Position Statement No. 2016/01: Guideline for Monitoring Genetic Modifications in Food

Orientation frame for the application of the legal regulations and monitoring genetic modifications in foods. Last revision: October 02, 2019

1. Preliminary statement

This guideline provides an overview of the national and EU-wide legal regulations on genetic modifications in foods and constructions and aids for interpretation applicable to these legal regulations. The guideline takes up the most relevant topics which have been discussed by the working group of food chemistry experts since 2003 and to which statements have been elaborated. It is primarily addressed to the official authorities responsible for food control.

Information on terms / abbreviations

The term "genetically modified organism", abbreviated as "GMO" has been legally defined: According to the German Genetic Engineering Act (implementing Directive No. 2001/18/EC), genetically modified organism means “an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." It must be added that a GMO in the legal sense is a fertile biological entity. Foods are often processed to an extent that they no longer consist of or contain fertile organisms. Instead, they are "produced from GMO" (cf. Chapter 2 of this Guideline). They thus fall under the legal regulations on genetic engineering applicable to foods and feeds (and not under the German Genetic Engineering Act). The same applies to foods containing ingredients which have been produced from GMOs.

Regulation (EC) No. 1829/2003 is of fundamental significance for this guideline, its objective are genetically modified foods and feeds. This guideline is concerned with foods and food control.
The abbreviation "GM" used in the following stands for "genetically modified".

Reference to the judgment of the European Court of Justice (ECJ) of 25 July, 2018

As a result of the ruling of the ECJ (Case C-528/16), organisms obtained with new methods / methods of so-called mutagenesis (e.g. CRISPR / Cas9) are also GMOs within the meaning of Regulation (EC) No. 1829/2003. Therefore, the controls of the official food control authorities must also include such organisms or products produced from these organisms if they are intended for food purposes (for further details see Section 10.1).

2. Relevant legal provisions

The handling of GM food is regulated by national law and legal provisions which have been agreed upon on the level of the European Union. Table 1 presents a list of the relevant regulations. They are also to be found elsewhere:

a) on the website of the German Federal Office of Consumer Protection and Food Safety (BVL; Bundesamt für Verbraucherschutz und Lebensmittelsicherheit):

   http://www.bvl.bund.de/DE/06_Gentechnik/02_Verbraucher/07_Rechtsvorschriften/gentechnik_Rechtsvorschriften_node.html

b) on the web site of the EU Commission:

   http://ec.europa.eu/food/plant/gmo/new/legislation/index_en.htm

Table 1: Relevant regulations on genetically modified organisms and products produced therefrom

Regulation	Regulatory
Regulation (EC) No. 1829/2003: Regulation of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed	Authorization procedures Labelling, threshold value Foundation of EU-RL and ENGL
Regulation (EC) No. 1830/2003: Regulation 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	System for traceability of GMOs and products made therefrom on all levels of market placement. Documentation trade transactions between GMO traders: who purchases / supplies which GMO or products produced therefrom to whom
Regulation (EC) No. 834/2007: Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (will be replaced by Regulation (EU) 2018/848 on organic production and labelling of organic products as of 1 January 2012)	Prohibition on the use of GMOs and products produced therefrom in organic products Threshold value of 0.9 %
Regulation (EC) No. 65/2004: Commission Regulation 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms	Definition of unique identifiers for GMOs
Regulation (EU) No. 1169/2011: Regulation of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers	General provisions related to Article 7 of the regulation on protecting consumers from deception (e.g. in cases of implicit advertisement)

Regulation (EU) No. 2017/625: 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 application of food and feed law, rules on animal health and welfare, plant health and plant protection products (Official Controls Regulation)	Official controls, designation and tasks of reference laboratories
Directive 2001/18/EC: Directive of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms	Directive on the deliberate release of genetically modified organisms into the environment and placing these organisms as products or in products on the market
Additionally on the national level (Germany):	
EC Genetic Engineering Implementation Act of 1 April 2008: 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	"Ohne Gentechnik” (without genetic engineering) food labelling Criminal liability associated with EU regulations

3. Institutions and competent authorities

Compiled in the following is information pertaining to the authorities and institutions which have special competences on European and national level, for example, as regards the authorization of GM food or relative to the provision of analysis methods.

3.1 Authorities/ institutions on EU level

European Food Safety Authority (EFSA)

The European Food Safety Authority (EFSA) was founded in 2002 on the basis of Regulation (EC) No. 178/2002. In the scope of its comprehensive responsibilities it is responsible for the safety assessment in the scope of the European authorization procedures for genetically modified food. Authorization is decided upon by the EU Commission involving the participation of the EU member states. For more information, refer to the websites of the EFSA and the web sites of the EU Commission.

European Union Reference Laboratory for Genetically Modified Food and Feed, EURL-GMFF

The EURL-GMFF was founded on the basis of Regulation (EC) No. 1829/2003. It is located at the Commission's Community Research Centre (JRC) in Ispra, Italy. The EURL and its tasks and duties are described in the Annex of the mentioned regulation and in EU Control Regulation No. 2017/625.

"The Community Reference Laboratory" is particularly responsible for:

- reception, processing, and maintenance of the appropriate positive and negative control samples and their distribution to national reference laboratories
- testing and validation of the detection method, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed (minimum requirements for such a method under http://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm).
- evaluating the data provided by the applicant for the authorization for placing the food or feed on the market, for the purpose of testing and validation of the methods for sampling and detection (http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx)
- submitting full evaluation reports to the authority" (EFSA)

European Network of GMO Laboratories (ENGL)

The European Network of GMO Laboratories (ENGL) was founded in 2002 in anticipation of Regulation (EC) No. 1829/2003. It is concerned with the challenges of detection, identification and quantification of GMOs, in particular by means of:

- validation of submitted detection methods in the scope of EU authorization procedures together with the EURL-GMFF
- recognition of relevant subjects pertaining to GMO analytics and creation of guidelines
- technology transfer between ENGL members and other GMO networks.

Late in 2013, 97 laboratories of 27 EU member states (21 of which from Germany), from Norway, Switzerland and Turkey were officially registered ENGL members. The ENGL is presided by the Commission's Community Research Centre (Joint Research Centre, JRC) in Ispra, Italy.

Food and Veterinary Office (FVO)

The Food and Veterinary Office (FVO) of the European Commission supports the EU Commission in reviewing whether the EU member states comply with the applicable legal food regulations in accordance with their authorization, monitoring and control obligations.

3.2 Authorities / institutions operating on the national level

German Federal Ministry of Food and Agriculture (BMEL; Bundesministerium für Ernährung und Landwirtschaft)

The BMEL, as part of the federal government, is principally responsible for green genetic engineering and it also represents the federal government in this area on EU and international level.

German Federal Office of Consumer Protection and Food Safety (BVL; Bundesamt für Verbraucherschutz und Lebensmittelsicherheit*) and National Reference Laboratory (NRL-GMO)*

The BVL is an autonomous higher federal authority under the jurisdiction of BMEL. In matters of genetic engineering, it is responsible for the authorization of deliberate releases in Germany. In addition, it is involved in the European authorization procedures for putting GMOs on the market and authorization of GM food and feed. The National Reference Laboratory for Genetically Modified Organisms (NRL-GMO) is also under the roof of the BVL. Within the framework of its duties, the reference laboratory supports the official control laboratories of the Federal States in accordance with Article 94 of Regulation (EU) No. 2017/625.

Competent Control Authorities in Germany

In Germany, food control is in the responsibility of the federal states. Food is analyzed for the presence of genetically modified components at the federal state laboratories. These laboratories are members of the ENGL.

