

Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz



Bundesamt für Verbraucherschutz und Lebensmittelsicherheit



Guideline for the control of GMOs in feed

(November 2011)

English translation of an official guideline document issued by the 16 German Länder (states) and published on their behalf by BVL, a federal agency, harmonizing procedures and interpretations of EU and national regulations in the process of local authorities controlling the feed industry

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The monitoring, manufacture, handling, usage, and placing on the market of feeds in relation to genetically modified organisms (GMOs)

Orientation framework for application of the legal regulations Developed by the GMO project group in feed of the LAV working group on feed, with involvement of the Federal Government and VDLUFA

1 Legal Regulations and Other Documents to be Considered

This orientation framework 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

Official Journal of the European Union No. L 268 dated 18.10.2003, pp. 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 of the European Union No. L 268 dated 18.10.2003, pp. 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 of the European Union No. L 010 dated 16.01.2004, pp. 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

Official Journal of the European Union No. L 102 dated 07.04.2004, pp. 14-25

Commission Recommendation of 4 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)

Official Journal of the European Union No. L 348 dated 24.11.2004, pp. 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

Official Journal of the European Union No. L 54 dated 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

Official Journal of the European Union No. L 166 dated 25.06.2011, p. 9

German Federal Law

Law on Implementing EU Genetic Engineering Legislation and on the identification of foodstuffs manufactured without the use of genetic engineering (EG-Gentechnik- Durchführungsgesetz – EGGenTDurchfG), of 22 June 2004 (BGB1 I p. 1244), last changed through article 2 of the law on 1 April 2008 (BGB1. I p. 499)

Feed Sampling and Analysis Regulation, version published on 15 March 2000 (BGBl. I p. 226), last changed by article 2 of the regulation on 14 March 2007 (BGBl. I p. 335)

Further Documents

Concept for the analysis of feedstuffs modified by genetic engineering, working paper of the PCR analytics working group within the Feedstuffs section of the Association of German Agricultural Analytic and Research Institutes, Status: February 2011.

Internet location (original document in German):

http://www.vdlufa.de/joomla/Dokumente/Fachgruppen/FG6/VI-O-32_GVO-Fumi Konzept Februar 2011.pdf

Sampling of feeds for analysis for the presence of GMO permitted in the EU as part of verification of the labelling regulations, Position of the PCR analytics working group within the Feedstuffs section of the Association of German Agricultural Analytic and Research Institutes (VDLUFA), (Status July 2010), Internet location (original document in German):

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

In accordance with EU Regulations (EC) 1829/2003 and 1830/2003, feed and food stuffs that contain, consist of (e.g. corn grains capable of reproduction), or are produced from genetically modified organisms (hereinafter referred to as GMO), must be labelled. This labelling requirement also applies in cases in which the genetically engineered modification can no longer be directly proven (e.g. in vegetable oils).

According to the definition in Art. 3 No. 4 of the EU Regulation (EC) 178/2002, "feedstuffs" in the context of these submissions include certain feed additives, in the sense of Regulation (EC) No. 1831/2003, Art. 2 (2 a), but do not include "processing aids" as defined in regulation (EC) No. 1831/2003, Art. 2 (2 h) or feeds generated "with the aid of" GMO (e.g. certain types of enzymes and vitamins).

With the introduction of legislation for changing the genetic engineering law, for changing the Law on Implementing EU Genetic Engineering Legislation and for changing the regulation concerning novel foods and novel food ingredients of 1 April 2008, (BGB1. I, 2008, p. 499), specific German regulations have been defined for the voluntary identification of foodstuffs manufactured without the use of genetic engineering methods. The requirements for labelling foodstuffs in this way with the declaration "Ohne Gentechnik" ("GMO-free") include, for animal products, a complete or temporary avoidance of feedstuffs that consist of, contain, or are made from GMOs, i.e. complete avoidance of feedstuffs identified in accordance with regulation (EC) No. 1829/2003 and feeds that would require such labelling, were they to be passed on to third parties (i.e. placed on the market).

