetic engineering. For animal products, the requirements imposed on such food labeling stating "Ohne Gentechnik" (which may be translated with "no genetic engineering") include, among others, a complete or temporary abandonment of feeds consisting of, containing or produced from GMOs, i.e. a complete abandonment of feeds labelled pursuant to Regulation (EC) No. 1829/2003 and such feeds which would have to be labelled if they had been sold to a third party (placed on the market).

2 EU Register of authorized GMOs (Regulation (EC) No. 1829/2003, Article 28)

The community's EU Register of authorized GMOs can be looked into on the internet under this address: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

More information is available on the websites of the European Food Safety Authority (EFSA), the European Union Reference Laboratory for GM Food and Feed (EU-RL GMFF), the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) and the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, 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 Labeling of feed containing or produced from GMOs

As a rule, there is a genetic engineering labeling requirement for feeds containing GMOs authorized in the EU or products produced therefrom. If the threshold value of 0.9% (Article 24 2. of Regulation (EC) No. 1829/2003) is exceeded, labeling must proceed in any case. One exception of the labeling requirement exists for feeds with GM proportions of 0.9% or less, provided that this proportion is either adventitious or technically unavoidable. The entrepreneur must be able to submit evidence to the competent authorities that he has taken adequate steps to avoid the existence of proportions consisting of, containing or produced from GMOs.

Tab. 1:

"Definitions" acc. to Regulation (EC) Nos. 1829/2003 and 1830/2003

Labeling statement	Example	Explanation
"genetically modified [designation of organism]"	whole GM soybeans as single-component feed or whole GM maize kernels unless still fertile	The feed consists of a genetically modified organism, statement of the unique identifier acc. to Article 4 (1-3) of Regulation (EC) No. 1830/2003
"genetically modified [designation of organism]"	compound feed containing whole GM grains or seeds unless still fertile (example: bird feed)	The feed contains GM soybeans or whole, reproducible grains, e.g. maize, statement of the unique identifier acc. to Article 4 (1-3) of Regulation (EC) No. 1830/2003
"produced from genetically modified [designation of organism]"	soybean oil from GM soybeans or compound feed containing soy extraction grist from GM soybeans or compound feed containing kibbled GM maize kernels	Labeling must proceed irrespective of the detectability in the final product because made from GMOs; no information about the unique identifier is passed on to the next customer.

If the operator is unable to prove to the competent authority that the introduction of the proportions consisting of, containing, or produced from GMOs into the feed has been adventitious or technically unavoidable, the labeling requirement will apply also if the GM proportion is 0.9% or less. The determination on behalf of the authority is the result of an individual assessment.

Whenever the labelled products are further processed all other feeds produced from them will also become subject to labeling. This applies irrespective of the place of manufacture (EU/third countries).

Note:

The affirmative statement "**Ohne Gentechnik**" applying to **food** of animal origin must only be used if the animals from which the foods were produced had not within a certain period prior to production of the food received any feed to be labelled pursuant to Regulation (EC) No. 1829/2003 or Regulation (EC)

No. 1830/2003, or, if placed on the market would have to be labelled (Section 3a (4) of the EGGenTDurchfG). Hence the same also applies to livestock owners who produce feed and feed it within their own business operations. The "Ohne Gentechnik" label of food of animal origin consequently refers to the Community-legal "genetic engineering labeling" of feeds. This bears no effect on the labeling requirements applicable to feeds.

4 Governmental monitoring

4.1 *Review of documents and traceability*

Next to analysis, the review of documents is an essential element of monitoring activities according to Regulations (EC) No. 1829/2003 and 1830/2003. This applies particularly to the monitoring of feeds produced from GMOs, but containing either little or no detectable DNA or proteins, such as oils, fats and starch.

The monitoring of labeling proceeds by considering the requirements stated in Articles 24 and 25 of Regulation 1829/2003.

The inspection of documents also includes reviewing the consistent labeling of feeds containing or consisting of GMOs, as required pursuant to Article 4 1. and 2. of Regulation (EC) No. 1830/2003, along the entire production chain, and the systems and standardized procedures to assure traceability to be installed pursuant to Article 4 4. of Regulation 1830/2003. However, the communication of the unique identifier ends with the person involved who processes the feed in such a manner that the GMO is no longer reproducible. In case of feeds produced from GMOs, Article 5 1. and 2 of Regulation (EC) No. 1830/2003 must be observed analogously.

With the exception of the final consumer (Article 3 6. of Regulation (EC) No. 1830/2003), the individual person involved is merely obliged to document the immediately previous and the next following step. The respective importer is also obliged to pass on to the purchasers of his feed information about the genetic modifications of the products.

