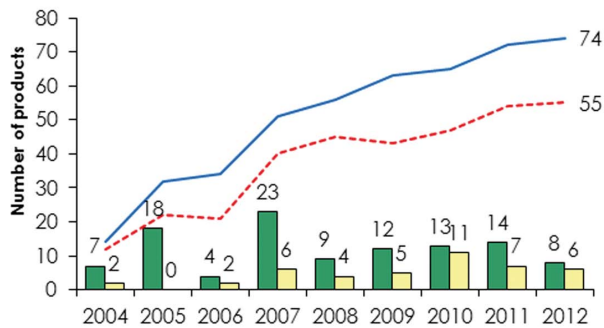


How many products are safe by EU standards?

By December 2012, 66 GM products were declared safe by EFSA. 48 of these were authorised in the EU, and another 19 were waiting for a political decision to be approved. The graph below shows the evolution of the EU authorisation system in recent years: 74 products are currently waiting for approval in total (blue line), amongst which 55 are being examined by EFSA (red line). Every year, more product applications for authorisation are being submitted (green bars) than authorisations are received (yellow bars).

GM Product submissions and authorisations



Source: EuropaBio. For explanation, see paragraph above.

Fast Facts

		Trend
Approved GM products worldwide ^v	319	▲
Number of individual GM approvals issued by various governments ^{iv}	2,497	▲
Share of GM crops in total global crops	10%	▲
Number of confirmed health problems linked to GMOs	0	—

What others say:

“(…) the political leadership in Europe has failed to emphasize the consistent scientific advice, which is that GM food and feed are as safe as conventional varieties.”^v

David Byrne, former EU Commissioner

“(…) there is no substantiated case of any adverse impact on human health, animal health or environmental health.”^{vi}

Anne Glover, Chief Scientific Adviser, European Commission

“Our Academy concluded that recently established methods of preparing transgenic organisms follow natural laws of biological evolution and bear no risks anchored in the methodology of genetic engineering.”

Pontifical Academy of Sciences of the Vatican

Want to know more?

- www.gmo-safety.eu (sponsored by the German government)
- http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu_funded_gmo_research.pdf – A decade of EU-funded GMO research (2001-2010)
- <http://ec.europa.eu/research/quality-of-life/gmo> – EC-Sponsored research on safety the genetically modified organisms (1985-2000)
- EFSA on GMOs with video: www.efsa.europa.eu/en/topics/topic/gmo.htm
- Cartoon on how the EU authorisation process works from GMO compass (website was set up with financial support from the EU): www.gmo-compass.org/flash/popup.php?lang=eng

- i Swiss programme website www.nfp59.ch/e_index.cfm
- ii www.nfp59.ch/e_index.cfm
- iii COGEM (Dutch government advisory committee on GMOs) 2009: “Should EU legislation be updated?”
- iv AISAAA Brief 44-2012: Global Status of Commercialized Biotech/ GM Crops: 2012: www.isaaa.org/resources/publications/briefs/44/executivesummary/default.asp
- v Quoted in Journal Feedstuffs 03/2009
- vi Quoted in Euractiv, 24/07/2012

GREENBIOTECHNOLOGY FACTSHEET

PRODUCT SAFETY

Are GMOs safe
to grow and eat?



All biotech crops on the market are **guaranteed by public authorities to be at least as safe as conventional crops, both for human and animal consumption, and also for the environment.**

To ensure this, stringent safety checks are required for every new GM crop product before it is allowed to be grown and sold. **The EU's safety assessment requirements are among the world's strictest.**

In practically all cases, products approved to enter the EU market have also been approved by several third countries.

After 16 years of commercial cultivation and consumption and trillions of GM meals eaten, not a single substantiated safety concern has been reported. **Scare stories have regularly turned out to be wrong and based on flawed studies, when checked by independent scientists and competent public authorities.**

Facts not fiction

It is difficult for citizens to distinguish between true and false information on GMOs. Scare stories on GMOs have regularly been in contradiction with science that is validated by public authorities, Governments around the world supervise comprehensive safety requirements before any GM product is placed on the market. GMOs have been studied more intensively for their safety than any other crops and foods.