2 EU Register of Genetically Modified Food and Feed (Regulation (EC) No. 1829/2003, Art. 28)

The EU register of genetically modified (GM) food and feed can be viewed at the following Internet address:

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

Further information can be found on the websites of the European Food Safety Authority (EFSA), The European Union Reference Laboratory for GM Food and Feed (JRC), the German Federal Institute for Risk Assessment (BfR), and the German Federal Office of Consumer Protection and Food Safety (BVL): http://www.efsa.europa.eu/de/topics/topic/gmo.htm http://www.efsa.europa.eu/de/topics/topic/gmo.htm http://www.efsa.europa.eu/de/topics/topic/gmo.htm http://www.efsa.europa.eu/de/topics/topic/gmo.htm http://www.byl.bund.de/cd/2391 http://www.byl.bund.de/DE/06 Gentechnik/gentechnik node.html

3 Labelling of Feeds Containing GMOs or Produced from GMOs

A GMO labelling requirement exists for all feeds or products that contain or are produced from EU authorised GMOs. All products that exceed the threshold value of 0.9 % (Art. 24 paragraph. 2 of Regulation (EC) No. 1829/2003) must be labelled. The labelling requirement does not apply to feeds that contain GMO in a proportion of 0.9% or below, provided that this presence is adventitious or technically unavoidable. The operator must be able to provide evidence to the authorities that they have taken appropriate steps to avoid the presence of materials consisting of, containing, or produced from a GMO.

Tab.: 1:

"Definitions" in accordance with Regulation (EC) No. 1829/2003 and 1830/2003

Label	Example	Explanation
"genetically modified [name of organism]"	Whole GM soyabean as single component feed or whole GM corn grains, if these are still capable of reproduction	The feed consists of a genetically modified organism, Specification of the unique identifier acc. to Art. 4 para. 1 to 3 of Regulation (EC) No. 1830/2003
"genetically modified [name of organism]"	Compound feed containing whole GM grains, if these are still capable of reproduction (e.g. bird feed)	The feed contains GM soyabeans or whole grains capable of reproduction, e.g. maize, Specification of the unique identifier acc. to Art. 4 para. 1 to 3 of Regulation (EC) No. 1830/2003
"made from genetically modified [name of organism]"	Soya oil made from GM soya beans or compound feeds that contains soya extraction residues from GM soyabeans or compound feed that contains crushed GM maize	The labelling must be provided independently of the traceability in the end product, since it is produced from a GMO; no information about the unique identifier is provided for the consumer.

If the operator is unable to present sufficient evidence to the competent authority that the

entry of components into the feed that contain, consist of, or are produced from GMO is adventitious or technically unavoidable, the labelling requirement also applies for products with a GM proportion of 0.9 % or below. The decision of the authorities is the result of an individual inspection.

If labelled products are to be further processed, all derivative feeds produced are also subject to labelling requirements. This applies regardless of the place of manufacture (EU/non-EU countries).

Note:

In **foods** of animal origin, the label **"Ohne Gentechnik** (GMO-free)" may only be used if the animals from whom the foodstuff is obtained have received no feed that is labelled according to Regulation (EC) No. 1829/2003 or Regulation (EC) No. 1830/2003 or, were it to be placed on the market, would be subject to such labelling (§ 3a, para.4, EGGenTDurchfG), for a specified period prior to obtaining the foodstuff from the animal. This therefore also applies for livestock owners who produce feed for use within their own operation. The "Ohne Gentechnik (GMO-free)" labelling of feeds. This does not change the labelling requirements for feeds.

4 Monitoring

4.1 Document checks and traceability

In addition to analytics, the documentation checks form an important element of monitoring according to Regulation (EC) Nos. 1829/2003 and 1830/2003. This applies specifically for the monitoring of feeds that are produced <u>from</u> GMOs, but which themselves contain little or no traces of DNA or proteins, e.g. oils, fats, and starches.

The labelling is checked in accordance with the requirements in articles 24 and 25 of EC Regulation 1829/2003.

The document check also includes monitoring the consistent labelling of feeds that contain or consist of GMO in accordance with Art. 4 para. 1 and 2 of Regulation 1830/2003, throughout the entire production chain and the systems and standardised procedures for ensuring traceability that are to be set up according to Art. 4 para. 4 of Regulation 1830/2003. The transmission of the unique identifier ends with the operator who processes the feed to an extent that the GMO is no longer capable of reproduction. Similarly, for feeds that are produced from GMO, Article 5 paragraphs 1 and 2 of Regulation (EC) No. 1830/2003 must also be adhered to.

Each individual operator is only required to document the steps immediately preceding and following their own – with the exception of the final consumer according to Art. 3 no. 6 Regulation (EC) No. 1830/2003. The importer is also required to provide the recipient of the feed with details regarding any genetic modification of the products.