Farmers who purchase feed containing or consisting of GMOs, or who place such feed on the market are also considered as involved persons pursuant to Article 3 5. of Regulation (EC) No. 1830/2003 and thus subject to the provisions of traceability and labeling (Articles 4 and 5 of Regulation (EC) No. 1830/2003). This also comprises the cash sale of feeds, i.e. trade and farmers must install systems for traceability and documentation for cash sales as well.

Besides, the "Guideline for Traceability (Leitfaden zur Rückverfolgbarkeit im Futtermittelsektor)" is referred to. The information given on the cash voucher must be sufficient to enable the identification of the merchandise by the purchaser (e.g. designation of the feed, amount, date of sale).

4.2 *Sampling of feed*

Official feed control observes the following when it makes sampling decisions:

➤ **Selection of the business operations to be monitored:**

The selection of the business operations to be monitored proceeds by paying particular attention to the respective product range, the composition of compound feeds and the manufacturing procedures. It is reasonable to monitor primarily the importers or manufacturers of single-

component feeds as well as manufacturers of compound feed. The distributors upstream and downstream of the manufacturing operations (e.g. trading companies or forwarders) should also be included in the monitoring process to a limited extent (e.g. to check for carryovers).

➤ **Selection of the feed to be sampled:**

Feeds must be labelled in compliance with the provisions of Regulation (EC) No. 1829/2003 and Regulation (EC) No. 1830/2003. Feeds lacking information on the use of genetically modified organisms (GMO) on their labels must therefore comply with the aforementioned regulations. Compliance with these regulations is also an essential prerequisite for advertising food of animal origin with the claim "Ohne Gentechnik". Upon selecting feeds for sampling, single-component feeds not labelled as "GM" should therefore particularly be taken into consideration, e.g. soybean, maize, or canola and processed products therefrom.

It is also possible to sample and analyze compound feeds – that for example contain these single-component feeds – when their compositions are considered and checked in each individual case. In case of positive findings, the manufacturing process and the applied feed components must be examined, with special regard of the production sequences. It should be noted that GM proportions are better analyzable in little processed or machined single-component feeds than in highly processed products. For further explanations please refer to the "Concept for the Analysis of Genetically Modified Feeds (Konzept zur Analytik von gentechnisch veränderten Futtermitteln)" of the VDLUFA.

➤ **Sampling modes:**

Official sampling for analyses on genetically modified feeds proceeds in accordance with the sampling scheme "Sampling of Feeds for the Analysis of Constituents of EU-authorized GMOs in the Scope of Auditing the Legal Labeling Requirement (Probenahme von Futtermitteln zur Untersuchung auf Bestandteile von in der EU zugelassenen GVO im Rahmen einer Überprüfung der Kennzeichnungspflicht)" released by VDLUFA. The sampling scheme implements the provisions of Regulation (EC) No. 152/2009, the German Feed Sampling and Analysis Regulation (FPA, Futtermittel-Probenahme- und Analyse-Verordnung) and the recommendations of the European Commission from Oct. 4, 2004.

Regulation (EU) No. 619/2011 must be observed in the event of samplings and analyses for genetically modified raw materials, for which authorization proceedings are in progress or an authorization is about to expire.

➤ **Sampling protocol and analysis order:**

A copy of the sampling protocol must be appended to each sample pursuant to Art. 10 of the German Feed Sampling and Analysis Regulation (FPA) and an analysis order.

The analyses can be divided into a screening method and qualitative and quantitative analyses. Positive results through a screening method requires additional specific analyses. A quantitative determination of GM proportions in compound feeds must take into account the composition of the feed. If necessary, the single components must be analyzed separately. The "Concept for the Analysis of Genetically Modified Feeds (Konzept zur Analytik von gentechnisch veränderten Futtermitteln)" released by VDLUFA is referred to.

4.3 Tasks of feed monitoring when monitoring the label "Ohne Gentechnik" in case of food of animal origin

It is in the responsibility of official food control to test whether the label of a food of animal origin claiming to be "Ohne Gentechnik" is permissible pursuant to Section 3a of the EGGenTDurchfG.

Monitoring activities carried out by feed control authorities might become necessary for the following reasons:

- When monitoring a "Ohne Gentechnik" label, the official food control authorities are entitled to make use of support rendered by official feed control authorities (administrative assistance, e.g. to monitor single-component feeds used at the site of a manufacture of compound feeds).
- Special monitoring activities may also ensue from own findings of the official feed control authorities (cases of concrete suspicion).
- In addition, the official feed control authorities may carry out feed analyses at the site of manufacturers, traders or farmers, independent of the use of the feed (random analyses). In this regard, it does not matter initially whether the result obtained can be brought into connection with any food regulatory "Ohne Gentechnik" labeling.