4. Authorization of genetically modified food

Food containing GMOs, consisting of or produced from GMOs, fall within the scope of Regulation (EC) No. 1829/2003 (Article 3 (1) b, c). They may only be placed on the market within the EU if they possess an EU-wide authorization. To obtain this authorization, they have to pass the authorization process according to Regulation (EC) No. 1829/2003. The decision made is then valid in all member states of the EU.

a) **GMOs not authorized within the EU:** According to Article 4 (2) of Regulation (EC) No. 1829/2003 no person shall place on the market a GMO designed to be used as food or food component or food referred to in Article 3 (1) [of the Regulation] unless it is covered by an authorization granted in accordance with this Section and the relevant conditions of the authorization are satisfied (zero tolerance). In this context it has hitherto not been of any relevance in which amounts a non-authorized GMO is detectable within a product. A corroborated detection is sufficient (ENGL 2011).

b) **GMOs authorized within the EU**: GMOs authorized in the EU may be applied and placed on the market under consideration of their purpose of use and further legal provisions, especially the labelling requirements.

   Authorized products are listed in a community registry of GM food and feed.

   Authorization is granted for a term of ten years. If deemed proper, a plan for post-market monitoring the products may be imposed. Respective authorizations can be renewed for ten more years.

c) Genetically modified (GM) food for which an EU authorization has been applied
For an official list of applications for authorization and detection methods for genetically modified food and feed, which were submitted according to Regulation (EC) No. 1829/2003, cf. http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

Current data pertaining to the authorization status can also be found under the flowing links: http://www.euginius.eu, http://www.transgen.de/zulassung/gvo/

d) **Special case of botanic impurities**
The term "botanical impurities" is derived from the feed sector and refers to inputs from components of a plant species not listed in the sales description or ingredient list. They are introduced, for example, by growing, harvest or processing. The term "botanical impurity" has also become established in genetic engineering in food or food ingredients. Here, it refers to inputs of components from a different plant species containing genetically modified amounts. For example, inputs of GM soy or GM maize were determined in wheat flour. Such botanical impurities are covered by Article 3 (1) b (foods containing GMO) or c (foods produced from GMOs) of the Regulation (EC) No. 1829/2003. They therefore fall within the scope of Regulation (EC) No. 1829/2003. They also fall within the scope of the "traceability regulation" (EC) No. 1830/2003. Food or food ingredients containing amounts of GMOs not authorized in the EU also from botanical impurities must not be place on the market according to Article 4 (2) of Regulation (EC) No. 1829/2003.

e) **Food produced "with the aid of" GMOs**

Food made with the aid of GMOs does not fall within the scope of Regulation (EC) No. 1829/2003 (recital 16 of the regulation). Examples are:

- food derived from animals (e.g. meat, milk, eggs) fed with GM feeds,
- food containing enzymes produced with GM microorganisms, food additives, flavorings and vitamins produced with the aid of GM microorganisms, whereby the GM microorganisms or their components are no longer contained in the product

4.1 Topic authorization: real life questions

*Can a **positive analysis result** of a **non-authorized GMO** be "undone" by a representative duplicate sample?*

No, a positive analysis result of a GMO not authorized in the EU suffices to render the sampled batch not marketable.

*How are results of amounts of non-authorized GMOs in **honeys** to be assessed?*

Honey with GM pollen falls within Article 3 (1) c of Regulation (EC) No. 1829/2003 as "food produced from GMOs" (decision of the EuGH, Sep. 6, 2011, Directive 2014/63/EU from May 15, 2014). If components of plant lines not authorized in the EU are detected in honey, such honey is considered as not marketable.

*May **honey**, from which the pollen of non-authorized GM lines have been removed by dissolution in water and sterile filtration be used to manufacture honey wine (mead)?*

A honey containing the pollen of non-authorized GM lines is not marketable as food and must not be processed as food, as it must be anticipated that material from the genetically modified organism will still be present in the product even after sterile filtration.

Are additives which are derived from raw materials from GMO and which were produced by one or several chemical, enzymatic or other modifications of these raw materials to be classified as “produced from GMO” in the meaning of Article 3 (1) c of Regulation (EC) No. 1829/2003?

Additives which are derived from raw materials from GMO and which were produced by one or several chemical, enzymatic or other modifications of these raw materials are to be classified as “produced from GMO” in the meaning of Article 3 (1) c of Regulation (EC) No. 1829/2003.

5. Labelling according to Regulation (EC) No. 1829/2003

Regulation (EC) No. 1829/2003 contains detailed provisions for genetically modified food intended to be sold or delivered to final consumers and/or community catering providers.

How retail trade and community catering providers receive the information which initiates a labelling obligation is regulated by **Regulation (EC) No. 1830/2003** referring to **traceability** (cf. Chapter 6).

Specific provisions regulating the labelling requirements of genetically modified food and feed are determined in Regulation (EC) No. 1829/2003. Articles 12 and 13 contain the labelling requirements applicable to food (cf. also Table 2). They apply to food which is sold or otherwise delivered to final consumers or community mass catering providers (restaurants, hospitals, canteens etc.).

According to Article 13 (1) of Regulation (EC) No. 1829/2003, for food which

− contains or consists of GMOs, or

− are produced from GMOs or contains ingredients which have been made of GMOs

the following specific labelling requirements apply:

a) The list of ingredients must state after the designation of the ingredient the addition **"genetically modified"** or **"produced from genetically modified (name of the ingredient)"**.

b) If the ingredient is specified in the list of ingredients under the name of a category/class the following labelling will be required in the list of ingredients:

   "contains genetically modified (name of the organism)“ or

   "Contains (name of ingredient) produced from genetically modified (name of organism)“.

   The statements according to a) and b) may also be reported as footnote to the list of ingredients.

c) If no list of ingredients is provided, the following labelling must be attached: "genetically modified" or "produced from genetically modified (name of organism)".

d) In case of un-packaged merchandise for the final consumer the required statements must be made in immediate relation to the food and in easily legible font size. This also means that, for example, the use of genetically modified food must also be informed in case of mass community catering and gastronomy operations, for example, by postings

and on food menus. For example, it is required to report the use of frying oil made of genetically modified raw materials.

5.1 Labelling and analytical evidence ("evidence-independent labelling")

It is not important for the labelling requirement (and the authorization requirement!) whether the components of GMOs can be identified in the food or not (cf. also Table 4) The authorization requirement invariably results in a labelling requirement (see below for exceptions).

5.2 Exemptions from the labelling requirement

Food or food ingredients will not require labelling if they are not produced from, but with the aid of genetically modified organisms (see Table 2). For example, a labelling requirement does not exist if

- food derived from animals (e.g. meat, milk, eggs) fed with GM feeds.
- food containing enzymes produced with GM microorganisms.
- food additives, flavorings and vitamins produced with the aid of GM microorganisms, whereby the GM microorganisms or their components are no longer contained in the product.

Table 2 Labelling of authorized GMOs in Food pursuant to Regulation (EC) No. 1829/2003

GMO type	Example	Labelling necessary?
GM plant	Maize kernels, soybeans	yes
Food produced from GM plants	Maize flour, glucose syrup made from maize, refined soybean oil	yes
Food of animal origin, manufactured with feeds made of GMOs	Meat, milk, eggs	no
Food manufactured with an enzyme derived from GM microorganisms	Cheese manufactured with "GM" chymosin; bakery products manufactured with "GM" amylases	no
Food additives consisting of GMOs of plant origin	Soy lecithin	yes
Food additives, flavorings and vitamins produced with the aid of GM microorganisms (GMM); GMM is no longer existent in the product (e.g. vitamin product)	Vitamin B2 (for prerequisites, see left column)	no

GM – genetically modified

5.3 Labelling threshold value

Food containing, consisting or produced from GMOs may be exempted from the labelling requirement under the conditions stated below:

1. The labelling threshold value of 0.9 % relative to the respective ingredient has not been exceeded *and*
2. The proportion is adventitious or technically unavoidable.