Farmers who purchase a feed or place a feed on the market that contains or consists of GMOs are also "operators" according to Art. 3 no. 5 of Regulation (EC) 1830/2003 and are thus subject to the conditions of traceability and labelling (Art. 4 and 5 of Regulation (EC) No. 1830/2003). This also includes the cash purchase of feeds. Traders and farmers are therefore required to set up traceability and documentation systems for cash purchases.

Furthermore, reference is made to the "Guide to Traceability in the Feed Sector". (German: "Leitfaden zur Rückverfolgbarkeit im Futtermittelsektor"). The details on the till receipt must be sufficient to enable identification of the goods by the purchaser (e.g. name of the feed, quantity and date of purchase).

4.2 Sampling of Feedstuffs

The official monitoring of feed considers the following factors when making a decision about the taking of samples:

Selection of the operations to the monitored:

The operations to be monitored are selected in particular in consideration of the relevant product ranges, the composition of the compound feeds and production methods. It is most practical to perform checks at importers or manufacturers of single component feeds and compound feed manufacturers as a priority. The sales and marketing levels upstream or downstream of the manufacturing operations (e.g. retail operations, transport companies) are also to be subject to monitoring, although to a lesser extent (e.g. to check for possible carry-over).

Selection of feeds to be sampled:

Feeds are to be labelled according to Regulation (EC) No. 1829/2003 and Regulation (EC) No. 1830/2003. Feeds whose labelling does not include any information relating to the use of genetically modified organisms must comply with the specifications of the aforementioned regulations. Compliance with these specifications is also an important prerequisite for awarding foods of animal origin the label "Ohne Gentechnik" (GMO-free). Therefore, when selecting feeds for sampling, single component feed products of, for example, soya, maize, or rape, and products produced from these that are not labelled as "GM" should therefore be taken into account. The sampling and analysis of compound feeds, e.g. that contain these single-component feeds, is also possible, in consideration of the composition to be analysed in individual cases. In the event of positive findings, the manufacturing processes and the feed components used are to be analysed, also taking the production processes into account. It should be noted that GM proportions in singlecomponent feeds that have only been lightly processed are easier to analyse than highly processed products. Further explanations, including on the choice of feed, can be taken from the VDLUFA "Konzept zur Analytik von gentechnisch veränderten Futtermitteln" (Concept for the Analysis of Genetically Modified Feeds).

Types of sampling:

The official sampling for analysis for genetically modified feeds is performed in accordance with the VDLUFA sample schema document "Probenahme von Futtermitteln zur Untersuchung auf Bestandteile von in der EU zugelassenen GVO im Rahmen einer Überprüfung der Kennzeichnungspflicht" (Sampling of feeds for analysis for components of EU-approved GMO during analysis of the labelling requirements). The sampling schema takes into account the specifications of Regulation (EC) No. 152/2009, the German Feed Sampling and Analysis Decree (FPA) and the recommendations of the Commission on 4 October 2004.

For sampling and analysis for genetically modified end products, for which an authorisation procedure is pending, or the authorisation of which has expired, Regulation (EU) No. 619/2011 must be considered.

Sampling protocol and analysis order:

A copy of the sampling protocol in accordance with § 10 of the FPA, and an analysis order is to be attached to each sample. The analysis can be classified into screening procedures and qualitative/quantitative analyses. Positive results of a screening procedure require more detailed specific evidence. In the quantitative determination of GM proportions in compound feeds, the composition of the compound feed must be considered. If necessary, the individual components are to be analysed individually. For more information, refer to the VDLUFA "Konzept zur Analytik von gentechnisch veränderten Futtermitteln" (Concept for the Analysis of Genetically Modified Feeds).

4.3 Feed monitoring tasks in the inspection of the "ohne Gentechnik" ("GMO-free") labelling of foods of animal origin

The inspection of whether the labelling of a food of animal origin as "Ohne Gentechnik/GM-free" is permitted according to § 3a of the German Law on Implementing EU Genetic Engineering Legislation (EG-Gentechnik-Durchführungsgesetz), is the responsibility of the official food monitoring authorities.

