THE GM IMPORT AUTHORISATION PROCESS IN THE EU: GUIDELINES... AND REALITIES

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Genetically modified (GM) food and feed products can only be authorised in the EU if they have undergone a rigorous risk assessment by the European Food Safety Authority (EFSA), which evaluates their impact on human and animal health, and environmental safety.

A positive scientific opinion from EFSA is the basis upon which the EU's risk managers decide on the authorisation of GM products for the internal market. Despite having well-defined procedures in legislation, the GM authorisation process in the EU remains lengthy and unpredictable because the legal timelines are rarely met.

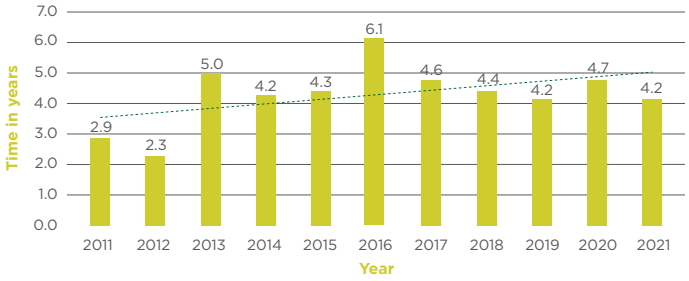
How long does the GM authorisation process take in the EU?[1,2]

Risk Assessment

Most delays in the GM product authorisation process in the EU occur during the phase known as risk assessment. During this period, EFSA evaluates the impact of the GM product on human and animal health, and on environmental safety.

For new products, the legal timeline to conduct the risk assessment is six months. But the reality is different: it takes EFSA on average more than four years to conduct a risk assessment. This is despite continuous advancement of scientific understanding and nearly 30 years of data generated to support the safety of GMOs.

Risk assessment for new products - average time in years from submission to EFSA opinion



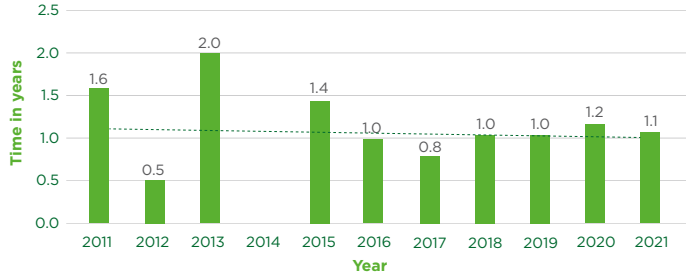
Risk Management

Once EFSA renders a positive scientific opinion, the risk management phase begins. This is the period where the EU's risk managers – namely the European Commission and EU Member States – decide if the product will be authorised for the internal market.

The authorisation for a GM product for import is voted on by the Standing Committee on GM Food and Feed under the EU's qualified majority rules. When the Standing Committee and the Appeal Committee do not manage to reach a qualified majority for a decision within the given time frame, the European Commission may authorise the products based on EFSA's positive risk assessment. The rules stipulate that a vote by the EU Member States should take place three months after the publication of the EFSA opinion.[5] A vote in the Appeal Committee, when needed, should take place within one month.

The reality is that the risk management phase continues to surpass the legally foreseen timeframe.[6]

Risk management of new products - average years from EFSA opinion to Commission approval



NB: No new products were approved by European Commission in 2014

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Improving the system

The GM import authorisation process has room for improvement. Practical steps the European Commission and EFSA could adopt to improve transparency and adhere to legal assessment timelines:

Establishing regular dialogue between applicants and EFSA.

EFSA could adopt clearly formulated, workable and science-based guidance documents and a case-by-case approach to risk assessment.

Timely voting of products in the Standing and Appeal Committees following legal timelines.

Adopting a transparent process so that each EFSA-assessed dossier is tabled at the soonest available slot.

Granting the timely approval of products after their vote.

CROPLIFE EUROPE CALLS FOR AN EFFICIENT AND PREDICTABLE AUTHORISATION PROCESS FOR THE IMPORT OF GM CROPS INTO THE EU, RESPECTING LEGALLY FORESEEN DEADLINES.

1 Figures reflect the 5-year average (2017-2021) for new products.
2 Note that for both the risk assessment and the risk management phases, factors unrelated to the functioning of the systems can lead to delays in the timelines. To avoid distortions of the averages due to such occurrences, all values presenting significant deviation from the mean have been excluded from the calculation.
3 https://open.efsa.europa.eu/questions
4 https://ec.europa.eu/food/horizontal-topics/committees/paff-committees/genetically-modified-food-and-feed-and-environmental_en
5 Reg. 1829/2003 (Art. 7.1)
6 Reg. 182/2011 (Art 5.4)

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