The burden of proof lies with the food trader.
The threshold value applies to both labelling of the final product according to Regulation (EC) No. 1829/2003 and to traceability labelling along the entire supply chain according to Regulation (EC) No. 1830/2003.

The experiences of the ALS Working Group "Monitoring of Genetically Modified Food (Überwachung gentechnisch veränderter Lebensmittel)" made in their practical monitoring routine revealed that amounts of GM components less than 0.1% (relative to the respective plant species and under the condition that only one ingredient of the examined species is contained) may in general be considered as adventitious or technically unavoidable.

If amounts of authorized GMOs within an ingredient range between 0.1% and 0.9% in a product, it shall have to be determined in the scope of an individual case decision whether a GMO labelling is necessary. Hence it has to be determined whether the amount is either adventitious or technically avoidable. Several factors are essential when it comes to interpreting the term "technically unavoidable", for example, the plant species, crop situation, availability, practicability and reasonability.

As a praxis-related approach, primarily the performed and documented self-monitoring measures and updated analysis results of food control should be drawn upon for the respective group of products. For more information, please refer to Waiblinger et al., 2007.

Updated analytical results for relevant product groups (e.g. for soy: tofu, sports nutrition, soy proteins) are regularly compiled by the control laboratories of the federal states who especially calculate the proportions of genetic modifications below which 95 % of all values determined lie (95th percentile values). The laboratories can draw upon the percentile values specific of the product group to assess the analysis results of a sample (Waiblinger et al. 2007, Waiblinger et al. 2011).

When reviewing the self-monitoring measures the following points can be audited

- operational self-monitoring system
- Type and frequency of analyses
- What is the amount determined?
- Which measures were taken?
- Supplier certificates
- Supplier audits
- Is it possible to shift to other suppliers?
- Potential GMO contaminations during the manufacturing process

Examples for testable criteria, which can be drawn upon in order to evaluate whether a contamination with GM material is adventitious or technically unavoidable, are:

− Comprehensible and appropriate documentation system for GMO absence in a relevant raw material (e.g. soy, maize, oilseed rape) along the entire chain from cultivation, harvest, transport, storage, to processing (Identity preservation (IP) system)

- Product specifications of the processor, which expressly disclaim using any GM material
- Declarations of the suppliers of GMO-relevant ingredients that no GM material has been supplied
- Results of laboratory analyses of GMO-relevant raw materials in the scope of the manufacturers´ self-monitoring measures.

It is also important what the responses are to results which repeatedly lie in the threshold range. Does a business operation apply additional measures, does it demonstrate activity, does it conduct additional targeted analyses?

If the food trader submits a comprehensible strategy to avoid GMOs the contamination may be considered in an individual case decision as adventitious or technically unavoidable.

5.4 Botanical impurities and labelling

As described in Section 4 d), so-called botanical impurities with GM components categorically fall within the scope of Regulations (EC) No. 1829/2003 and 1830/2003. For the evaluation of botanical impurities containing *non-authorized* GM material please refer to Section 4 d).

5.4.1 Botanical impurities with authorized GM material

In case of detectable contaminations with *authorized* GM components it must first be elucidated whether the identified plant species is a botanical impurity in the first place or an ingredient is subject to specific labelling requirements according to the Regulation on the Provision of Food Information to Consumers (Regulation (EC) No. 1169/2011), for example, when using a reworked product.

The conditions for an exemption from the labelling requirement for genetically engineered modifications, such as the adventitious or technically unavoidable introduction must be meticulously examined in every single case even with regard to a botanical impurity with authorized GMOs.

If the percentage of the species containing GM amounts is less than 0.1% it must be generally assumed that the contamination is either adventitious or technically unavoidable.

5.5 Labelling requirement: real life questions

*How and where must labelling of GM food proceed in case of its **delivery to restaurants and facilities of mass community catering**?*

Genetically engineered food must be labeled as such when delivered to restaurants or facilities of mass community catering. This should proceed – in analogy to the labelling of additives – on food menus or price lists immediately after the respective food or with a footnote or, if no food menus or price lists are displayed or handed out, in another posting or written communication.

*In case of positive results of up to 0.9 % (authorized GMOs) must the determined contaminants be generally regarded as adventitious and technically unavoidable, if it can be proven that the merchandise has been run through a so-called **identity preservation (IP) system**?*

The contractually agreed measures (characteristics of the IP system) for the assessment of the question whether the presence of genetically engineered material must be regarded as adventitious or technically unavoidable must exist and their execution must be documented. The sole statement that it is "IP" merchandise is insufficient.

*Must the processor and/or seller of a food or feed always label if he has **knowledge of the contamination** with authorized GMOs?*

No, as concerns the question of labelling requirement, it has to be examined whether the contamination is either adventitious or technically unavoidable (cf. also Waiblinger et al. 2007). If this can be demonstrated – for example, by compliance with Good Agricultural

Practice like maintaining isolation distances, separation measures, documented self-monitoring measures – labelling may be dispensed with.

Does the evidence of genetically modified components of a plant species in the range of the threshold value (>0.9 %) activate the labelling requirement in accordance with Regulation (EC) No. 1829/2003 if the sample contained ***more than one ingredient from the plant species determined****?*

No, a labelling requirement is not immediately activated in this case. It is therefore necessary to determine the input source of the genetically engineered modification. For the purpose of final clarification, a review of each single ingredient might be necessary. The protocol of the 2nd Meeting of the STALUT "GM Food and Feed and Environmental Risks" from June 23, 2004 (http://ec.europa.eu /food/plant/standing_committees/sc_modif_genet /index_en.htm) (under c): "Operation of the 0.9 labelling threshold") is referred to.

As far as the 0.9% threshold value is concerned, do the proportions determined in initial lines by applying molecular biological methods have to be added if the ***GMOs originate from several initial lines*** *(so-called* gene *stacked events)?*

No the proportions determined for each event are not to be added unless it can be demonstrated, e.g. by the food trader, that the analytically determined events are attributable to one stacked event.

Regarding the 0.9% threshold value, are the relative fractions of different GMO of one species that are not derived from a stacked event (e.g. soya events GTS 40-3-2 and MON 89788), to be summed up with regard to one ingredient (here soya flour)?

Regarding the 0.9% threshold value, the relative fractions of different GMO of one species (e.g. soya) that are not derived from a stacked event (e.g. soya events GTS 40-3-2 and MON 89788) are to be summed up with regard to one ingredient (here soya flour) (see recital 25 of Regulation (EC) No. 1829/2003 and the Guidance Document on Measurement Uncertainty for GMO Testing Laboratories of the JRC).

Does the transfer of information on an altered composition, which is partly requested in a GMO authorization decision, also need to be passed on if the presence of the respective GMO in the food is at such low levels that the alteration of the composition is practically neglectible?

Generally, additional information on an altered composition only needs to be declared if they fall under the scope of Article 12 of the Regulation (EC) No. 1829/2003.

Furthermore, according to Article 13 (2) a of the Regulation (EC) No. 1829/2003 this additional information on an altered composition on the food labels which is intended for the end consumer or facilities for communal catering needs to be stated only if a food differs from the respective conventional product beyond the natural variation.

Does pure ethanol, manufactured with conventional yeasts from GM maize as the substrate, have to be labeled when used in food as an ingredient?

Products created by metabolisation in a conventional organism are not considered as "produced from GMOs" and therefore must not be labeled.

