Increasing Timelines for Risk Assessment of GMOs in EFSA

Scientific opinion now takes over five years, up from less than two years in 2006

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- Genetically modified (GM) applications for food and feed imports or cultivation can only be authorised in the EU, if they have passed a rigorous safety assessment by the European Food Safety Authority (EFSA) based on scientific evidence[1].
- In 2006, the risk assessment of GM applications took on average less than two years, while in 2014 more than five years were needed for risk assessment[2] despite increasing experience with GMOs and not a single substantiated case of ill effect in nearly two decades of GMO commercialisation.
- As of the 6th of July 2015, over 40 GM applications are pending at EFSA level awaiting risk assessment. The oldest product in the system has been awaiting EFSA's scientific opinion for more than 8 years[3].
- As a comparison, in 2011[3] the average time required for a complete GM product approval was around 25 months in the U.S., 27 months in Brazil and 30 months in Canada.
- There appears to be a correlation between the rapidly increasing EFSA timelines and the publication of numerous additional EFSA guidance documents, frequently changing what data is required from applicants. EFSA has published 16 new guidance documents since 2006 and 11 additional ones are currently being drafted and planned to be published in the course of 2015 and 2016.
- New requirements contained in these guidance documents are often applied retroactively to all applications under EFSA review. Therefore, it is often impossible for applicants to know at the time of preparation and submission of their dossiers what will actually be required to finalise the risk assessment procedure[4].
- In December 2013, Implementing Regulation EU (No) 503/2013 came into force, which also obliges applicants to submit studies added for political reasons, although EFSA has stated that these are unnecessary for risk assessment[5]. This undermines EFSA's credibility and is likely to further slowdown authorisations.
- This matters because the extensive duration of the risk assessment adds further to undue delays in the GMO approval process at the political level following the risk assessment[6], resulting in asynchronous approvals and impacting global GM commodity trade. European livestock farmers are highly dependent on imports of GM commodities.

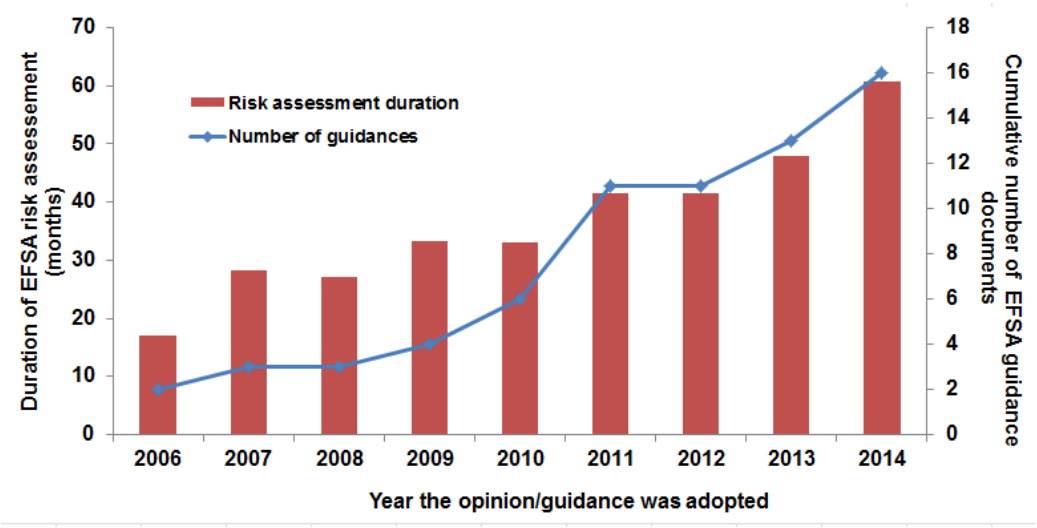

Figure 1 : EFSA timelines for risk assessment of GMOs and the development of Guidance documents

[1] What is the approval process for import of GMOs in the EU?, EuropaBio July 2014
[2] This calculation does not include inconclusive opinions. For each year, it was analysed how long the applications that received an opinion in that year had been pending in EFSA and the average was calculated.
[3] Monsanto cotton *MON88913xMON15985* was submitted to EFSA in April 2007
[4] Approvals of GMOs in the European Union, EuropaBio, October 2011
[5] EFSA editorial: New Commission Implementing Regulation on Risk Assessment of GM plant applications: novel elements and challenges, December 2013
[6] Time for the Commission to Authorize Safe GMO Imports, EuropaBio, January 2015 & Five reasons for the Commission to continue granting Europe's livestock farmers freedom of choice, EuropaBio, April 2015