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Questions and answers on the low level presence (LLP) of GMOs in feed imports

What is this new GM Regulation about?

There are currently no harmonised rules for the control of imports of **feed materials** from third countries, which may contain traces of **genetically modified organisms (GMOs) not covered by EU authorisations.** Experience has shown that in the absence of such rules, the official laboratories and the competent authorities in the Member States apply different methods of sampling for the detection of such traces and for the interpretation of the results of the analytical tests. This may lead to different conclusions as regards the compliance of a product with Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[1]. As a result of the lack of harmonised rules, operators are faced with legal and economic uncertainty and there is a risk that the functioning of the internal market will be affected due to possible random checks within the EU.

The EU **animal feed sector is highly dependent** on agricultural commodities imports. Different soybean (33 million tons in soya meal equivalents in the 2008-09 season) and maize products (four million tons imported in the 2008-09 season), coming mainly from Brazil, Argentina and the US, are an essential supplement for our livestock sector. The cultivation in third countries of GMOs for which the EU authorisation procedure is pending (so-called **asynchronous authorisations**) is associated to risks of traces or low level presence (LLP) of these GMOs in imported commodities. Exporters and importers face serious economic risks due to tha lack of harmonized rules for controls, which could also lead to shortages in feed supply.

The harmonisation of rules for the controls of non-authorised GM feed is thus addressing the current uncertainty that EU operators face when placing feed on the market.

How will this Regulation bring legal certainty for operators? Why is a level of 0.1% defined as technical zero[2]?

The adoption at EU level of robust sampling and detection methods, and the introduction of harmonised rules for the interpretation of the results of the analysis, will ensure that the **same results are obtained for the same products throughout the EU**. Therefore, not only will feed operators be in a position to ensure that their products will be subject to the same harmonised rules, but they will also be able to carry out their own controls by using the same methods that are used for the official controls.

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[1] OJ L 268, 18.10.2003, p 1.

[2] In the Regulation, the technical zero is referred to as the Minimum Requited Performanec Limit or MRPL

The key element of the Regulation is setting out a **technical zero at the level of 0.1 %.** This is the lowest level of GM material, which is considered by the EU-Reference Laboratory (EU RL) for the validation of quantitative methods. It is the lowest level where results are satisfactorily reproducible between official laboratories when appropriate sampling protocols and methods of analysis for measuring feed samples are applied. This is why it is referred to as the **"Minimum Required Performance Limit" (MRPL)** in the Regulation.

In order to ensure robust results, Member States will have to declare a product as non-compliant when, taking into account the margin for error in the results (uncertainty), the level of 0.1% is exceeded. This being said, Member States will have also to record findings that are bellow 0.1% and inform the Commission and other Member States **on a yearly basis**, if such findings are sporadic, or immediately if they are recurrent within a three-month period.

What are the GMOs that are covered by this Regulation?

The first category of the GM material that is covered by the Regulation is **GM feed material authorised in a third country and for which an authorisation procedure has been pending in the EU for more than three months**. This GM Feed material will only be covered when the validation of a quantitative method of detection for this particular GMO by the EU Reference Laboratory is completed. Providing a method of detection is a requirement for all GMO applications under EU legislation. Certified reference material also has to be available.

A second category of products is **GM feed material that was authorised in the EU but for which the authorisation has not be renewed** due to the phasing out of cultivation of these GMOs for which however the safety assessment is still valid. At present, this is the case for two GM maize (Bt176 and GA21xMON810) and three oilseed rape products (Ms1xRf1, Ms1xRf2 and Topas 19/2). In the same way, a third category is covering the GM feed material currently authorised and the authorisation of which will not be renewed due to their phasing out.

The Commission will publish the list of GM material fulfilling the conditions of the Regulation on its website.

Is this Regulation in accordance with the zero tolerance policy on GMOs?

Yes. Not only does the Regulation not deviate from the zero tolerance policy but **it renders this notion even clearer by means of defining the technical zero in realistic and operational terms**. The level of 0.1% is the lowest level which the EU RL has set for the validation of event specific methods under the authorisation process, and for the time being these are the only validated methods available for official control. The uncertainty of analytical results below this figure is currently unknown.

Is this approach also used for other products?

Yes. For the official control of the absence of residues from some non-authorised veterinary medicines, Minimum Required Performance Limits (MRPL) have been established.

For the control of the pesticide/product combinations for which no specific MRL has been established in EU legislation, a strict default value taking into account the routine methods of analysis available has been established.

In both cases, the MRPL and the default value have been established with the intention to harmonise the analytical performance of methods for substances for which no permitted limit has been established.

What was the procedure followed for the adoption of this Regulation?

At the meeting of the Standing Committee on the Food Chain and Animal Health (SCoFCAH) of 22 February 2011, the Member States voted in favour of the Commission Regulation. It has been subject to the scrutiny of the European Parliament and of the Council for three months. Since neither the Parliament nor the Council objected to the Regulation during this period of time, the **Commission adopted the Regulation on 24 June 2011**.