*Are **honeys** subject to the GMO labelling requirement and how is the threshold value of 0.9% to be applied?*

Honey with GMO pollen falls within Article 3 (1) c of Regulation (EC) No. 1829/2003 as a "food produced from GMOs" (decision of the EuGH, Sep. 6, 2011). According to Article 12 (2) of Regulation (EC) No. 1829/2003, a food is exempted from labelling requirements if the proportion of the GM components in the food does not exceed 0.9% and the presence of GM components is either adventitious or technically unavoidable. The proportion of pollen including other water-insoluble substances in honey generally amounts at maximum to 0.1%. The percentage of GM pollen permitted as food also usually lies clearly below this value. In addition, an assessment value of 0.1% applies in general monitoring practice.

*Must the **unique identifier** of a (fertile) GMO be reported according to Article 4 of Regulation (EC) No. 1830/2003 even if the GMO appears in a food raw material only as an impurity?*

If a food raw material consists of a fertile material originating from more than one plant species, in which one GM plant species is a contaminant (e.g. deliveries of GM soybeans contaminated with GM maize kernels), the unique identifier of the contaminant will have to be communicated if the rule of exception stated in Article 4 (8) of Regulation (EC) No. 1830/2003 does not apply, i.e. if the proportion of GMOs in the entire product is either higher than 0.9% or lower than 0.9% but neither adventitious nor technically unavoidable.

What is the wording for the labeling of a product produced from GMO and whose only ingredient is listed in the voluntary list of ingredients?

A product without a list of ingredients which consists of only one ingredient and was produced from GMO is to be labeled according to Article 13 (1) c of Regulation (EC) No. 1830/2003. However, if a voluntary list of ingredients is provided, the declarations according to Article 13 (1) a of Regulation (EC) No. 1830/2003 are to be used, as here the specifications for the labeling of an ingredient produced from a GMO within a list of ingredients are layed down. This also applies for lists of ingredients with only one ingredient.

How to deal with pre-packaged food from a third country with a foreign-language genetic engineering label if there is no genetic engineering label in German? In the case of exclusively foreign-language genetic engineering labelling for foods from third countries, the responsible food business operator must demonstrate, within the framework of its general due diligence obligations in accordance with Article 17 (1) of Regulation (EC) No. 178/2002, that the ingredient / food in question does not have to be labelled in accordance with Article 13 of Regulation (EC) No. 1829/2003. This can e.g. done by certificates.

6. Traceability according to Regulation (EC) No. 1830/2003

This Regulation is supposed to facilitate the exact labelling of food and feed produced from GMOs according to Regulation (EC) No. 1829/2003 (cf. Chapter 5 of this Guideline). For this reason, Regulation (EC) No. 1830/2003 contains provisions for the traceability and labelling applicable to each phase of market placement. The labelling requirements depend on two categories:

I. products consisting of or containing GMOs (e.g. whole fruits, seeds or grains; Article 4), and

II. food (and feed) produced from GMOs (e.g. corn starch, soybean oil; Article 5)

For products belonging to **category I**, the following written declarations must be transmitted with each delivery, starting with the first placing on the market:

- declaration that the product contains or consists of GMOs
- declaration of the unique identifier of the GMO

The exact wording is not defined here.

Note:

Regulation (EC) No. 65/2004 contains more detailed information on the unique identifier. The unique identifiers of each GMO are listed in the pertinent registers of the Commission: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

The unique identifier is a sequence of letters and numbers which contain information about

- *the applicant, and*
- the *genetically engineered modification,*

e.g. the genetically modified Roundup Ready™ soybean of Monsanto: MON-Ø4Ø32-6 authorized in the EU.
The unique modifier has only to be declared in case of fertile products; e.g. for fertile GM soybeans and GM maize kernels, however, not for the subsequent processing products which are not fertile, such as soybean oil or corn starch.

For products belonging to **category II**, the following written declarations must be transmitted with each delivery:

- *declaration of the ingredients produced from GMOs*
- *in case of products without a list of ingredients, a declaration that the product was produced from GMOs*

The unique identifier has not to be reported in this case.

As a rule, the responsible persons must archive the information of Regulation (EC) No. 1830/2003 for at least five years, so that it is possible to determine at all times from whom and to whom the product in question has been provided (*one step up, one step down*).

It should be noted that the provisions of Regulation (EC) No. 1830/2003 are not only applicable to food and feed, but to "GMOs" in general, e.g. also to seeds.

7. "ohne Gentechnik” (“without genetic engineering") label

Food traders are permitted to advertise their produce with the label "without genetic engineering" on a voluntary basis under the provision that the requirements according to Section 3a of the EC Genetic Engineering Implementation Act (EG-Gentechnik-Durchführungsgesetz; EGGenTDurchfG) are fulfilled.

To this end, traceable evidence according to Section 3b of the EC Genetic Engineering Implementation Act must be submitted and state that manufacturing has fulfilled the demanded criteria.

Note:
The nationwide green-white "ohne-Gentechnik" ("without genetic engineering") seal in Germany (Fig. 1.) can be used for labelling. The seal "ohne-Gentechnik" ("without genetic engineering") is a trademark-protected word-pictogram brand whose owner is the Federal Republic of Germany, as represented by the Federal Minister of Food and Agriculture. The ministry has exclusively commissioned the Verband Lebensmittel ohne Gentechnik e.V. (VLOG; http://www.ohnegentechnik.org/) with the task of issuance and management of user licenses. Interested companies are therefore requested to address exclusively this association.

The use of a company-owned "Without genetic engineering" seal and simple statement in text form are still permissible if the requirements according to the Sections 3a and 3b of the EC Genetic Engineering Implementation Act are fulfilled.

As far as the control of genetically modified food is concerned, it is the responsibility of official food control to monitor the labelling according to the EC Genetic Engineering Implementation Act. Monitoring the maintenance of the provisions regulating the use of a voluntary seal such as that of the VLOG, however, is subject to private-law agreements.

7.1 Wording

If a food is to be placed on the market bearing a claim which indicates that the manufacture of the food had proceeded without applying genetic engineering procedures, the wording "ohne-Gentechnik" ("without genetic engineering") alone will be permitted for labelling (Section 3a of the EC Genetic Engineering Implementation Act). It is consequently not permissible if a produce is advertised in the same sense, however, by using a variant expression (e.g. "guaranteed free of genetic engineering" or "guaranteed not genetically manipulated"). By analogous application of Article 54 of the Food and Feed Code (LFGB, Lebensmittel- und Futtermittelgesetzbuch), food derived from other EU member states and produced without applying genetic engineering procedures may be placed on the market with a claim equivalent to that of the "ohne Gentechnik" ("without genetic engineering") label — under the condition that the wording is permitted to be used in the according member state and the pertinent requirements for such "without genetic engineering" label have been complied with. If the requirements which the respective member state imposes on the "without genetic engineering” labelling of food deviate from the provisions of the EC Genetic Engineering Implementation Act, these deviations must be indicated to an extent that is required for the protection of consumers.

7.2 Prerequisites and certifications

Apart from the wording, Sections 3a and 3b of the EC Genetic Engineering Implementation Act define conditions and required certifications for the "ohne-Gentechnik" ("without genetic engineering") labelling (cf. also Table 3).

Conditions

In summary, food or food additives must only be labeled as "ohne-Gentechnik" ("without genetic engineering"),

- if they do not consist of genetically modified organisms (GMOs), are not produced from GMOs, and also do not contain any GMO components, neither adventitious nor technically unavoidable (in the sense of Regulation (EC) No. 1829/2003), and
- if for production, treatment, processing or mixing of these foods or food ingredients no food, food additives, processing aids or, if applicable, other substances not considered as an ingredient haven been produced with a GMO..

