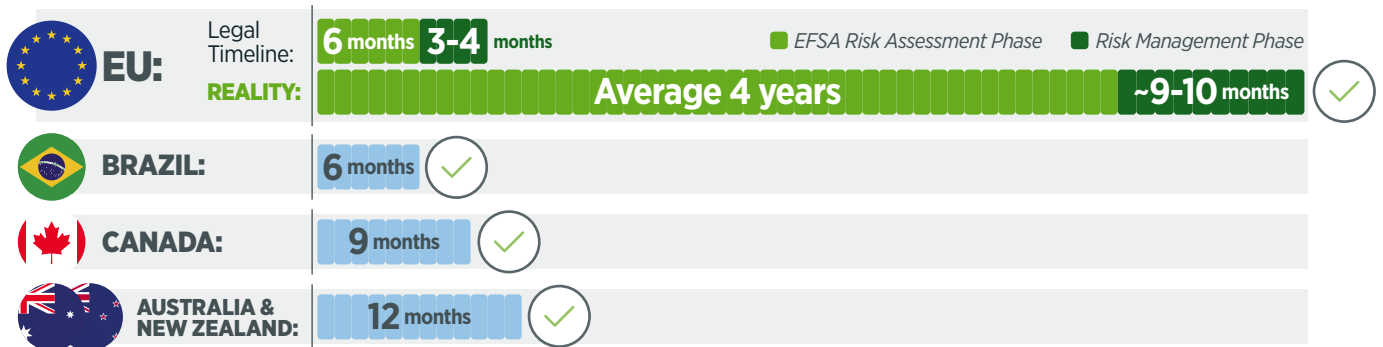


HOW TO ENHANCE REGULATORY EFFICIENCY FOR BIOTECH PRODUCTS

GM AUTHORISATIONS IN THE EU: ROBUST BUT SLOW

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 on the environment. 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 EU internal market. Despite having well-defined procedures in legislation, the GM authorisation process in the EU remains lengthy and unpredictable.

For new products, the legal timeline to conduct the risk assessment is six months. But the reality is different: it takes EFSA on average four years to conduct a risk assessment. This significant delay creates undue burdens on European businesses, in particular when compared with their peers from other regions, some being Europe's most important trading partners. Completing GMO approvals takes an average of 6 months in Brazil, 9 months in Canada, and 12 months in Australia and New Zealand.

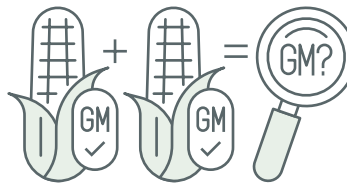


WHY IT TAKES SO LONG

We identify three key issues that cause the process to take so long in Europe:



First of which, is the overuse of the “**stop-the-clock**” mechanism, creating linear processing bottlenecks and extending timelines, despite nearly 30 years of data demonstrating the safety of GMOs. At the same time, the **requirement for periodic renewal of authorisations** diverts resources that could be used for the assessment of new types of products. Addressing both issues would improve the efficiency of the system.



Secondly, Europe **regulates GM crops combined by conventional breeding as completely new products** with extensive data requirements, a policy for which there is no scientific rationale. Globally, many regulatory agencies do not regulate GM stacked events and instead focus on assessing and approving individual GM traits. In the EU, GM events stacked through conventional breeding require a separate risk assessment that is almost as long as for single events. EFSA's data requirements for GM stacked events are nearly the same as those for individual GM products.



Third, EU legislation on the authorisation of GM imports **requires a 90-day animal feeding study** to be systematically conducted for each single event, even though scientists broadly agree these studies provide little added value unless there is a specific scientific reason to conduct them. Even EFSA questions the mandatory nature of these studies.¹ In addition, for newly expressed proteins EFSA requires a 28-day repeat dose feeding study, making the EU the only geographic region requiring this on an almost systematic basis.

1. Devos, Y., Naegeli, H., Perry, J. N., & Waigmann, E. (2016). 90-day rodent feeding studies on whole GM food/feed: Is the mandatory EU requirement for 90-day rodent feeding studies on whole GM food/feed fit for purpose and consistent with animal welfare ethics? EMBO Reports, 17(7), 942-945. <https://doi.org/10.15252/embr.201642739>

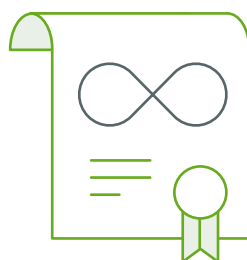
3 SOLUTIONS TO STREAMLINE THE GM AUTHORISATION PROCESS IN EUROPE

Given the extensive experience with assessing GM food and feed products in the EU, the GM import authorisation process has room for simplification without lowering safety standards. The following three areas present clear opportunities for streamlining:



1 STREAMLINING STACKED EVENT ASSESSMENT:

The EFSA should streamline the assessment of GM events stacked through conventional breeding by only assessing three aspects outlined in § 1.2.2. of Annex II of Implementing Regulation (EU) 503/2013: expression, stability and potential for interactions. Additional data should be requested only when a specific risk has been identified.



2 REMOVING RENEWAL REQUIREMENTS:

GM import authorisations are valid for 10 years in the EU whereas no renewals are required in the majority of regions. There are existing mechanisms such as monitoring and the obligation to notify new scientific information that ensure that all GM products on the EU market are safe. Similar to the Commission proposals on reforming the renewal process in other food and feed areas - such as feed additives and GM microorganisms - the Commission should halt the renewal requirement for GM food and feed.



3 CASE-BY-CASE FEEDING STUDIES:

In light of the unambiguous scientific evidence, there should be a shift away from the mandatory nature of 90-day and 28-day studies for the risk assessment of GM crops towards a case-by-case approach to protein safety assessment. This could be achieved by enabling the use of Article 5(2) of Implementing Regulation (EU) 503/2013 allowing for the derogation of certain requirements when that information is not scientifically necessary or technically possible to supply. Such approach aligns with the EU's 3R Directive to reduce unnecessary animal testing and improve animal welfare.

The adoption of these proposals would remove duplicative or scientifically unnecessary requirements, and reduce burden on both EFSA and applicants. This would eventually allow for diversion of EFSA resources towards the assessment of novel innovations that may pose actual risks.

**WE SUPPORT A PREDICTABLE,
SCIENCE BASED AUTHORISATION
PROCESS FOR GM FOOD AND FEED**