



### Fact Sheet: Questions and Answers on EU's policies on GMOs

Brussels, 22 April 2015

#### What are GMOs?

Food and feed generally originate from plants and animals grown and bred by humans for several thousands of years. Over time, those plants and animals with the most desirable traits were chosen for breeding the next generations of food and feed. This was, for example, the case for plants with an increased resistance to environmental pressures such as diseases, or with an increased yield.

These desirable traits appeared through naturally occurring variations in the genetic make-up of those plants and animals. In recent times, it has become possible to modify the genetic make-up of living cells and organisms using techniques of modern biotechnology called gene technology. The genetic material is modified artificially to give it a new property (e.g. a plant's resistance to a disease, insect or drought, a plant's tolerance to an herbicide, improving a food's quality or nutritional value, increased crop productivity).

Such organisms are called "genetically modified organisms" (GMOs). Food and feed which contain or consist of such GMOs, or are produced from GMOs, are called "genetically modified (GM) food or feed".

#### What is the EU approach on GMOs?

The approach chosen in the EU as regards GMOs is a **precautionary approach imposing a pre-market authorisation for any GMO to be placed on the market and a post-market environmental monitoring for any authorised GMO**. This approach ensures a high level of protection of human and animal health and the environment.

The GMO legislation lays down specific procedures for assessing and authorising GMOs that are time-limited and transparent. The risk assessment is performed on the basis of harmonised criteria which are recognised as being amongst the most stringent in the world.

The European Food Safety Authority (EFSA), in collaboration with Member States' scientific bodies, is responsible for the risk assessment which needs to demonstrate that, under its intended conditions of use, the product is safe for human and animal health and the environment.

Once finalised, the risk assessment is the basis upon which the Commission proposes a decision to Member States accepting or rejecting the authorisation for the placing on the market of a GMO. Both the Commission and Member States are therefore involved in the authorisation of these GMOs.

The legislation also imposes a post-market monitoring of the environment for each authorised GMO allowing the Commission and Member States to take appropriate measures in case a non-anticipated adverse effect is identified.

Finally, in order to provide consumers with information and freedom of choice, traceability and labelling obligations are imposed for any authorised GMO.

#### What is the procedure for authorising the placing on the market of GMOs?

Regulation (EC) No 1829/2003 on genetically modified food and feed lays down a procedure for issuing decisions granting or rejecting authorisations for the placing on the market of genetically modified food and feed as well as for cultivation for the production of food and feed.

Applications are submitted first to the competent authority of a Member State. The application must clearly define the scope of the application, contain studies and data demonstrating the safety of the product, indicate which parts are confidential and must include a monitoring plan, a labelling proposal and a detection method.

The application and any supplementary information supplied by the applicant must be made available to EFSA, which is responsible for the scientific risk assessment covering risk to both the environment and human and animal health. The risk assessment is performed in close collaboration with Member States' scientific bodies. The opinion is made available to the public and a public consultation is open for a period of one month.

Within three months of receiving the opinion of EFSA, the Commission prepares a draft implementing decision granting or refusing authorisation. The Commission may diverge from EFSA's opinion, but it must then justify its position.

The Commission's draft decision submitted to Member States is voted on under qualified majority rules. In case the Standing Committee and the Appeal Committee do not manage to adopt the decision by qualified majority within a given time frame, it is up to the Commission to adopt the final decision.

### **How is GM food and feed risk assessed?**

A company interested in placing a new GM food and feed on the EU market has to submit a file demonstrating the safety for human and animal health and the environment of the product in question.

Studies to be performed in order to demonstrate the safety of the GM food and feed to be placed on the market have to comply with Regulation (EC) 503/2013 on applications for authorisation of GM food and feed. This Regulation provides the requirements to be fulfilled when submitting a GM food and feed application including the studies to be performed and the protocol to be followed in conducting these studies.

Once received, the file is assessed by the European Food Safety authority (EFSA) in collaboration with Member States' scientific bodies. EFSA has the possibility to request additional studies/data from the company if it is not satisfied with the submitted ones. The risk assessment is finalised by the publication by EFSA of an opinion concluding on the safety of the GM food and feed. A one month public consultation is then launched in order to give the public the opportunity to comment on the EFSA opinion before any risk management decision is taken.

### **Are all EU-authorized GMOs safe for health and the environment?**

All EU-authorized GMOs have been proved to be safe before their placing on the EU market. This has been concluded by the European Food Safety authority (EFSA) in collaboration with Member States for each individual GMO present on the market.

Annual reports of the environmental monitoring conducted for all authorized GMOs have not identified any adverse effects to the environment.

Finally, EFSA is monitoring all new scientific publications which could have an impact on the safety of the authorised GMOs and until now, none of them have changed the conclusions of the adopted EFSA opinions.