Note: Components derived from authorized GMOs may usually be tolerated in slight traces, i.e. at a maximum of 0.1%.

The following applies to food of animal origin (e.g. milk, meat, eggs):

- No feed labeled as GM shall be used for feeding of the animals within a specific period of time prior to the production of the food, neither any feed which would require labelling had it been placed on the market. It is, however, permitted before this time period. Beginning with the time periods stated in the Annex of Sections 3a (4) 2 minor GM components of up to 0.9% are permissible in feeds only if their input has been adventitious or technically unavoidable according to Regulation (EC) No. 1829/2003.
- Feed additives which consist of, contain or were produced from GMOs must not be used.

Note: No limitations exist for the application of veterinary drugs or using feed additives such as enzymes, amino acids or vitamins which have been produced with the aid of GM microorganisms (GMM) and the GMM (or components derived therefrom) are no longer present in the product. Furthermore, as opposed to the Regulation (EC) No. 837/2007*, no limitations specific of genetic engineering exist for the use of plant protection products, fertilizers and soil conditioners.*

Certifications

A "ohne-Gentechnik" ("without genetic engineering") label obliges to keep adequate certifications to confirm that the requirements stated above have been fulfilled. According to Section 3b of the EC Genetic Engineering Implementation Act these are in particular

- binding statements on the part of the upstream supplier that the prerequisites for the "ohne-Gentechnik" ("without genetic engineering") labelling have been complied with
- in case of food / food ingredients or feed falling under the labelling requirement, labels or accompanying documents of the primary products used
- analysis reports or documentation showing that no GM components, except for minimal traces (see above) are contained.

Additional comments on certifications for feeds:

- There is no legal equivalent of the "ohne-Gentechnik" ("without genetic engineering") label applicable to feed. The use of a pertinent seal/advertisement lies in the responsibility of the manufacturer.

In case of detectability of authorized GM components up to 0.9%: The mere certification that the proportion is below 0.9% is not interpretable as being sufficient evidence. Its Adventitiousness and/or technical unavoidability must be proven to the competent authorities.

As concerns the tasks of feed control in connection with inspecting the "ohne-Gentechnik" ("without genetic engineering") label in cases of food of animal origin, the “Guideline for Monitoring GMOs in Feed ("Leitfaden zur Kontrolle von GVO in Futtermitteln“)" is referred to (LAV & VDLUFA 2011).

7.3 Official monitoring

It is recommended to examine comprehensively in the scope of so-called "initial inspections" soon after the use of the "ohne-Gentechnik" ("without genetic engineering") label has become known whether the requirements of the label have been fulfilled. Afterwards, the official inspections can be carried out risk-oriented as usual.

However, the conformity with the labelling prerequisites cannot be verified with analytical detection methods for many food types, as much processed products like refined oils or sugars no longer contain a sufficient amount of detectable DNA. In these cases, only document inspections (e.g. declarations from suppliers, delivery papers) on site or, if available, analyses of the individual ingredients or raw materials can produce further information (cf. also Table 4).

Food of animal origin

Any feeding of genetically modified feeds is also not (yet) analyzable in products of animal origin such as milk, meat or eggs. An official monitoring of food of animal origin might necessitate the involvement of feed control authorities according to Section 3a of the EC Genetic Engineering Implementation Act. This (also) follows from the circumstance that food of animal origin (meat, eggs, milk) may be advertised with the indication "ohne-Gentechnik" ("without genetic engineering") if no GM feeds have been used to feed the animals within a period specified for each animals species separately before production of the food. This would have to be examined by document inspection and/or an accompanying randomized analysis of feed given to the food-supplying animals.

7.4 Potentially misleading

Given certain products, the "ohne-Gentechnik" ("without genetic engineering") label might be suited to mislead the consumer.

It is prohibited according to Article 7 (1) c of Regulation (EC) No. 1169/2011 to place on the market food with misleading information by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics (implicit

advertising). The promotionally effective statement "ohne-Gentechnik" ("without genetic engineering") should be reserved to products for which an additional control effort concerning the avoidance of genetic modifications can be made plausible; e.g. if GMO variants are grown commercially or released on a large scale.

In general, it must be ascertained if a special risk of use or of an input of GM ingredients, processing agents or feeds is attached to the product.

8. Organic food production

The EU regulation on organic production and labelling of organic products (Regulation (EC) No. 834/2007) contains specific requirements concerning the application of genetic engineering to produce of organic production.

The requirements are comparable, but not identical, with the requirements applicable to the "ohne-Gentechnik" ("without genetic engineering") labeling for food. For essential differences see Table 3.

There is a general **prohibition on the use** of GMOs (Article 9) and products consisting of or produced from GMOs, which comprises apart from food also feeds, processing aids, seed, fertilizers, soil conditioners, vegetative reproduction material, microorganisms and animals.

Note: The term "produced by GMOs" denotes products and/ or ingredients which were produced with the aid of a GMO as the last living organism in a processing procedure, but do not consist of, contain or have been made from GMOs, e.g. vitamins which were produced with the aid of GM microorganisms.

The following exceptions from the prohibition on the use of GMOs exist:

- veterinary drugs produced with GMOs
- Additives of foods and feeds if they must be used and are not available on the market other than produced by GMOs.

Furthermore – despite the prohibition on use – pursuant to Article 9 (2) of Regulation (EC) No. 834/2007 adventitious or technically unavoidable contaminations (Waiblinger et al. 2007) with GMOs and products manufactured therefrom may be contained in foods or feeds and/or their ingredients up to a threshold value of 0.9%, without contradicting labelling a food as "organic" pursuant to Regulation (EC) No. 834/2007.

Table 3: Labelling regulations for GMOs, comparison of requirements for conventional, organic products as well as "GMO free" foods

	Unlabeled (conventional) food Regulation (EC) No. 1829/2003 and (EC) No. 1830/2003	"ohne Gentechnik" (without genetic engineering) pursuant to EC Genetic Engineering Implementation Act	"Organic", "Eco" Regulation (EC) No. 834/2007
Impurities due to components consisting of non-authorized GMOs/tolerance limit	permissible up to **0.9%** in case of adventitious or technically unavoidable proportions	permissible are only unintentional and unavoidable traces (without threshold limit value). Benchmark value of **0.1%**	permissible up to **0.9%** in case of adventitious or technically unavoidable proportions
Food: enzymes, additives, vitamins, amino acids produced with GM microorganisms	permissible	permissible unless - substances are authorized for organic products and - no other substances except those made of GMOs are available on the market	cf. "ohne Gentechnik” (Without genetic engineering)
Feed consisting of GM plants	permissible	permissible up to **0.9%**, in case of adventitious or technically unavoidable proportions*	permissible up to **0,9%** in case of adventitious or technically unavoidable proportions
Feed additives: enzymes, supplements, amino acids, vitamins produced with GM microorganisms	permissible	permissible	permissible unless - substances are authorized for organic products and - no other substances except those made of GMOs are available on the market
Application of veterinary drug consisting of GMOs	permissible	permissible	permissible
Plant protection products, fertilizers, sol conditioners produced from GMOs	permissible	permissible	not permissible

* …within the waiting periods which are defined for the respective animal species listed in the Annex (re section 3a subs. 4 sentence 2) EGGenTDurchfG (EC Genetic Engineering Implementation Act)

9. "Without genetic engineering" and "organic": real life questions

9.1. Requirements for the "ohne-Gentechnik" ("without genetic engineering")" label"

*How are **contaminations with components of authorized GMOs** in "*ohne-Gentechnik" ("without genetic engineering") *products to be interpreted?*

The use of food containing amounts of GMOs categorically disqualifies the "ohne-Gentechnik" ("without genetic engineering") label. Small traces, i.e. proportion of up to 0.1% can be currently tolerated (cf. prerequisites and certifications).