Feed monitoring inspections may arise for the following reasons:

- Food monitoring authorities may, as part of their inspection of an "Ohne Gentechnik/GM-free" label, call on the support of the government authorities responsible for feed monitoring (official help, e.g. for checking the single feed components used by a manufacturer of compound feed);
- Specific controls may also result from the realisations of the competent authorities responsible for government monitoring of feeds (concrete suspicions);
- Furthermore, official feed monitoring may also be performed at manufacturers, traders, and farmers independently of the use of a feed (random sample). In this case it is initially immaterial whether the results may be associated with "Ohne Gentechnik/GM-free" labelling according to food regulations.

In accordance with the requirements of Regulation (EC) No. 852/2004, food monitoring at livestock farms may determine which feeds are fed to the animals. In this case, it shall be checked whether the animal from which the food originates is fed using a feed, that has been labelled according to article 24 and 25 of Regulation (EC) No. 1829/2003 or article 4 or 5 of Regulation (EC) No. 1830/2003 or, if they would have been subject to labelling had they been placed on the market (= transferred to a third party). If results are found that lead to the requirement for tracing or sampling a feed, the government agency responsible for feed monitoring must be involved. As part of these inspections, a delivery may be sampled and/or the origin of the feed traced back to the manufacturer. In this case, it is possible that the documentation and implemented measures at all levels of sales and manufacturing must be inspected. According to the legal regulations for feedstuffs, the farmer is not required to retain records of feeds they have fed. The farmer must ensure the traceability of the feed based on their own documentation (e.g. delivery notes, invoices).

According to para. 3b of the German Law on Implementing EU Genetic Engineering Legislation (EG-Gentechnik-Durchführungsgesetz), the person who places the food labelled as "Ohne Gentechnik/GM-free" on the market or who applies to do so, must provide evidence

relating to the preparation, processing, or mixing of the food, or **the feeding of the animals**, that the prescribed requirements for usage of this labelling have been complied with. Suitable evidence for products of animal origin include, in particular:

- 1. Binding declarations from the supplier that the requirements for labelling have fulfilled, or
- 2. In the event of feeding, labels or accompanying documents relating to the final products used (feeds).

Example regulations named in paragraph 3b are linked by 'or'. Number 1 is taken from the removed § 5 of the German Regulation Concerning Novel Foods and Novel Food Ingredients (NLV), which is the predecessor of the current "Ohne Gentechnik" labelling legislation. According to margin item 7 of the comments for the regulation of the NLV, it is "assumed that explanations provided by manufacturers or suppliers that appear not to be feasible do not represent sufficient evidence". The same applies if it is established that the manufacturer or supplier has submitted multiple inaccurate declarations. In the absence of relevant points of reference it is, however, to be assumed that these declarations represent sufficient evidence".

In relation to the period of time before the foodstuff is obtained during which feeding with GM feeds is prohibited, the species-specific time periods named in the following table apply.

Tab 2

Period of time before obtaining the food, during which feeding with "GMO"-labelled feeds is prohibited in line with the "Ohne Gentechnik" (GMO-free) labelling requirements:

No.	Species	Period
1	Equines and cattle (including species of	Twelve months, and always a
	ox and bison) for meat purposes	minimum of three-quarters of the
		lifetime
2	Small ruminants	Six months
3	Pigs	Four months
4	Milk-producing animals	Three months
5	Poultry for meat purposes, that has	Ten weeks
	been stalled before the age of three	
	days old	
6	Poultry for eggs	Six weeks

5 Evaluation and Procedure in the Event of Positive GMO Findings

Labelling requirements do not apply to feed containing material which contains, consists of, or is produced from EU authorised GMOs or derived products, in which the proportion of GMOs is no higher than 0.9 % (Article 24 para. 2 of Regulation (EC) No. 1829/2003), provided that this transgenic content is adventitious or technically unavoidable. This threshold also applies for exception from the obligation for data transfer for traceability (article 4 para. 7 and 8 and article 5 paragraph 4 of Regulation (EC) No. 1830/2003). The operator is responsible for providing this evidence.

The threshold only applies to EU authorised GMOs and their derivatives. No threshold exists for EU unauthorised GMOs and their derivatives (see article 16 paragraph 2 of Regulation (EC) No. 1829/2003). Appropriate analysis methods must therefore be employed to

determine whether a feed contains such GMOs and derived products.

The labelling regulation, in consideration of the threshold value, applies for singlecomponent and compound feeds:

Single-component feed:

The threshold applies for single-component feed. Single-component feeds may contain several genetically engineered lines. If different lines are present within one single-component feed, the GM content of each individual GMO line shall be added together for the purposes of checking compliance with the threshold.