Pursuant to the provisions of Regulation (EC) No. 852/2004 the food control authorities might determine which feeds are fed at the site of a farmer owning livestock. Thereby it will be tested whether the animal from which the food originated has been fed with feed labelled in accordance with Articles 24 and 25 of Regulation (EC) No. 1829/2003 or Articles 4 or 5 of Regulation (EC) No. 1830/2003, or, would have to be labelled had they been placed on the market (sold to a third party). If such indications require that a feed is retraced or sampled, the official feed control authorities must be involved. In the scope of such monitoring action, a delivery might be sampled and/or the origin of the feed retraced all the way to the manufacturer, whereby it is possible to review the documentations and the measures taken on all manufacturing and distribution levels. The farmer is not obliged, according to the applicable feed regulatory provisions, to keep the declarations of the feeds he fed. However, he is obliged to assure the traceability of the feeds with the documents he possesses (e.g. delivery notes, invoices).

Pursuant to Section 3b of the EGGenTDurchfG, the party placing food on the market or advertising it labelled with a claim "Ohne Gentechnik" shall provide documentation regarding the preparation, treatment, processing or mixing of the food or the feeding of animals that the requirements prescribed for the use of the claim have been adhered to. Suitable documentation shall be the following in particular

1. binding statements on the part of the upstream supplier that the prerequisites for labelling have been complied with, or
2. in case of feeding, labels or accompanying documents of the primary products used (feeds).

The examples stated in Section 3b are linked to each other by "or". Number 1 has been derived from the expired Article 5 of the Novel Food and Food Ingredients Regulation (NLV), the antecedent regulation of the current regulation of the "Ohne Gentechnik" label. According to margin note 7 of the Commentary edited by Zipfel on the NLV, "it must be assumed that declarations of manufacturers or suppliers which obviously cannot be correct do not suffice for as evidence. The same applies if it has been determined that the manufacturer and/or supplier has repeatedly submitted incorrect declarations. Without the pertinent indications, however, it must be anticipated that such declarations are sufficient evidence."

Another feature is that the regulation defines animal-specific time intervals during which any feeding of GM feeds is not permissible prior to food production (see Table below).

Tab. 2:

Time interval prior to production of the food within which feed to be labelled as genetically-modified is not permissible within the frame of the "Ohne Gentechnik ("without genetic engineering")" labelling

Ser. No	Animal species	Period
1	with equine animals and cattle (incl. Bubalus and Bison species) for meat production	twelve months and definitely at least three-quarters of their lives
2	with small ruminants	six months
3	with swine	four months
4	with animals for milk production	three months
5	with poultry for meat production which was moved to a poultry house before it was three days old	ten weeks
6	with poultry for egg production	six months

5 Evaluation and procedure in case of positive findings of GMO

Exempted from the labeling requirement are feeds with a proportion of EU-authorized GMOs or products manufactured therefrom that are not higher than 0.9% of the feed (Article 24 2. of Regulation (EC) No. 1829/2003), provided that this transgenic proportion is either adventitious or technically unavoidable. This threshold value also applies to exceptions of the obligation to transmit data for the purpose of traceability (Article 4 7. and 8. as well as Article 5 4. of Regulation (EC) No. 1830/2003). The burden of proof lies with the entrepreneur.

This threshold value only applies to EU-authorized GMOs and products manufactured therefrom. For GMOs not authorized in the EU (cf. Article 16 2. of Regulation (EC) No. 1829/2003), a threshold value does not exist, i.e. it must be tested by applying adequate analytical methods whether feeds contain such GMOs and products manufactured therefrom.

The labeling requirement considering the threshold provision applies to single-component feeds and compound feeds:

Single-component feeds:

The threshold value applies to the single-component feed. Single-component feeds might contain multiple authorized genetically modified lines. If a single-component contains various lines the GM proportion of the single GM lines must be added up to verify compliance with the threshold value.

Compound feeds:

The legally determined threshold value pursuant to Regulation (EC) No. 1829/2003 Article 24 2. in conjunction with Regulation (EC) No. 641/2004 Article 19 2. applies to the feed and each feed (e.g. single-component feeds) of which it is composed. This means that apart from the compound feed the individual feed components of a compound feed are subject to the requirements of the abovementioned regulations regarding threshold values and labeling.