*Are the statements "manufactured without genetic engineering" and "against genetic engineering" allowed particularly with regard to the regulation of Section 3a (1) of the EC Genetic Engineering Implementation Act (**wording**)?*

The information "manufactured without genetic engineering" and/or "against genetic engineering" are considered as information indicating that the food has been manufactured without any application of genetic engineering procedures. It is therefore not compatible with the formal requirements imposed on the wording pursuant to Section 3a (1) of the EC Genetic Engineering Implementation Act. Only the statement "ohne-Gentechnik" ("without genetic engineering") must be used.

With regard to Section 3a (1) of the EC Genetic Engineering Implementation Act, is it permissible to supplement the statement "ohne-Gentechnik" ("without genetic engineering") with additional connected, more specific statements such as “traditional feeding”?

The wording "ohne-Gentechnik" ("without genetic engineering") is mandatory. The label "ohne-Gentechnik" ("without genetic engineering") can, however, be supplemented with further specifications as long as these specifications are not misleading and all requirements of Section 3a (1) of the EC Genetic Engineering Implementation Act are fulfilled.

9.2 Deception in general

*Are statements like **"GMO free because organic"** misleading?*

The claim "ohne-Gentechnik" ("without genetic engineering") is only permitted if no GM components can be detected (minor traces, i.e. proportions of up to 0.1% are currently tolerable). However, the threshold value of 0.9% pursuant to Article 12 of Regulation (EC) No. 1829/2003 also applies to produce of organic farming (Article 9 (2) of Regulation (EC) No. 834/2007). However, a "ohne-Gentechnik" ("without genetic engineering") label would not be possible in this case because the conditions pursuant to Section 3a (3) of the EC Genetic Engineering Implementation Act are not fulfilled. Statements or claims such as "GMO free because organic" create the impression that in principle all organic foods may be advertised by claiming that they are "GMO free". The causal link between the terms "GMO free" and "organic" is misleading in the sense of Article 7 of Regulation (EU) No. 1169/2011.

9.3 Deception due to implicit advertisement

*With which **food group** (i.e. with which reference food) are comparisons drawn when "ohne-Gentechnik" ("without genetic engineering") labeling of food is assessed with respect to implicit advertisement?*

The assessment usually focuses on the respective product group, whereby special regulations, e.g. prohibitions on the use of specific substances (additives or enzymes) remain unconsidered in case of organic products. Example "ohne-Gentechnik" ("without genetic engineering") organic wheat flour – reference group: wheat flours in general.

*Does the label **"ohne-Gentechnik" ("without genetic engineering")** represent an implicit advertisement **when applied to an organic product**?*

The "ohne-Gentechnik" ("without genetic engineering") label is also applicable to products of organic farming, under the provision that the requirements of the EC Genetic Engineering Implementation Act are fulfilled.

Is the "ohne-Gentechnik" ("without genetic engineering") *label applicable to **unprocessed vegetable products** (e.g. cereals), for which **neither cultivation nor cultivation authorization** exist worldwide, with respect to implicit advertisement?*

The "ohne-Gentechnik" ("without genetic engineering") label must usually be assessed as misleading in case of plants for which neither cultivation nor cultivation authorization for a GM variant exist worldwide, as it is an implicit advertisement in the sense of Article 7 (1) c of Regulation (EU) No. 1169/2011.

If deliberate releases with GM variants of the plant species concerned are carried out on a large scale and/or if contaminations with GM plants are known to exist, a "ohne-Gentechnik" ("without genetic engineering") advertisement will be possible, provided that a specific additional effort to avoid the application of genetic engineering procedures can be evidenced (e.g. avoidance of GM counterparts of the respective plant species, e.g. rice, wheat).

In addition, the judgment of a misleading claim may be abandoned if an input of genetic modifications by means of "botanical impurities", e.g. by soybeans, is a realistic scenario and avoidance strategies, whose success can be analytically proven, are carried out.

*Is the "ohne-Gentechnik" ("without genetic engineering") label permissible for **products processed from non-GMO-relevant raw materials** (e.g. milled products, apple juice, beer) with respect to implicit advertisement?*

A "ohne-Gentechnik" ("without genetic engineering") label for these products might be justifiable if there is a risk of using or introducing genetically modified materials in the individual case. If the food trader submits evidence of specific additional effort, e.g. to avoid potential GM introductions, including botanical impurities or manufacturing without enzymes produced with the aid of genetically modified organisms, an assessment of an misleading claim in the sense of Article 7 (1) c of Regulation (EU) No. 1169/2011 can be refrained from.

For example, a special risk might exist when pectin-degrading enzymes produced with the aid of GM microorganisms are applied to apple and fruit juices.

Is the label "ohne-Gentechnik" ("without genetic engineering") *applicable to* ***honey and other bee products*** *(pollen, royal jelly)?*

Yes, the "ohne-Gentechnik" ("without genetic engineering") label is applicable to honey and bee products (pollen, royal jelly) because of the detectability of GM DNA in honey, provided that the requirements of the EC Genetic Engineering Implementation Act are fulfilled.

9.4 "Ohne-Gentechnik" ("Without genetic engineering"), other questions

When is a "ohne-Gentechnik" ("without genetic engineering") *label applicable to* ***starter cultures from dairy raw products****?*

If the starter cultures do not consist of genetically modified organisms, there will be no reason speaking against using milk from GM feeding in the manufacture of starter cultures labeled "ohne-Gentechnik" ("without genetic engineering"). This also applies if, for technical reasons, the starter culture preparations contain residues of milk from GM feeding. If the dairy products themselves are used as starter cultures and the milk is still contained in the finished food as an ingredient of a starter culture, then they must comply with the requirements of Section 3a (4) of the EC Genetic Engineering Implementation Act.

Does the usage of skimmed milk powder which is used for the production of starting culture preparations (e.g. for the production of milk or meat products) oppose a "ohne-Gentechnik" ("without genetic engineering") labeling if the skimmed milk powder does not fulfil the requirements of Section 3a of the EC Genetic Engineering Implementation Act?

Skimmed milk powder, which is used as freeze protection for the production of starting culture preparations, is an ingredient of the starting culture. If the starting culture is used with its ingredients (= composite ingredient) for the production of food, these ingredients become ingredients of the final product if they are present in the final product. Therefore, in case of skimmed milk powder used as freeze protection in starting culture preparations, for example, the requirements of the EC Genetic Engineering Implementation Act for food and food ingredients of animal origin need to be considered (feed).

The usage of ingredients of a starting culture preparation opposes a "ohne-Gentechnik" ("without genetic engineering") labeling, if they don’t meet the requirements of Section 3a of the EC Genetic Engineering Implementation Act.

Is the claim "ohne-Gentechnik" ("without genetic engineering") *permissible if food processing machines running with* ***technical lubricants*** *derived from genetically modified organisms have been used?*

Yes, the claim "ohne-Gentechnik" ("without genetic engineering") is permissible.

*Is the use of **glucose syrup for fruit preparations for "Ohne-Gentechnik" ("Without genetic engineering") products** (e.g. fruit yogurts) permissible if the glucose syrup has been manufactured by saccharification with **amylases derived from GM microorganisms amylases**?*

Amylases which have been produced by GM microorganisms are to be considered as processing aids produced "by using GMOs" in the sense of Section 3a (5) of the EC Genetic Engineering Implementation Act. The requirement the latter mentions is not limited to food (fruit yogurt) placed on the market with the claim "ohne-Gentechnik" ("without genetic engineering"), instead, it applies to all ingredients (glucose syrup) including enzymes which are used as a processing aid to manufacture the food ingredient.