Safety record in practice

More than 2 trillion meals containing GM ingredients have been eaten over the last 15 years by hundreds of millions of people without one health incident having been identified. Occasional scare stories seem to suggest otherwise. But these tend to focus on issues that are not specific to GM at all, for example by provoking undesirable laboratory effects with unrealistically high doses of plant protection products, which may equally be applied on conventional (non GM) crops.

What do our public authorities say?

59 countries around the world have issued a total of 2497 individual approvals for GM products, based on internationally agreed criteria for safety assessment. Two European Commission reports published in 2001 and 2011 covering 25 years' worth of research on the effects of GM crops on health and the environment have confirmed GMOs are at least as safe as conventional crops. In 2012, the Swiss national research programme concluded that there is "no evidence for health or environmental harms posed by green gene technology". Similar results have been found by the German Federal Ministry of Research in a 300 projects programme which was conducted by 60 universities and cost 100 million €".



How does the EU ensure safety?

In the EU, the official safety check (risk assessment) is carried out by the European Food Safety Authority (EFSA), which operates according to a legal framework that was approved by the Member States and the European Parliament. EFSA has a panel of independent scientific experts that ensures that the highest standards of safety are applied. It co-operates closely with national authorities of all Member States. Every individual product is screened both for its specific new characteristics and for any differences in nutritional characteristics between the biotech crop and its non-biotech counterpart. The applicant submits a dossier with all the required studies on the product in question to EFSA – usually 4,000 to 5,000 pages.

Public sector GMO Research in Europe

"EU Commission-sponsored Research on Safety of Genetically Modified Organisms" (1985-2000)

"The use of more precise technology and the greater regulatory scrutiny probably makes GMOs even safer than conventional plants and foods."

"A decade of EU-funded GMO research" (2001-2010)

- 50 EU projects
- More than **400 independent research groups**
- European research grants of some **EUR 300 million**

Biotechnology, and in particular GMOs, are not per se more risky than conventional plant breeding technologies

At least as safe as conventional crops

Safety is assessed on a case-by-case basis because GM plants are not all the same, and the objective is to assess if the product in question is as safe as its conventional counterpart. For example, biotech insect-resistant maize plants produce a protein that controls the "corn borer" pest, a moth whose larvae bore into the stems and maize cobs of the plants, causing severe damage and yield losses. In this case, the EFSA scientists look at the safety of the proteins produced by the insect-resistant maize to stop the corn borer. They also analyse whether there are other differences between biotech insect-resistant maize and its conventional (non-biotech) maize counterpart. GM crops are also assessed for their impact on

the environment, which ensures that it does not cause any harm to non-target organisms and the surrounding environment.

Health benefits for consumers

Some GM crops are actually safer than their conventional counterparts. According to the Swiss national research programme NFP 59 published in August 2012, "the use of Bt maize can have positive health effects. It can lead to less contamination of food and feedstuffs by neuro toxic or cancerogenous mycotoxins". Other products that fall into this category are GM crops for healthier oils, and "golden rice", which is close to commercial approval in the Philippines and was developed to prevent diseases such as blindness, caused by lack of vitamin A.

Science and politics

Once the environmental, human and animal health safety assessments are done and the product in question has been assessed as safe, EFSA publishes this assessment in the form of a scientific opinion. This opinion has to be taken into account by decision makers. In the EU, unlike many third countries, a GM product that is deemed safe is not automatically allowed to enter the EU market. Instead, there is a political decision taken by Member States representatives. A number of Member States consistently vote against the approval of new products, despite the official scientific evidence of their safety.

Regulatory timeline and cost

On average, it takes 45 months for an individual GM product from submission of the dossier to reception of a product authorisation. EFSA's scientific process takes 29 months, and it takes another 16 months from the publication of EFSA's scientific opinion to the actual authorisation. The cost of a GM product authorisation in the EU has been estimated by an advisory body to the Dutch government to be around € 7-10 millionⁱⁱⁱ. This represents a total regulatory cost borne by industry of € 336 to € 480 million for 48 EU-approved products, and it does not include on-going costs for the 74 products which are currently in the authorisation procedure. Cost is not as much an issue as the lack of certainty on whether a political decision will be taken or not, in light of scientific evidence.