

[Regulation 1829/2003](#) on genetically modified food and feed prohibits the placing on the EU market a GMO for food and feed use or a food / feed containing or consisting of GMO or produced from GMO unless an authorisation is granted.

[Regulation 1829/2003](#) also covers labelling provision for products falling within the scope of the legislation. In order to understand how a business should interpret this regulation it is necessary to look at the definition in Article 2 and Recital 16.

The definition of Genetically Modified food/feed is covered in **Article 2** (7) of [Regulation 1829/2003](#)

*“Genetically modified feed means feed containing, consisting of or produced from GMOs”*

The definition of produced from GMO is covered in **Article 2** (10) of [Regulation 1829/2003](#)

*“produced from GMOs’ means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs”*

**Recital 16** (pg. 4 [Regulation 1829/2003](#)) provides explanation and further clarity:

It explicitly excludes food and feed that is produced with a GMO from the scope of the regulation. **It follows therefore that Feed additives, produced with the help of genetically modified microorganisms (GMMs) do not fall under the scope of 1829/2003.**

*“This Regulation should cover food and feed produced ‘from’ a GMO but not food and feed (produced) ‘with’ a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. **Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation.** Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation”*

In the case of additives, the supplier has the obligation to inform the customer about the status of purchased products in relation to [Regulation 1829/2003](#)..

Furthermore, additives are authorised under regulation [1831/2003](#) and the feed additive authorisation legislation within the [Feed Additives Register](#) should indicate the method of production method of the additive (chemical synthesis, fermentation etc.). It is recommended that for due diligence members ask their suppliers these questions in order to perform a risk assessment

# EU GMO legislation and Additives

## Guidance Document

### Clarification

Food and feed material that are **produced with** genetically modified microorganisms (GMMs) are in general out of the scope of the regulations. **The critical determining factor is whether material derived from a GMO is present in the food or feed.** If a GMO is not present in the food and feed, then such food/ feed does not fall within the scope of the Regulation. In these cases, the GMMs is a processing aid and is removed from the final product and there is no detectable material from the substrate in the final additive. At a SCoFAH meeting in September 24<sup>th</sup> 2004 official clarification was provided as follows:

*Food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified microorganism (GMM) which is kept under contained conditions and is not present in the final product are not included in the scope of Regulation (EC) No 1829/2003. These food and feed have to be considered as having been produced **with** the GMM, rather than **from** the GMM.*

*Food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified micro-organism (GMM) which is present in the final product, totally or partially, whether alive or not, are included in the scope of Regulation (EC) No 1829/2003, in regard of both authorisation and labelling.*

### Examples:

Maize (conventional)	→	Glucose	Out of scope
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Maize Conventional	→ <b>GMM</b>	Glucose + detectable GMM	In scope
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Maize (GM)	→ <b>GMM</b>	Glucose	In scope
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### GM Substrates:

GM Substrate	→ <b>Yeast</b>	Ethanol	Out of scope
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GM Feed	→ <b>Cow</b>	Milk	Out of scope
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Can I test or detect for any GMO ?	Yes	in general in scope
Can I test or detect for any GMO ?	No	in general not in scope