An introduction of GMOs and products manufactured therefrom might also proceed by carrying over (from other components or the mixing technology) in the production process. If the analysis of the individual components leads to the result that the proportion of GMOs relative to the single components

does not exceed the threshold value of 0.9%, there will be no labeling requirement for any of these single components. If the proportion of GMOs relative to the compound feed is above 0.9%, labeling will be required (compare **Annex 1 No. 4b and 5**).

However, Regulation (EC) No. 1829/2003 does not provide a predetermined formulation for this case, as components derived from the carryover are not declared. For this reason, an analogous application of Article 25 2. b of Regulation (EC) No. 1829/2003 comes into question (as the non-declaration makes labeling behind the designation of the feed impossible, labeling proceeds separately). If this solution is rejected, the minimum requirement for labeling according to the provisions stated in Article 5 1. (b) of Regulation (EC) No. 1830/2003.

After reviewing the individual case, such a result should induce the entrepreneur to take further actions in order to avoid the introduction of GMOs and products manufactured therefrom, e.g. by goods reception, the manufacturing process or loading.

What does "adventitious or technically unavoidable" mean?

The exception from the labeling requirement depends on two conditions:

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

The evaluation whether a determined contamination is either adventitious or technically unavoidable should always be preceded by reviewing the individual case. The following criteria must be examined in each individual case:

Pursuant to Article 24 3. of Regulation (EC) No. 1829/2003, the entrepreneur must prove that he has taken adequate steps to avoid the presence of GM proportions (acc. to Article 24 2. of Regulation (EC) No. 1829/2003). Entrepreneurs must be in a position to supply evidence to satisfy the competent authorities.

If an entrepreneur has taken contractual precautions in order to avoid the presence of genetically modified material (for example, by means of installing an IP system = identity preservation system), the presence of GM material in a concentration not exceeding 0.9% should be regarded as adventitious or technically unavoidable.

A feed manufacturer who produces, uses or treats both GM-containing and GM-free feeds must separate both product lines spatially or temporally. In case of a temporal separation he has to prevent the introduction of GMOs or products manufactured therefrom as much as possible, e.g. by means of system purges and/or suitable cleaning of the machinery. The submission of evidence as to the acceptability and the execution of the measures, in particular by means of self-monitoring, lies in the responsibility of the entrepreneur.

For feed deliveries within the Community the Regulation (EC) No. 1829/2003 and Regulation (EC) No.1830/2003 govern the labeling requirement applicable to feeds containing GM proportions. In the event of feed deliveries from third countries, in which no comparable labeling system exists, the requirements must be contractually agreed by the entrepreneur and secured by certificates and self-monitoring. The available documents must be reviewed in their entirety and related to the individual case.

If relevant amounts of a feed, in which the existence of GM proportions cannot be ruled out, are delivered, inquiries made with the suppliers will be both tolerable and necessary as to whether and what kind of protective measures have been taken to prevent a carryover of GM proportions.

If repeated inspections of a business operation regularly revealed GM proportions in a certain range below the threshold value, this does not justify the feed operation to conclude that the contamination is

adventitious or technically unavoidable and labeling may therefore be dispensed with under any circumstances. Acceptable due diligence obligations in the responsibility of business operations are, for example, actions designed to prevent carryovers, testing delivered merchandise and obligating upstream suppliers. These actions must be reviewed in each individual case by the competent authorities.

If it is determined that a feed contains GM proportions up to 0.9%, may it be adventitiously or technically unavoidably, and consequently must not be labelled, this classification regarding the labeling requirement shall remain applicable to all other feeds manufactured from it, provided that the measures applied to avoid further input of GM proportions are sufficient and the threshold value of 0.9% is not exceeded in the further flow of goods.

GM proportions in feeds as a result of an introduction in the form of botanical impurities

According to Annex I 2. of Regulation (EC) No. 767/2009 the botanical purity of single-component feeds must amount at least to 95%, unless another percentage in the catalogue pursuant to Article 24 has been determined. Botanical impurities are contaminations with plant material not having a negative impact on animals, like straw and seeds from other crops or weeds. The proportion of botanic impurities, such as the residues of other oil seeds or oil fruits that originate from a previous manufacturing method must not exceed a maximum of 0.5% for each oil seed or oil fruit.

In case of single-component feeds containing botanical impurities from other plant species which in turn contain GM proportions, the maintenance of the threshold value of 0.9% applicable to the single-component feed (= 100%) must be determined (compare Annex 1 No. 2).

Compound feeds might contain single-component feed with botanical impurities from other plant species which in turn contain GM proportions.

