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 × MIR604 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

2019/2860(RSP) - 14/11/2019 - Text adopted by Parliament, single reading

The European Parliament adopted a resolution by 467 votes to 171, with 27 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 × MIR604 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

On 16 December 2011, Syngenta Crop Protection AG submitted an authorisation application. The application also covered the placing on the market of products containing or consisting of the stacked GM maize for uses other than food and feed, with the exception of cultivation.

Member State comments

Member States submitted many critical comments to EFSA during the three-month consultation period which followed the publication of a favourable opinion from the European Food Safety Authority (EFSA) on 27 February 2019.

Those critical comments included that neither whole plant toxicity studies with the stacked GM maize were undertaken, nor specific tests for potential combinatory effects of all transgenes contained in the stacked GM maize, that uncertainties about the effects of Cry toxins on mammals and humans persist, that the comparative assessment does not provide any evidence for safety, that the monitoring plan does not ensure that relevant information is gathered, nor does it comply with Directive 2001/18/EC of the European Parliament and of the Council and that the possibility of interaction between the herbicide residues and their metabolites has not been studied, nor their levels measures.

An independent study found that the toxicological assessment carried out by EFSA is not acceptable since the safety of the crop for import has not been demonstrated, that the assessment cannot be said to fulfil the requirements for assessing risks to the immune system and that the environmental risk assessment is not conclusive.

Lack of assessment of herbicide residues, metabolites and cocktail effects

Members noted that a number of studies show that herbicide-tolerant GM crops result in a higher use of 'complementary' herbicides, in large part because of the emergence of herbicide-tolerant weeds. As a consequence, it has to be expected that the stacked GM maize will be exposed to both higher and repeated doses of glufosinate and glyphosate, and that therefore a higher quantity of residues may be present in the harvest. Glufosinate is classified as toxic to reproduction 1B and the approval of glufosinate for use in the Union expired on 31 July 2018. In addition, questions remain about the carcinogenicity of glyphosate.

Maximum residue levels, Bt proteins

The resolution noted that according to a 2018 EFSA review of the existing MRLs for glyphosate, available data were insufficient to derive MRLs and risk assessment values for glyphosate in relation to GM maize with an EPSPS modification. The stacked GM maize has the EPSPS modification.

A number of studies show that side effects have been observed that may affect the immune system following 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.

The EFSA is called on to further develop and systematically use methods that permit the identification of unintended effects of stacked GM events, such as in relation to the adjuvant properties of Bt toxins.

Undemocratic decision-making

Members stressed that the Commission recognised the fact that GMO authorisation decisions continue to be adopted by the Commission without a qualified majority of Member States in favour, which is very much the exception for product authorisations as a whole but has become the norm for decision-making on GM food and feed authorisations, is problematic. That practice has, on several occasions, been deplored by the Commission President as not being democratic.

On the basis of these comments, Parliament called on the Commission:

- to withdraw its draft implementing decision;

- in the meantime, to stop authorising GMOs when no opinion is delivered by Member States in the Appeal Committee, whether for cultivation or for food and feed uses, in accordance with Regulation (EU) No 182/2011 (comitology);

- not to authorise herbicide-tolerant GM crops until the health risks associated with the residues have been comprehensively investigated on a case-by-case basis, which requires a full assessment of the residues from spraying the GM crops with complementary herbicides, their metabolites and any combinatorial effects;

- 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 the import for food or feed uses of any GM plant which has been made tolerant to a herbicide-active substance that is not authorised for use in the Union;

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

Parliament reiterated its commitment to advancing work on the Commission proposal amending Regulation (EU) No 182/2011.

The Commission is urged to treat the Union's obligations under international agreements, such as the Paris Climate Agreement, the UN Convention on Biological Diversity and the UN Sustainable Development Goals, and to give them the weight they deserve, as well as communicating on how they have been taken into account in the decision-making process.