Using glucose syrup for fruit preparations for "ohne-Gentechnik" ("without genetic engineering") products (e.g. fruit yogurts) is therefore not permissible if the glucose syrup has been manufactured by saccharification with amylases derived from genetically modified microorganisms.

Does the feeding period pursuant of the Annex of the EC Genetic Engineering Implementation Act start anew if it is subsequently revealed that the feed given to animals for the production of "ohne-Gentechnik" ("without genetic engineering") *food has not been labeled as genetically modified, although it should have been?*

In the event that during the production of food of animal origin supposed to be placed on the market with the claim "ohne-Gentechnik" ("without genetic engineering"), feeds not labeled pursuant to Article 24 or 25 of Regulation (EC) No. 1829/2003 or Article 4 or 5 of Regulation (EC) No. 1830/2003 have been used, but would have been subject to labelling, the feeding period generally starts anew pursuant to the Annex of the EC Genetic Engineering Implementation Act.

As a result of the ECJ ruling of 25 July 2018 (case C-528/16) regarding the procedures/methods of mutagenesis, must the statement "without genetic engineering" for food be classified as a misleading statement within the meaning of Regulation (EU) No. 1169/2011 if techniques of classical mutagenesis were applied?

The statement "without genetic engineering" in the sense of § 3a EGGenTDurchfG is not to be classified as a misleading statement within the meaning of Regulation (EU) No. 1169/2011 in case of foods using classical mutagenesis techniques.
The above mentioned ECJ judgment only refers to the GMO definition of Directive 2001/18 /EC. Even after the above mentioned ECJ judgment, organisms obtained by classical mutagenesis are not GMOs according to the foodstuff regulations on genetic engineering (VO (EG) No. 1829/2003 or VO (EG) No. 1830/2003). As a result, the use of such organisms in food "without genetic engineering" is still permitted.

10. Monitoring

10.1 Analytical monitoring

The analysis for genetic modifications usually proceeds by applying the molecular biological method of the so-called polymerase chain reaction (PCR). It allows for the identification of heterogenic genetically modified hereditary material in a sample and the amount of DNA of the respective GM plant line (event), relative to the total DNA of a species (e.g. DNA from Roundup Ready soy event 40-3-2, relative to the DNA of the species soy).

Table 4 shows products which are suited for sampling and an analysis of modifications induced by genetic engineering procedures. In the third column products are listed which fall within the scope of Regulations (EC) No. 1829/2003 and (EC) No. 1830/2003, but are not suited for an analysis because the respective plant species lack a sufficient amount of hereditary material. Also for products from GMOs that have been produced using so-called new breeding techniques, according to the current state of knowledge analytical detection is only possible in exceptional cases.

In these cases monitoring will only be possible by retracing the raw materials and reviewing the documents.

10.2 Sampling

A representative sampling procedure is particularly important in case of "near-harvest" raw materials (seeds, grains). The recommended sampling scheme is available on the websites of the BVL (ALS 2019/06). It is based on the available guidelines and standards. The facilitated procedure mentioned therein (single sample of approx. 500 g = laboratory sample) is applicable to all fine-powdery products of homogenous appearance such as flours or starches.

A sampling scheme for the analysis of non-authorized GMOs in foods is also referred to. It is also generally accessible (ALS 2019/07). It is supposed to be used in cases of suspected contaminations with traces of non-authorized GMOs.

10.3 Recommendations for GMO food

General recommendations for laboratories analyzing food for genetic modifications are also published on the websites of the BVL (ALS 2019/08).

In addition, special guidelines for analytics, for example, in cases of actual cases of contamination (linseed, honey, rice, wheat) are available on the web pages of the BVL (http://www.bvl.bund.de) and/ or the European reference laboratory for GM Food and Feed (http://gmo-crl.jrc.ec.europa.eu/).

Table 4 Food and food ingredients for analysis of GM components (examples)

Potential GM species	Products which can be tested	Products which cannot be tested
Soy	Soybeans, soybean flour, soy grist, soy protein, tofu as well as food manufactured therefrom (if possible, proportion > 5 %), soy lecithin	Refined soybean oil, soy sauce
Maize	Maize kernels (popcorn maize, sweet corn); cornmeal, polenta, corn chips, native and perhaps also modified corn starch	Glucose syrup made from maize, corn oil
Rapeseed	Rapeseed and blossom honey, mustard (botanical impurities)	Refined rapeseed oil, margarine / vegetable fat based on rapeseed
Rice	Rice noodles, long-grain rice incl. Basmati, rice meal	
Papaya	Papaya fruits, dried and deep-frozen papayas	Alcoholic extracts from papaya (occasionally in dietary supplements), papaya juice
Linseed	Whole linseeds; where applicable, bread with linseeds	Refined linseed oil
Potatoes	Potato flour, starch, deep-frozen products, etc.	Spirit from potatoes
Tomatoes	Tomato purée, tomato ketchup	
Sugar beet	Intermediate products of sugar refining	Sugar raffinates
Salmon	Salmon and products made therefrom (e.g. instant meals)	Salmon oil products (dietary supplements)
Cotton	Cotton seeds and grist	Refined cottonseed oil

10.4 Assessment and procedures in case of positive results

With regard to the authorization and labelling requirements for GM food (cf. Chapter 4 and 5 of this guideline), four cases can be distinguished:

1) Detection of components of non-authorized GMOs:

Here the zero tolerance rule applies. The product cannot be placed on the market.

The risk assessment of non-authorized GMO generally draws upon the following internet addresses:

- EFSA (http://www.efsa.europa.eu/en/panels/gmo),
- EUginius (http://www.euginius.eu/euginius/pages/home.jsf),
- Biosafety Clearing-House (http://biosicherheit-bch.de/BCH/EN/Home/home_node.html).

Additional information can be found on the homepage of the BVL. In addition, in cases of uncertainties the members of the working group can contact gentechnik@bvl.bund.de.

2) Detection of components of authorized GMOs: amount relative to the respective ingredient > 0.9%:

a. The product is correctly labeled (indication of the use of genetically modified organisms): no deviation from the norm.

b. The product is not labeled. The specific labelling requirements were not complied with, the product must not be placed on the market.

3) Detection of components of authorized GMOs: amount relative to the respective ingredient does not exceed 0.1%:

The proportion is regarded as adventitious and technically unavoidable.

4) Detection of components of authorized GMOs: amount relative to the respective ingredient ranges between 0.1% and 0.9%:

It has to be reviewed in the scope of an individual case decision whether the contamination is adventitious or technical unavoidable (cf. Chapter 5 of this guideline). If no evidence can be established the product shall be labeled in agreement with the applicable legal provisions.

10.5 Company audits and reviews of documents

Appendix 1 contains an exemplary **Check List for Company Audits** with a focus on "Genetic Modifications in Food" (Goerlich et al. 2011).

Appendix 2 contains an exemplary template of an **Analytical Report**. It describes the parameters which should be documented in a food analysis, which should be inspected particularly in the scope of urgency measures concerning **non-authorized genetically modified organisms** (especially upon first placing on the market at border control offices).