Compound feedstuffs:

In accordance with Regulation (EC) No. 1829/2003 article 24 paragraph 2 in the context of Regulation (EC) No. 641/2004 article 9 paragraphs 2, the legally defined threshold value applies for the feed and each component contained in the feed (e.g. individual single-component feeds). This means that, in addition to the compound feeds, the individual feed components of a compound feed are also subject to the requirements of the aforementioned Regulation with regard to the threshold values and labelling.

GMOs and products produced from GMOs may also enter into the feed as a result of carryover in the manufacturing process (carry-over of components or via mixing methods). If the analysis of the individual components reveals that the GMO content in relation to the individual components does not exceed the threshold value of 0.9 %, none of the relevant single components is subject to the labelling requirement. If the GMO content of the compound feed is greater than 0.9 %, labelling is required (see appendix 1 no. 4b and 5).

The Regulation (EC) No. 1829/2003 does not, however, account for this case, since the components from the carry-over are not declared. An analogous application of art. 25 para. 2b of Regulation 1829/2003 can therefore be considered (since, due to the non-declaration, labelling after the name of the feed products is not possible, the labelling is performed separately). If this method is rejected, however, the minimum requirement for labelling from the requirement of art. 5 para. 1 lit. b) of Regulation 1830/2003 still applies.

Following investigation of the individual case within the company, findings of this nature should lead to further measures in order to prevent the entry of GMOs and products produced from GMOs, e.g. via the goods receipt process, the manufacturing process, or during loading.

What is the definition of "adventitious or technically unavoidable"?

The exception from the labelling requirements depends on two prerequisites:

The threshold level of 0.9 % GM content must not be exceeded, and

The presence of the GM content must be "adventitious or technically unavoidable".

The assessment of whether identified impurities are adventitious or technically unavoidable should always be preceded by an individual case investigation. Depending on the individual case, the following criteria are to be checked:

According to Art. 24 para. 3 of Regulation (EC) No. 1829/2003, the operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of GM content (acc. to Art. 24 para. 2 of Regulation (EC) no. 1829/2003). The burden of proof lies with the operator.

If an operator has contractually taken appropriate care to avoid the presence of genetically modified material (for example, using an IP System = Identity Preservation System), the presence of GM material in a concentration no higher than 0.9 % may be considered adventitious or technically unavoidable.

A feed manufacturer who produces, uses, or handles both GM-containing and GM-free feed must separate the two product lines either spatially or chronologically to prevent mixing. In the case of chronological separation, the manufacturer must prevent the entry of GMOs or products made from GMOs as far as possible, e.g. through the use of rinse batches and/or appropriate cleaning of the plants. The operator is responsible to supply evidence of the suitability and execution of measures, in particular their own inspections.

For deliveries of feed within the European Union, the Regulations (EC) No. 1829/2003 and (EC) No. 1830/2003 regulate the labelling requirements for feeds with GM content. In the case of feed deliveries from non-EU countries in which no comparable labelling system is in place, the requirements must be contractually agreed by the operator and ensured by certificates and the operator's own inspections. All documents provided must be fully examined and evaluated in relation to individual cases. If a feed in which GM content cannot be excluded is delivered in relevant quantities, it is reasonable and necessary to enquire of the supplier whether, and which protective measures have been implemented with regard to preventing the carry-over of GM content.

If, as a result of recurring inspections, GM content of a particular bandwidth below the threshold value is regularly identified within an operation, this does not authorise the feed company to automatically draw the conclusion that the impurity is adventitious or technically unavoidable, and thus that labelling is never required. Due care obligations that are the responsibility of the operator include, for example, measures for the prevention of carry-over, the inspection of delivered goods, and the obligation of suppliers. This is to be checked by the responsible authority in individual cases.

If it is established that a feed contains up to 0.9 % GM content for adventitious or technically unavoidable reasons, and this therefore is not to be labelled, this classification also applies for the labelling of all further feed products derived from this feed, provided that in the further processing of the feed, the measures for preventing the entry of further GM content are sufficient and the threshold value of 0.9 % is not exceeded.

GM content in feed due to entry as botanical impurities

In accordance with Annex I no. 2 of Regulation (EC) No. 767/2009, the botanical purity of single-component feed materials shall not be less than 95 %, unless a different level has been defined in the catalogue according to Article 24. Botanical impurities comprise impurities of plant materials that do not have adverse effects on the animals, e.g. straw and seeds of other cultivated species or weeds. The content of botanical impurities such as residues of other seed oils or oil fruits derived from a previous manufacturing process shall not exceed 0.5% for each type of oil seed or fruit.

