Procedure file

Basic information

RSP - Resolutions on topical subjects	2019/2553(RSP)	Procedure completed
Resolution on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × 1507 × GA21 and sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 Subject 3.10.09.06 Agro-genetics, GMOs		

Key players

	Committee responsible	Rapporteur	Appointed
European Parliament	ENVI Environment, Public Health and Food Safety		21/01/2019
			21/01/2019
		PIETIKÄINEN Sirpa	21/01/2019
			21/01/2019
		BALAS Guillaume	21/01/2019
		MAZURONIS Valentinas	
		STAES Bart	
		EVI Eleonora	
European Commission	Commission DG	Commissioner	
	Agriculture and Rural Development	HOGAN Phil	

Key events

13/03/2019	Results of vote in Parliament		
13/03/2019	Decision by Parliament	T8-0198/2019	Summary
13/03/2019	End of procedure in Parliament		

Technical information

Procedure reference	2019/2553(RSP)
Procedure type	RSP - Resolutions on topical subjects
Procedure subtype	Resolution on implementing act or powers
Legal basis	Rules of Procedure EP 112-p2
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/15428

Documentation gateway

Motion for a resolution		B8-0142/2019	11/03/2019	EP	
Text adopted by Parliament, single reading		T8-0198/2019	13/03/2019	EP	Summary
Commission response to text adopted in plenary		SP(2019)444	30/08/2019	EC	

Resolution on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × 1507 × GA21 and sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507

The European Parliament adopted by 431 votes to 157 with 30 abstentions, a resolution objecting to the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × 1507 × GA21 and sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The application for placing on the market was submitted on 10 August 2010 to the national competent authority of Germany by Syngenta Crop Protection AG through its affiliated company Syngenta Crop Protection NV/SA. The European Food Safety Authority (EFSA) adopted a favourable opinion in relation to this application.

The four-event stack maize Bt11 x MIR162 x 1507 x GA21 was produced by conventional crossing to combine four single maize events leading to expression of, inter alia , two different Cry proteins (also known as Bt proteins) for protection against certain lepidopteran pests, and expressions of proteins for tolerance against glyphosate and glufosinate.

Main observations

Lack of data on the three sub-combinations

Members noted that the applicant did not provide data for any of the three sub-combinations, nor did they justify why they do not consider it to be necessary for the risk assessment. Furthermore, EFSA did not request data on the three sub-combinations.

Moreover, the minority opinion adopted by a member of the EFSA GMO Panel indicated that studies show that side effects have been observed that may affect the immune system following certain conditions of exposure to Bt proteins and that some Bt proteins may have adjuvant properties, meaning that they can increase the allergenicity of other proteins that they come into contact with.

Lack of assessment and controls of complementary herbicides and their residues

Members considered that application of the complementary herbicides, in this case glufosinate and glyphosate, is part of regular agricultural practice in the cultivation of herbicide-resistant plants. Thus. it can be expected that they will be exposed to both higher and repeated doses, which will not only lead to a higher burden of residues in the harvest, and therefore in the imported product, but may also influence the composition of the GM plant and its agronomic characteristics.

Questions remain concerning the carcinogenicity of glyphosate. In 2015 the World Health Organisations International Agency for Research on Cancer classified glyphosate as a probable carcinogen for humans, contrary to the views of EFSA and the European Chemicals Agency (ECHA).

Members also stressed the following points:

- information on residue levels of herbicides and their metabolites is essential for a thorough risk assessment of herbicide-tolerant GM plants. However, the residues from spraying GM maize or the three sub-combinations with herbicides have not been assessed;

- as part of the coordinated multiannual control programme of the Union for 2019, 2020 and 2021, Member States are not obliged to measure glufosinate or glyphosate residues on any maize imports in order to check compliance with maximum residue levels (MRLs). Thus, it cannot be guaranteed that glyphosate and glufosinate residues on GM maize Bt11 × MIR162 × 1507 × GA21 or the three sub-combinations will comply with Union MRLs.

The vote on 14 January 2019 of the Standing Committee on the Food Chain and Animal Health delivered no opinion, meaning that the authorisation was not supported by a qualified majority of Member States.

The Commission deplored the fact that, since the entry into force of the GMO authorization procedure, the Commission has adopted authorisation decisions without the support of the opinion of the Member States committee. The return of the dossier to the Commission for final decision, which is very much the exception for the procedure as a whole, has become the norm for decision-making on genetically modified food and feed authorisations.

In the light of these considerations, Parliament considered that the draft Commission implementing decision is not consistent with Union law, which aims to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, and environmental and consumer interests in relation to genetically modified food and feed, while ensuring the effective functioning of the internal market.

Accordingly, Parliament called on the Commission to:

- withdraw its draft implementing decision;

- not to authorise the import, for food or feed uses, of any GM plants which have been made tolerant to a herbicide that is not authorised for use in the Union, in this case glufosinate;

- not to authorise any herbicide-tolerant GM plants without a full assessment of the residues from spraying with complementary herbicides, metabolites and commercial formulations as applied in the countries of cultivation;

- fully integrate the risk assessment of the application of complementary herbicides and their residues into the risk assessment of herbicide-tolerant GM plants, regardless of whether the GM plant concerned is to be cultivated in the Union or is for import into the Union for food and feed uses;

- not to authorise any sub-combinations of stacked events unless they have been thoroughly evaluated by EFSA on the basis of complete data submitted by the applicant;

- suspend any implementing decision regarding applications for authorisation of GMOs until the authorisation procedure has been revised in such a way as to address the shortcomings of the current procedure, which has proven inadequate;

- withdraw proposals for GMO authorisations if no opinion is delivered by the Standing Committee on the Food Chain and Animal Health, whether for cultivation or for food and feed uses.

EFSA was called upon to further develop and systematically use methods that permit the identification of unintended effects of stacked GM events which are known and expected, such as in relation to the adjuvant properties of Bt toxins.

Parliament reiterated its commitment to advancing work on the Commission proposal amending Regulation (EU) No 182/2011. It called on the Council to move forward with its work in relation to that Commission proposal.