Mandatory feeding studies for GM crops should be abolished because they contradict EU science and ethical principles

EuropaBio position paper on mandatory GM feeding studies

15 November 2018

EuropaBio, the European Association for Bioindustries, urgently calls upon the EU to comply with EU legislation on animal testing and abolish needless mandatory 90-day rodent feeding studies in relation to genetically modified (GM) crops. Such generally applicable, mandatory studies serve no useful purpose when there is no testable hypothesis. They also contradict the advice of the EU's scientific authority on food safety and the results of EU funded research projects, posing legitimate ethical and economic concerns and jeopardising animal welfare as well as innovation. It is time for the EU to initiate a return to science-based decision making and demonstrate its commitment to the EU's scientific and ethical principles on animal testing.

Introduction

GM food and feed imports or cultivation of GM crops can only be authorised in the EU following a rigorous risk assessment[1]. Risk assessment is legally defined to mean "a **scientifically based** process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation"[2]. EuropaBio supports a transparent and efficient risk assessment process to ensure that the benefits of such products to EU farmers and consumers can be realised. Safety assessments should always be based on scientific knowledge and adhere to the highest ethical and scientific principles. However, the current mandatory requirement for 90-day feeding studies for the risk assessment of GM crops is neither scientifically nor ethically justified. It should hence be removed from the EU risk assessment requirements in order to better reflect the scientific consensus and comply with EU legislation concerning the protection of animals used for scientific purposes. A review of this requirement is explicitly foreseen in relevant GM legislation,[3] but so far the EU Commission has not taken any actions to take into account the newest scientific information and reduce animal testing in this context.

The origin and review of the requirement

Implementing Regulation (EU) No 503/2013[4] originally set out the requirement for **90-day feeding studies** for GM crops predominantly to accommodate the diverging views of

[1] What is the approval process for import of GMOs in the EU?, EuropaBio, July 2014
[2] General Food Law Regulation (EC) 178/2002, Art. 3,11
[3] Preamble (12) of Regulation 503/2013, supported by Art. 12, notes: "feeding trials in the context of GMO risk assessments should be reviewed in the light of the outcome of (the research project) expected (…) by the end of 2015" as well as other credible scientific knowledge.
[4] EC Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of GM food and feed in accordance with Regulation (EC) No 1829/2003

EuropaBio aisbl, Av de l'Armée 6 - B 1040 Bruxelles - BELGIUM
Tel: (+32.2) 735 03 13 - Fax: (+32.2) 735 49 60
Website : www.europabio.org VAT: BE 0477.520.310

some EU Member States at a time when the safety of GM crops was being challenged by a highly publicised rodent study by French Professor Gilles-Eric Séralini. Due to serious flaws found in the design, reporting and analysis of the Seralini study, this study was rejected by EFSA, as well as by other risk assessment authorities in at least seven EU countries and elsewhere[5], and has since been retracted from the Journal Food and Chemical Toxicology [6]. Since then, EFSA has repeatedly pointed out that the 90-day feeding studies should not be mandatory and should only be performed on a case-by-case basis.[7]

Implementing Regulation (EU) No 503/2013[3] also mandated a review of the requirement and publication of the review results by 30 June 2016 at the latest and required the European Commission to monitor all new scientific information. Over the past five years, the EU and its Member States have funded multiple dedicated research projects to address perceived uncertainties in relation to the need for 90-day feeding studies. All of these studies have reconfirmed EFSA's assessment that mandatory 90-day feeding studies are unnecessary. Two recent EU-funded research projects - worth more than **€ 11 million of taxpayer's money** and sacrificing more than **1700 animals**[8] - clearly concluded that **"*we do not see the need to continue with the mandatory requirement to conduct untargeted animal feeding studies for each novel GM plant*"**.[9] In addition to confirming the limited added value of mandatory 90-day feeding studies, scientists on the two research consortia confirmed the safety of GM maize, which has been safely cultivated in Spain and other parts of the world for over two decades and has also been proven to provide food and feed safety benefits[10]. In fact, there has not been a single substantiated case of ill effect in over two decades of GMO commercialisation, with over three trillion GMO meals having been eaten worldwide. And over the past 25 years, the EU has spent well over € 300 million on over 50 complementary studies on GMOs, consistently confirming the world-wide scientific consensus that all safety assessed GM crops are at least as safe as conventionally bred crops[11].

Following science can save animals' lives and EU taxpayer money

Despite the recent EU research results unanimously rejecting the need for mandatory feeding trials, the European Commission continues to maintain the requirement for the submission of a 90-day feeding study.[12] The result is that, in addition to the more than € 11 million of taxpayer's money and use of more than 1700 animals in the public research projects, each 90-day feeding study, performed to comply with the mandatory

[5] Public Authorities reject GMO scare study, EuropaBio, December 2012; Scientific Community Rejects Poor Science, EuropaBio, October 2012

[6] Elsevier Announces Article Retraction from Journal Food and Chemical Toxicology. Elsevier, November 2013

[7] *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?* Devos, Y.; et al.; 2016.

[8] Number of animals sacrificed- Grace project: 560; G-TwYST project: 1160

[9] Policy Brief: Animal Feeding Studies for GMO Risk Assessment. Lessons from two large EU research projects

[10] Impact of GE maize on agronomic, environmental and toxicological traits: a meta-analysis of 21 years of field data , Nature, April 2018

[11] A decade of EU-funded GMO research (2001 - 2010): European Commission, 2010

[12] In January 2017 the Commission informed the Member States that the requirement for conducting 90-day feeding studies will not be revised. EC Summary report of January 2017 Standing & Regulatory Committee meeting).

requirement, requires a large number of animals to be sacrificed and costs significant and unnecessary time and money[13]. This clearly contravenes Directive 2010/63/EU[14], which foresees that animal testing should only be conducted when absolutely necessary and when no other experimental alternatives exist.

Time to comply with the EU's scientific and ethical principles

The conclusions of two EU research projects help to show that **the mandatory requirement for 90-day studies clearly goes against the intention of the EU legislation** on the protection of the animals used for scientific purposes, where the use of laboratory animals should only be permitted when justifiable and should be kept to a minimum. Furthermore, **mandatory 90-day studies go against the scientific advice of EFSA, EU consortia of independent scientists and the principles on Replacement, Reduction and Refinement** of animal use in scientific procedures. For all these reasons, the mandatory 90-day study requirement should be abolished as soon as possible.

For more information:

- G-TWYST and GRACE Policy Brief on animal feeding studies for GMO risk assessment
- GMOinfo news, 11 July 2018: EU debunks Seralini scare yet again, but maintains mandatory testing
- Parliament Magazine: Scratching the surface: why mandatory GMO feeding studies just do not make sense
- Le Figaro, 3 July 2018: OGM : une manipulation scientifico-médiatique soigneusement préparée
- See also
    - EuropaBio position paper and press release on transparency and sustainability of risk assessment;
    - Europe benefits greatly from GM crop imports, and GM maize cultivation in Spain has provided considerable benefits after almost 20 years;
    - The same GMOs approved in other countries in 2 years often take up to 7 years for import approval in the EU. See EuropaBio's risk assessment timeline factsheet.

About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents 78 corporate and associate members and bio regions, and 15 national biotechnology associations in turn representing over 1800 biotech SMEs. Read more about our work at www.europabio.org.

[13] It normally takes 1 year and costs 270.000$ or more to conduct a 90-day study by the applicant.
[14] Directive 2010/63/EU of the EP and Council of 22 September 2010 on the protection of animals used for scientific purposes.