For <u>single-component feeds</u> with botanical impurities from other plant species, which in turn contain GM material, compliance with the threshold value of 0.9 % for the single-component feed (= 100 %) is to be determined (see Annex 1 no. 2).

<u>Compound feeds</u> may contain single feed materials with botanical impurities from other plant species, which in turn could contain GM material. In these cases, each individual as a component of the compound feed must be analysed in order to establish whether the GM content in the individual feed components is adventitious or technically unavoidable.

The compliance with the threshold must be calculated based on the relevant single feed component in which GM content has been identified. If the threshold value is exceeded in a single-component feed that is a component of a compound feed, this single-component feed must be declared as "genetically modified [name of organism]" on the compound feed declaration.

Annex 1: GMO Labelling - Examples

Basis: Article 24 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 per cent of the feed and of each feed of which it is composed, provided that this presence is adventitious or technically unavoidable."

Findings	Labelling
1. GM maize in maize, content0.9 %, adventitious or technically unavoidable	<u>No labelling</u> of GM maize
2. GM soya in maize, proportion < 5 % = Botanical impurity	 The soya content must not be specified as a component, The GM soya content is therefore determined based on the total quantity of maize and labelled if applicable (see 2b):
a. Content of GM soya in maize 0.9%, adventitious or technically unavoidable:	- No labelling of GM soya *
b. Content of GM soya in maize > 0.9 %:	- <u>Labelling</u> of GM soya *
3. GM soya in maize, content > 5% = Components to be declared:	 The soya content must be specified in the composition, The proportion of GM soya must be determined based on the total quantity of soya and labelled if applicable (see 3b):
a. Content of GM soya in soya0.9 %, adventitious or technically unavoidable:	- No labelling of GM soya
b. Content of GM soya in soya > 0.9%	- <u>Labelling</u> of GM soya

4. GM soya in compound feed, soya is listed as a component in the compound feed:	The GM soya content is determined as a proportion of the total and must be labelled if applicable:
a. Content of GM soya in soya 0.9 %, adventitious or technically unavoidable:	- <u>No labelling</u> of GM soya
b. Content of GM soya in soya > 0.9 %:	- <u>Labelling</u> of GM soya

Findings	Labelling	
 b1. Possible special configuration with low proportion of declared soya in compound feed: the proportion of GM soya does not originate from the individual soya component used, but instead from the botanical impurity of another single component feed used in a compound feed (with a higher proportion in the compound feed, but GM soya content related to this single component feed 0.9 %): 	 Principle: No GM labelling requirement in the compound feed, if none of the individual components requires labelling; therefore: If applicable, no labelling requirement in the case of > 0.9 % GM soya in relation to the declared soya content in the compound feed * 	
 5. GM soya in compound feed, soya is not listed as a component, proportion of soya < 5 % = botanical impurity: 	 The soya content does not have to be specified in the composition; The GM soya content must be determined as a proportion of the total quantity of the compound feed, and labelled if applicable* 	

* For example calculations, see Annex 2

Sources:

1. Working Document SANCO, Section on GM Food, Feed and Environmental Risk, 19.10.2009

2. BTSF Training course: Better Training for Safer Food -Training Course on Food Law, November 2009, Barcelona

Findings from Table in Annex 1	Example of Findings and Calculation
Re. 2.a.	 2 % soya in maize 25 % GM soya in relation to soya content = 0.5 % GM in relation to single feed component maize
Re. 2.b.	 2 % soya in maize 100 % GM soya in relation to soya content = 2 % GM in relation to single feed component maize
Re. 4.b1.	Declared in compound feed: 2 % soya 10 % maize 88 % XY Results from analysis of compound feed: 4.5 % GM soya in relation to declared soya content <u>but:</u> Findings from analysis of the single-component feed used (retained sample) show: 0.5 % GM soya in relation to soya 0.8 % GM soya in relation to maize 0.0 % GM in XY No labelling requirement!
Re. 5.	2 % soya (not declared) in compound feed 25 % GM soya in relation to soya content = 0.5 % GM in relation to compound feed, no labelling requirement

Annex 2: GMO Labelling – Example Calculations for Annex 1

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

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