### **What are the changes that came into force recently on authorising the cultivation of GMOs?**

The newly adopted Directive (EU) 2015/412 gives Member States more flexibility to decide on the cultivation of genetically modified crops, under certain conditions, at two distinct points in time:

- during the authorization procedure: a Member State can ask to **amend the geographical scope of the application** to ensure that its territory will not be covered by the EU authorisation;
- after a GMO has been authorized: a Member State may **prohibit or restrict the cultivation of the crop based on grounds** related amongst others to environmental or agricultural policy objectives, or other compelling grounds such as town and country-planning, land use, socio-economic impacts, co-existence and public policy.

Before the adoption of this Directive, Member States could provisionally prohibit or restrict the use of a GMO on their territory only if they had new evidence that the organism concerned constitutes a risk to human health or the environment or in the case of an emergency. No Member State which had adopted a so-called "safeguard clause" had ever been in a position to put forward new evidence.

## Are any GMOs already cultivated in the EU?

Yes. **One GM maize –MON 810– is commercially cultivated in the EU.** This product's genetic modification aims to protect the crop against a harmful pest – the European corn borer. It was authorised in 1998.

MON 810 is cultivated in 5 Member States with a total coverage (in 2013) of almost 150,000 hectares (including 137,000 hectares in Spain). That's less than 1.5% of the total EU maize surface. GMOs were cultivated on 175 million hectares worldwide in 2013 (mostly soya, maize, oilseed rape and cotton). For the record: in 2010, a **GM starch potato**, known as "Amflora" potato, was authorised for cultivation and industrial processing in the EU. It is no longer authorised in the EU.

There are 8 pending applications for GMO cultivation in the EU, including renewal of MON810 authorisation. 4 have had a positive EFSA opinion; 4 are awaiting an EFSA opinion.

## What are the GMOs that are authorised in the EU for feed and food uses?

Besides cultivation, the placing on the EU market of GMOs and the use of their derived products in the food and feed chain is subject to an EU authorisation, conditional upon the demonstration of an absence of risk for human and animal health and for the environment, following a thorough assessment by the European Food Safety Authority in collaboration with Member States' scientific bodies.

As of today, **58 GMOs are authorised in the EU for food and feed uses (covering maize, cotton, soybean, oilseed rape, sugar beet).** 58 application files are pending, out of which 17 have a positive EFSA opinion and 1 has an inconclusive opinion. The list of authorised GM plants and the precise scope of their authorisation is available in the EU register of GM food and feed, which can be found here: [http://ec.europa.eu/food/dyna/gm\\_register/index\\_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)

## Is there much GM food and feed on the EU market?

The EU imports substantial quantities of GM feed, but very little GM food.

Data shows that the Union needs more than 36 million tonnes of equivalent soybean per year to feed its livestock. However, the Union produces only 1.4 million tonnes of soybean annually (which is *de facto* non-GM as no GM soya is authorised for cultivation in the EU).

The Union livestock sector is therefore highly dependent on third countries' production for its vegetable proteins. **In 2013, the Union imported 18.5 million tonnes of soymeal and 13.5 million tonnes of soybean, representing more than 60% of the Union plant protein needs.**

These imports mainly originate from third countries where the cultivation of GMOs is widespread - 90% originate from 4 third countries where the percentage of the soybean-cultivated area planted with GM soybean is around 90%. In 2013, 43.8% originated from Brazil, where 89% of soybean cultivation was GM – 22.4% originated from Argentina, where 100% of soybean cultivation was GM – 15.9% originated from the US, where 93% of soybean cultivation was GM – 7.3% originated from Paraguay, where 95% of soybean cultivation was GM.

**As regards food, the number of GM products available for purchase on the Union market is small.** Many food business operators have made the choice of not placing GM food on the shelves. This may be linked to the labelling obligations of the GMO legal framework, as well as the availability of non-GM alternatives.

## Is GM food and feed labelled?

The EU legislation imposes GM labelling on any GM food and feed containing, consisting of, or produced from a GMO, except if the presence is below 0.9% of the food/feed, or the ingredient is adventitious or technically unavoidable.

The EU legislation does not forbid the use of "GM-free" labels signalling that foodstuffs do not contain GM crops, or were not produced using GMOs, provided that they respect the general rules on food labelling, in particular that the information provided to consumers is not misleading. Some Member States have adopted GM-free labelling schemes for their food and feed products.

## What changes is the Commission proposing on GM food/feed?

See [press release](#) and [fact sheet](#).

**For more information please see:**

[http://ec.europa.eu/food/plant/gmo/new/index\\_en.htm](http://ec.europa.eu/food/plant/gmo/new/index_en.htm)

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