

ANNEX

Legal grounds for denying the authorisation for cultivation of GM maize crops 1507, Bt11 and MON810

1. Introduction

On 27 March 2017, in accordance with Article 6 of Regulation 182/2011, the Appeal Committee voted on the draft implementing acts concerning the authorisation for the cultivation of GM maize crops 1507 and Bt11, and the re-authorisation of GM maize MON810. Sixteen member states voted against the authorisation of 1507 and Bt11, and 14 member states also opposed the re-authorisation of MON810. However, no qualified majority was achieved. Therefore the Committee did not deliver an opinion in accordance with Article 5(1) of the Regulation.

The European Commission is now under the obligation to act since it needs to respond to the applicants, DuPont Pioneer, Syngenta and Monsanto. However, the Commission is not obliged to adopt the draft acts as they stand.

This briefing outlines that the Commission can lawfully reject the applications for authorisation despite the favourable opinions delivered by the European Food Safety Authority (EFSA). It argues that the Commission is in fact obliged to do so since it would otherwise violate the rules governing the assessment and management of risks related to the release of GM crops into the environment, as well as the principles of sincere cooperation and institutional balance set out in the Treaty on the Functioning of the European Union (TFEU).

2. Exercise of risk management function

EFSA has stated that the cultivation of these GM crops is “unlikely” to have any adverse effect on the environment so long as “appropriate management measures” are applied.^{1,2,3} However, the Commission is not bound, in the exercise of its powers under Article 5(3) of the Regulation, by the risk assessment carried out by EFSA. Recent case law confirms this.⁴

Indeed, the EU framework underpinning all EU and national measures relating to food and feed (Regulation 178/2002) marks a clear distinction between risk assessment, which is EFSA’s task, and risk management functions, which belong to the Commission and the Committee. This distinction would lose any significance if the Commission were simply obliged, in the absence of an opinion by the Appeal Committee, to uphold the outcome of EFSA’s risk assessment without any possibility to depart from it.

Article 6 of Regulation 178/2002 states that “*risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority ..., other factors legitimate to the matter under consideration and the precautionary principle ...*”.

¹ EFSA (2012) Scientific Opinion updating the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize 1507 for cultivation. EFSA Journal 2011;9(11):2429

² EFSA (2011) Statement supplementing the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize Bt11 for cultivation. EFSA Journal 2478, 1-44

³ EFSA (2012) Scientific Opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize MON 810. EFSA Journal 2012; 10(12):3017.

⁴ Judgements of the General Court in Case T-177/13, paragraph 103, and Case T-475/07, paragraph 87

In view of assessing the situation, the Commission must have due regard to the reasons that have led Committee members to vote against the draft implementing acts. The Commission must take into account not only the existing evidence, but also the level of scientific uncertainty over specific issues, as well as other legal or factual circumstances.

A number of EU member states have raised safety concerns for the environment and human health, partly due to the GM crops' tolerance to glufosinate ammonium, a dangerous herbicide. They have done so both in discussions with EFSA and in the Regulatory Committee.⁵ In their view, the cultivation of these GM crops, under proposed conditions, cannot be considered safe for human health and the environment, as required by EU GMO law.

3. Deficient environmental risk assessment

In its risk assessments of 1507 and Bt11, EFSA has acknowledged adverse effects on non-target butterflies and moths. However, it underestimated the exposure of these non-target species by more than 90% because it assumed that maize pollen only travels short distances, which is contrary to measurements collected over 10 years.⁶ A recent response to the EFSA assessments shows that the scientific debate about the protection of sensitive moth and butterfly species is far from over.⁷

EFSA disregarded potentially adverse effects on a myriad of other species, including aquatic insects, which can have repercussions on ecosystems by disrupting the food chain.⁸ It also failed to assess the impact of current agricultural practices such as glyphosate use, which could enhance toxicity to aquatic life affected by runoffs.⁹ Likewise, EFSA also dismissed any possible health impacts on vertebrates, including mammals,¹⁰ and played down possible safety implications of the genomic irregularities resulting from the genetic engineering process.

GM maize 1507 and Bt11 are also genetically modified to withstand spraying with glufosinate, a potent herbicide, which has been linked to severe health and environmental impacts by both EFSA and the European Chemical Agency (ECHA).¹¹ However, EFSA did not assess any potential adverse effects caused by the anticipated greater use of this herbicide.

