

Resolution on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 5307 (SYN-Ø53Ø7-1)

2019/2522(RSP) - 31/01/2019 - Text adopted by Parliament, single reading

The European Parliament adopted by 385 votes to 204, with 55 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 5307 (SYN-Ø53Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed.

The application for marketing authorisation was submitted on 7 April 2011 by Syngenta Crop Protection AG, via its affiliate Syngenta Crop Protection NV/SA, to the competent German national authority.

Comments from the Parliament and the Member States

Members noted that the genetically modified maize 5307 produces a new insecticidal protein, eCry3.1Ab, which is toxic to some beetles and weevils and also expresses the phosphomannose isomerase (PMI) protein, which is used as a selection marker.

In its 2015 opinion, the European Food Safety Authority (EFSA) concluded that it was not in a position to complete its risk assessment for food and feed due to shortcomings in the 28-day toxicity study provided by the applicant. The applicant then submitted a new toxicity study, as requested by EFSA. This did not meet all the requirements of the Organisation for Economic Co-operation and Development (OECD) guidelines for repeated-dose 28-day oral toxicity studies in rodents.

Parliament highlighted the following points:

- although Cry proteins (Bt toxins) have been recognised as having adjuvant properties, which means that they could enhance the allergenic properties of other foods, this aspect was not analysed by EFSA. Bt toxins could thus be mixed with allergens in food and feed, such as soybean;
- it has been shown that the toxicity of Bt toxins can be enhanced by interactions with other compounds such as plant enzymes, other Bt toxins and herbicide spray residues;
- testing of the isolated Bt toxin does not allow conclusions to be drawn about its health impact after consumption.

Member States expressed many criticisms during the three-month consultation period following the publication of EFSA's opinions in 2015 and 2018. According to one competent authority, the expression levels of eCry3.1Ab protein in genetically modified maize grains 5307 exceed the default maximum residue limits of 0.01 mg/kg as set out in Regulation (EC) No 396/2005 of the European Parliament and of the Council.

Decision-making process

The Commission has repeatedly deplored the fact that since the current GMO authorisation procedure entered into force, each authorisation decision has been taken by the Commission without the support of the opinion of the Member States' Standing Committee on the Food Chain and Animal Health. Thus, the referral of the dossier to the Commission for a final decision, which should have been an exception, has become the rule in the decision-making process on authorisations of genetically modified food and feed.

On the basis of these considerations, Parliament considered that the Commission's implementing decision was not compatible with Union law, which requires that bases are set out in order to ensure a high level of protection of human life and health, animal health and welfare, the environment and consumer interests, while ensuring the proper functioning of the internal market.

As a result, Parliament called on the Commission to:

- withdraw its draft implementing decision;
- suspend any implementing decision on applications for authorisation of genetically modified organisms until the authorisation procedure has been revised in order to remedy the shortcomings of the current procedure, which has proved inadequate;
- withdraw proposals for authorisations of GMOs – whether for cultivation or for food and feed purposes – if the Standing Committee on the Food Chain and Animal Health does not deliver an opinion.

Parliament reiterated its commitment to make progress in its work on the Commission's proposal to amend Regulation (EU) No 182/2011. It called on the Council to give urgent attention to completing its work on this Commission proposal.