In these cases each single-component feed as a component of the compound feed must be analyzed in order to determine whether the proportions in the single-component feeds are adventitious or technically unavoidable.

The calculation of the threshold value conformity must proceed on the basis of the respective single-component feed in which GM proportions have been determined. Provided that the threshold value has been exceeded in a single-component feed, which is itself a component of a compound feed, this single-component feed must be reported as "genetically modified [name of the organism]" on the compound feed declaration.

Annex 1: GMO labeling – examples

Foundation: Article 24 of Regulation (EC) No. 1829/2003:

"This Section shall not apply to feed containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9% of the feed and of the feed components, provided that this presence is adventitious or technically unavoidable".

Diagnosis	Label
1. GM maize in maize, proportion $\leq 0.9\%$, adventitious or technically unavoidable	no labeling requirement for GM maize
2. GM soy in maize, proportion $< 5\%$ = botanical impurity a. Proportion of GM soy in maize $\leq 0.9\%$, adventitious or technically unavoidable: b. Proportion of GM soy in maize $> 0.9\%$:	- The proportion of soy must not be declared as a component, - The proportion of GM soy must therefore be determined relative to the total amount of maize and, if necessary, labelled accordingly (cf. 2b): - No labeling requirement for GM soy * - Labeling requirement for GM soy *
3. GM soy in maize, proportion $> 5\%$ = component to be declared: a. Proportion of GM soy in soy $\leq 0.9\%$, adventitious or technically unavoidable: b. Proportion of GM soy in soy $> 0.9\%$:	- The proportion of soy in the composition must be stated, - The proportion of GM soy must be determined relative to the total amount of soy and, if necessary, labelled (cf. 3b): - No labeling requirement for GM soy - Labeling requirement for GM soy
4. GM soy in compound feed, soy is listed as a component of compound feed: a. Proportion of GM soy in soy $\leq 0.9\%$, adventitious or technically unavoidable: b. Proportion of GM soy in soy $> 0.9\%$: b1. Potential special constellation in case of a low proportion of declared soy in compound feed: the proportion of GM soy does not originate from the soy used as a single-component feed, but from botanical impurities of another single-component feed added to the compound feed (with a higher	The proportion of GM soy relative to the total amount of soy is determined and, if necessary, must be labelled: - No labeling requirement for GM soy - Labeling requirement of GM soy Principle: no GM labeling requirement in the compound feed is necessary if none of the single components are subject to a labeling requirement;

proportion in the compound feed, but GM soy proportion related to this single-component feed \leq 0.9 %):	Therefore: perhaps no labeling requirement if > 0.9 % GM soy relative to the declared soy proportion in the compound feed; *
5. GM soy in compound feed, soy is not listed as a component, proportion of soy < 5 % = botanical impurity:	<ul style="list-style-type: none"> - The proportion of soy in the composition does not have to be stated; - The proportion of GM soy must be determined relative to the total amount of the compound feed and labelled if necessary;*

* Cf. Appendix 2 for calculation examples

Sources:

1. Working Document SANCO, Section on GM Food, Feed and Environmental Risk vom 19.10.2009
2. BTSF-Schulung: Better Training for Safer Food -Training Course on Food Law, November 2009, Barcelona

Annex 2: GMO labeling – calculation examples related to Appendix 1

Finding from Table in Appendix 1	Example for finding and calculation
ad 2.a.	2 % soy in maize 25 % GM soy related to the overall soy proportion = 0.5 % GM related to the single-component feed maize
ad 2.b.	2 % soy in maize 100 % GM soy related to the overall soy proportion = 2 % GM related to the single-component feed maize
ad 4.b1.	Declared in compound feed: 2 % soy 10 % maize 88 % XY Result of the compound-feed analysis: 4.5 % GM soy related to declared soy proportion <u>But:</u> The result of the analysis of the single-component feeds applied (retention sample) reveals: 0.5 % GM soy related to soy 0.8 % GM soy related to maize 0.0 % GM in XY No labeling requirement!
ad 5.	2 % soy (not declared) in the compound feed 25 % GM soy to the proportion of soy = 0.5 % GM to the proportion of soy No labeling requirement ----- 2 % soy (not declared) in the compound feed 80 % GM soy related to the proportion of soy = 1.6 % GM related to the compound feed Labeling requirement

Examples of 2.a. and 2.b. derived from: Working Document SANCO, Section on GM Food, Feed and Environmental Risk from Oct. 19, 2009

Example of 4.b1 from: Better Training for Safer Food -Training Course on Food Law, November 2009, Barcelona