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Annex 1

Checklist - Genetic Engineering **Audit of business operation - genetically modified foods**	
Date of audit / time:	
Auditing authority (seal)	Audited business operation (seal)
Participants:	
I. General Part:	
Information pertaining to the business operation:	
Type of business operation:	
Size of the business operation:	
Number of employees:	
Information pertaining to manufacturing:	
Which **raw materials** relevant to genetic engineering are processed?	
soybeans □ maize kernels/cobs □ rapeseeds □	
other (e.g. rice grains, linseeds, papaya):	
Which **products processed** from the abovementioned raw materials are used for manufacturing or processing?	
Soybeans: flour □ grit □ grist □ flakes □ oil □ protein (egg white, protein isolate) □ other:	
Maize: flour □ polenta □ grist □ flakes □ cornstarch □ oil □	

other:

Rapeseed:

oil □ honey □ other:

Other products processed from raw materials except soy, maize and rapeseed:

Which **additives** of the above-mentioned raw materials are used in manufacturing or processing?

soy lecithin □ vitamin E □ dextrins □ dextrose □ glucose syrup □

citric acid □ vitamin B_2 □ other:

Processed amounts (inclusive of ingredients from relevant plant species, e.g. soy lecithin):

Soybean:	t / year:	Maize:	t / year:	Rapeseed:	t / year:
Rice:	t / year:	Other:	t / year		

Supplier of raw material from the **EU**:

(Raw Material/Company/Address)

Raw material suppliers from **third countries**:

(Raw material/company/address)

Prepackaged distribution?	yes □ no □
Distributed as bulk merchandise to further processors?	yes □ no □
Does the business operation produce as a subcontractor for other manufacturers?	yes □ no □

If yes, which products are produced for which manufacturer?

Are semi-finished products purchased as well?	yes □ no □
Which semi-finished products are purchased and from where?	

II. Traceability of GM raw materials and processed products (Regulation (EC) No. 1830/2003) (only to be completed if genetically modified raw materials and processed products are used)	
Do systems and standardized procedures exist in order to store the stated information on GMOs for a period of five years?	yes □ no □
Are the data stated in the following and referring to suppliers and purchasers immediately and completely available?	
Goods receiving department:	
Name and address of the supplier/s	yes □ no □
Type of the products delivered (unambiguous designation)	yes □ no □
Unambiguous codification of the product (identification)	yes □ no □
Date of delivery (receiving goods department)	yes □ no □
Dimension or amount	yes □ no □
Declaration that the raw material consists of or contains GMOs (Article 4)	yes □ no □
Declaration of the unique identifier (e.g. MON-Ø4Ø32-6), provided that is a reproducible GMO (Article 4)	yes □ no □
Declaration of each food ingredient produced from GMOs (Article 5)	yes □ no □
What is the wording of the labelling designation of raw materials, intermediate and final products? (please enclose copies!)	
Are the containers holding the genetically modified raw materials labeled with regard to genetic engineering?	yes □ no □
Shipping department:	
Name and address of the supplier/s	yes □ no □

Type of the products delivered (unambiguous designation)	yes □ no □
Unambiguous codification of the product (identification)	yes □ no □
Date of delivery (shipping department)	yes □ no □
Dimension or amount	yes □ no □
Declaration that the raw material consists of or contains GMOs (Article 4)	yes □ no □
Declaration of the unique identifier (e.g. MON-Ø4Ø32-6), provided that is a reproducible GMO (Article 4)	yes □ no □
Declaration of each food ingredient produced from GMOs (Article 5)	yes □ no □
III. Self-monitoring systems	
Raw materials/ products	
Are there specifications applicable to the supplier/s referring to requirements of relevance to genetic engineering (for example that the supplier is not permitted to deliver raw materials subject to GMO labelling)?	
Soy and processed products*	yes □ no □
Maize and processed products*	yes □ no □
Rapeseed and processed products*	yes □ no □
Other:	yes □ no □
Are current, meaningful certificates/ statements/ testimonials applying to the suppliers?	yes □ no □
Are **self-inspections/audits** carried out?	yes □ no □
Are analyses commissioned to external laboratories?	yes □ no □
Are analysis reports available?	yes □ no □
Are the analysis reports sufficient and plausible? (Accreditation for GMO analytics acc. to ISO 17025; declaration of methods, parameters, detection limits)	yes □ no □
Have retention samples been taken?	yes □ no □
Is there a special sampling scheme?	yes □ no □
Are the supplies subject to regular auditing procedures?	yes □ no □
Have GMO contaminations already become known?	yes □ no □

Are products labeled as genetically modified "… genetically modified …“)?	yes □ no □
In the event that both genetically modified and conventional raw materials have been processed:	
Is the blending of genetically modified products and conventional products prevented/minimized during production?	yes □ no □
Does processing proceed in separate rooms/spaces?	yes □ no □
Does processing proceed in separate machinery?	yes □ no □
Does processing proceed in the same machinery but at different times?	yes □ no □
Are there standard operating procedures dealing with this subject?	yes □ no □
Is there a separate production protocol for processing genetically modified raw materials?	yes □ no □
Is the labelling of genetically modified products and conventional products sufficient?	yes □ no □
Is confusion prevented during storage?	yes □ no □
Is the amount of GMO-labeled raw material in a plausible relation to the amount of GMO-labeled intermediate or final products?	yes □ no □
Determined deficiencies:	
Other remarks:	

Are products claimed to be "ohne Gentechnik” (“without genetic engineering")?	yes □ no □ If yes, use separate checklist

Annex 2

Information leaflet for the review of analysis reports of the analysis of food for non-authorized genetically modified organisms

The template of an analytic report shown below describes parameters which should be documented in the scope of an analysis of food and which are to be inspected in the scope of urgency measures concerning **non-authorized** genetically modified organisms (especially on first placing on the market at border control offices). The template is to serve these offices as a guideline and enable them as much as possible to evaluate the validity of a submitted analytical report. The foundation of these requirements are international norms such as ISO 24276:2013-10. Firstly, the origin and identity of the analyzed sample should be made unequivocally clear on account of the data the analytical report contains. Secondly, the validity of the analytical results should be verifiable, especially based on information stating the **sample size** and the **analyzed amount of DNA**, the sample-related detection limit of the analytical method by experts of the analytical facility.

Description of the parameters to be documented	**Possible parameter declarations**
Name and address of the executing laboratory :	<<name>>
Analysis report number:	<<000>>
Sponsor:	<<company/authority/office>>
Name and signature of the person responsible for the analysis:	<<name>>
Number of the sample:	<<111>>
Sample description:	e.g. rice, grains
Sampling date:	DD.MM.YYYY
Site of sample withdrawal:	<<company/street/location/ship>>
Description of the sampling procedure:	e.g. ALS sampling scheme for non-authorized GMOs, batch size over 500 t
If applicable, further declarations and sample descriptions:	e.g. Shelf life/lot number
Sample reception:	DD.MM.YYYY
Onset of analysis:	DD.MM.YYYY
End of analysis:	DD.MM.YYYY

31 Description of the parameters to be documented	**Possible parameter declarations**
Size of the laboratory sample:	e.g. 2.5 kg in case of rice
In case of partial sampling: **number and mass of the samples to be analyzed**	e.g. 4 x 240 g in case of rice
Amount of DNA analyzed: preferentially in copies of a species-specific reference gene	e.g. rice phospholipase-D, PLD; > 20,000 copies
Detection method used: further description of the DNA sequences identified	Construct-specific or event-specific, qualitative or quantitative e.g. construct-specific *P35S-bar,* qualitative
In case of **negative results** the estimated, practically achievable **detection limit relative to the respective sample** (cf. also ISO 24276:2013-10) is to be stated. Alternatively, the detection limit of the transgene-specific detection method (e.g. in copies) may be stated in conjunction with the amount of amplified reference gene used in the analysis.	e.g. LL601 rice not determinable, < 0.01% e.g. LL601 rice not determinable, < 10 LL601 copies (> 20,000 copies of rice reference gene)
Reference material, with which the estimation of detection limit proceeded.	e.g. DNA from rice meal, 0.1% LL601 (Bayer Crop Science)