When new risks emerged after DuPont Pioneer, Syngenta and Monsanto had filed their applications, no supplementary risk assessment was provided. These risks are linked to the occurrence in Europe

⁵ DG Sante, Summary report of the joint meeting of the Standing Committee on Plants, Animals, Food and Feed and the Regulatory Committee under Directive 2001/18/EC, 27 January 2017

⁶ Hofmann F, Otto M, Wosniok W (2014) Maize pollen deposition in relation to the distance from the nearest pollen source under common cultivation—results of 10 years of monitoring (2001–2010). *Environmental Sciences Europe* 26:24; Hofmann F et al (2016) Accumulation and variability of maize pollen deposition on leaves of European Lepidoptera host plants and relation to release rates and deposition determined by standardised technical sampling. *Environmental Sciences Europe* 28:14

⁷ Kruse-Plass et al (2017) Reply to the EFSA (2016) on the relevance of recent publications (Hofmann et al. 2014, 2016) on environmental risk assessment and management of Bt-maize events (MON810, Bt11 and 1507), *Environmental Sciences Europe* 29:12

⁸ Hilbeck A and Otto M (2015) Specificity and Combinatorial Effects of *Bacillus Thuringiensis* Cry Toxins in the Context of GMO Environmental Risk Assessment. *Frontiers in Environmental Science* 3:71

⁹ Bøhn T et al (2016) *Daphnia magna* negatively affected by chronic exposure to purified Cry-toxins, *Food and Chemical Toxicology* 2016 May; 91:130-40

¹⁰ Rubio-Infante N and Moreno-Fierros L (2016) An overview of the safety and biological effects of *Bacillus thuringiensis* Cry toxins in mammals, *Journal of Applied Toxicology* 36, Issue 5, May 2016, 630–648

¹¹ European Chemical Agency classification of glufosinate: <https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/notification-details/35913/1054366>

EFSA (2012) Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance glufosinate. *EFSA Journal* 2012;10(3):2609

of a plant species known as teosinte. Teosinte can hybridize with maize and produce viable offspring. Thereby, also the transgenes can be transferred from maize into teosinte populations.

Directive 2001/18 requires the assessment of the “*potential for gene transfer to the same or other sexually compatible plant species*” and any adverse effects this may have. According to Annex II C.2 no.2 to Directive 2001/18, the evaluation of the consequences of adverse effects of a genetically modified plant “*should assume that such an adverse effect will occur*”.

When it became known that teosinte was growing in maize fields in Spain, the Commission’s DG SANTE asked EFSA to report on the potential risks. EFSA concluded that “*there are no data in the scientific information on teosinte supplied by the European Commission that indicate the necessity to revise the previous ERA conclusions and risk management recommendations for maize MON810, Bt11, 1507 and GA21*”.¹² Given the limited amount of available information on teosinte and its behaviour in the European environment, the EFSA report cannot qualify as a risk assessment based on a worst case scenario, as required by Directive 2001/18.

Since a specific, known risk has not been covered by the environmental risk assessments, the authorisation of 1507 and Bt11, and re-authorisation of MON810 would disregard the provisions of Directive 2001/18.

4. Obligation not to go against the predominant position in the appeal committee

Recital 14 of Regulation 182/2011 provides guidance on how the Commission should exercise its decision making powers, in accordance with Article 5(3) of the Regulation.

The said Recital reads as follows: “*When considering the adoption of other draft implementing acts concerning particularly sensitive sectors, notably taxation, consumer health, food safety and protection of the environment, the Commission, in order to find a balanced solution, will, as far as possible, act in such a way as to avoid going against any predominant position which might emerge within the appeal committee against the appropriateness of an implementing act.*”

The recital is relevant in the present case: (1) the draft implementing act in discussion concerns several of the sensitive sectors identified in the recital (consumer health, food safety and the protection of the environment) and, (2) a predominant position against the appropriateness of the draft implementing act has emerged in the appeal committee.

The recital indicates that the Commission’s powers under Article 5(3) are not unfettered: they must be exercised consistently with the principles of sincere cooperation and institutional balance set out in Articles 4(3) and 13(2) TFEU.

In order to fulfil its obligations under the EU Treaty (whose importance in procedures leading to adoption of implementing measure is illustrated by Recital 14), **the Commission is required not to adopt a draft act against the predominant position within the appeal committee, unless it can demonstrate that it is under a strict legal obligation to do so. In light of the issues highlighted in paragraphs 2 and 3, above, it can be excluded that such obligation exists.**

¹² EFSA (2016) Relevance of new scientific evidence on the occurrence of teosinte in maize fields in Spain and France for previous environmental risk conclusions and risk management recommendations on the cultivation of maize events MON 810, Bt 11, 1507 and GA21. Technical Report of 23-9-2016.