



Federal Ministry
of Food, Agriculture and
Consumer Protection

Legislation on GMO in the European Union and Germany

Dr. Sabine Kruse

Federal Ministry of Food, Agriculture and Consumer Protection

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European Legislation

1. Regulation (EC) No 1829/2003 on **genetically modified food and feed**
2. Regulation (EC) No 1830/2003 concerning the **traceability and labelling** of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms traceability
3. Regulation (EC) No 1946/2003 on **cross-border movements** of genetically modified organisms
4. Recommendation 2004/787/EC on technical guidance for **sampling and detection** of genetically modified organisms
5. Regulation (EC) No 619/2011 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

Regulation (EC) No 1829/2003



- ↪ Information of the consumers by **labelling** of the products containing, consisting of or produced from GMOs
- ↪ Establishing of **threshold levels** for labelling
- ↪ Requirements on **traceability** across the feed chain
- ↪ Harmonized **authorization** system in Europe
- ↪ Consideration of **environmental impact**

Regulation (EC) No 1829/2003

Genetically modified organisms (GMOs) are organisms, such as plants and animals, whose genetic characteristics are being modified artificially*) in order to give them a new property.

Feed which contain or consist of such GMOs, or are produced from GMOs, are called **genetically modified feed**.

*) regulated in Directive 2001/18/EU

Regulation (EC) No 1829/2003

- Labelling provides **information** for consumers and allows them to make an informed choice.
- Feed must carry a **label** which refers to the presence of GMOs.
- The labelling requirements do **not apply** to feed which contains, consists of, or is produced from **GMOs in a proportion no higher than 0.9 % of the feed ingredients** considered individually and if **this presence is adventitious or technically unavoidable**.
- In order to establish that the presence of this material is adventitious or technically unavoidable, **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 such material**.

Regulation (EC) No 1829/2003

Labelling requirements for feed

In the case of pre-packaged products consisting of, or containing, GMOs, the list of ingredients must indicate

“genetically modified” [name of the organism]”

**Maize
(genetically modified)**

Regulation (EC) No 1829/2003

Labelling requirements for feed

In the case of pre-packaged products consisting of, or containing, GMOs, the list of ingredients must indicate

"produced from genetically modified [name of the organism]"

**Soya meal
(produced from genetically modified soya)**

Regulation (EC) No 1829/2003

Labelling requirements for feed

In the case a feed is different from its conventional counterpart and it is fixed in the authorization in the list of ingredients must indicate specific information

**Rice middlings
(produced from genetically modified rice
with high content beta carotene)**

Regulation (EC) No 1830/2003



- Products consisting of, or containing, GMOs and feed produced from GMOs are also subject to traceability requirements.
- **Traceability** is the ability to track GMOs and feed produced from GMOs at all stages of the supply chain.
- Traceability makes it possible to label all GM feed, to closely **monitor the potential effects** on the environment and on health and, where necessary, to **withdraw products** if an unexpected risk to human health or to the environment is detected.

Regulation (EC) No 1830/2003

- The traceability means that a **operator** who introduces a product to the supply chain or receives such a product (farmers, feed producers, etc), must be able to **identify their supplier and the companies to which the products have been supplied.**

← **one step back and one step forward** →

- **Operators must provide** the following, in writing, to whom they supply the product:
 - an indication that the product - or certain ingredients – contains, consists of, or is obtained from GMOs; and
 - information on **the unique identifier(s)*** for these GMOs.

*)Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms

Regulation (EC) No 1830/2003

- In the case of products consisting of or containing **mixtures of GMOs** to be used only as feed or for processing, this information may be replaced by a declaration of use by the operator. It has to be **accompanied by a list of the unique identifiers for all those GMOs** that have been used to constitute the mixture.
- Operators must ensure that **the information** is passed on in writing to those who are **next in the supply chain**.
- For a period of **five years** after every transaction within the supply chain, every **operator must keep this information** and be able to identify the operator from whom he or she obtained the products and the one to whom he or she supplied them.

Regulation (EC) No 1946/2003



- Implementaion of the **Cartagena Protocol** on Biosafety to the Convention on Biological Diversity
- Control of **transboundary movement** of GMOs
- Legal framework for **export** of GMOs from EU to third countries
- **Notification** of export for deliberate release into the environment
- Transport, handling and packaging of GMO must be safe
- Guarantee of **traceability**
- Comprehensive **information** in case of suspicion
- Consideration of the **precautionary principle**

Recommendation 2004/787/EC



- The Commission recommended **technical guidance for sampling and detection** of genetically modified organisms and material produced from genetically modified organisms.
 - This guidance cover **products** (e.g. seeds, food, feed) **that have received authorizations** for their placing on the market.
 - The sampling and detection should be carried out using sound scientific and statistical protocols in this guidance.
- **For official feed control the sampling rules of Regulation (EG) No 152/2009 applies.**

Regulation (EC) No 619/2011



- Prior to this Regulation, GM food and feed legislation did not provide rules for the **control of the presence in feed** of material which contains, consists of or is produced from **GMOs undergoing EU authorisation or for GMOs with an expired authorisation**.
- Consequently, EU countries' official controls applied different approaches for these GMOs.
- The Regulation EC 619/2011 harmonizes the implementation of the **zero-tolerance policy on non-authorised genetically modified material** in feed.
- This Regulation is addressed EU business operator's legal uncertainty when marketing **feed imported from non-EU countries**.

Regulation (EC) No 619/2011

Key points

- ✓ Sets a **technical zero at a level of 0.1 %** - the lowest level of GM material considered by the EU Reference Laboratory for the validation of quantitative methods.
- ✓ Harmonizes sampling and testing controls in all EU countries.
- ✓ Limited to GM feed material under specific conditions.

Regulation (EC) No 619/2011

GM material must comply with the following criteria:

- ☒ be authorised for commercialisation in a non-EU country
- ☒ have a valid EFSA application or have an expired authorisation in the EU
- ☒ authorisation pending for more than 3 months
- ☒ have not been identified by EFSA as susceptible to have adverse effects on health or the environment when present under 0.1%;
- ☒ quantitative method of analysis published by the EU reference laboratory;
- ☒ certified reference material must be available for EU-countries and third parties.

Guideline for Official Control of GMO in Feed



For the interpretation and implementation of the legislation regarding GMO in feed guidelines has been published

Leitfaden

zur Kontrolle von
GVO in Futtermitteln

(Stand November 2011)

„Supervision of production, handling, use and placing on the market of feed related to genetically modified Organisms (GMO)”