

**Follow up to the European Parliament non-legislative resolution on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87403 (MON-874Ø3-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

- 1. Resolution tabled pursuant to Rule 106(2) and (3) of the European Parliament's Rules of Procedure**
- 2. Reference numbers:** 2019/2523 (RSP) / B8-0075/2019 / P8\_TA-PROV(2019)0059
- 3. Date of adoption of the resolution:** 31 January 2019
- 4. Competent Parliamentary Committee:** Committee on Environment, Public Health and Food Safety (ENVI)
- 5. Brief analysis/assessment of the resolution and requests made in it:**

The resolution calls for the withdrawal of the draft Commission implementing decision (**paragraph 3**), based on the grounds that the draft implementing decision at stake exceeds the implementing powers provided for in Regulation (EC) No 1829/2003 (**paragraph 1**) and that it is not compatible with the aim of Regulation (EC) No 1829/2003 and the general principles of Regulation (EC) No 178/2002, i.e. protection of human life and health, animal health and welfare, the environment and consumer interests (**paragraph 2**). In addition, the resolution calls on the Commission to suspend any implementing decision regarding authorisation of genetically modified organisms until the authorisation procedure has been revised in such a way as to address the shortcomings of the current procedure, which has proven to be inadequate (**paragraph 5**) and to withdraw proposals for genetically modified organisms (GMO) authorisations if no opinion is delivered by the Standing Committee on the Food Chain and Animal Health (**paragraph 6**). Finally, the resolution reiterates the Parliament commitment to advancing work on the Commission proposal amending Regulation (EU) No 182/2011 and calls on the Council to move forward with its work in relation to that Commission proposal as a matter of urgency (**paragraph 4**).

The resolution recalls that maize is genetically modified to increase the ear biomass through the expression of a modified gene derived from another plant species (**recital B**). The resolution mentions that the experimental data provided by the applicant showed a small effect of the intended trait (**recitals C and E**), which was acknowledged by the European Food Safety Authority (EFSA) (**recitals E and G**), and that different environmental factors might influence the expression of the trait (**recital F**). In addition, the resolution refers to a study according to which the exact mechanisms involved in the expression of the gene are poorly understood (**recital D**), and questions the risk assessment of this genetically modified maize performed by EFSA (**recital H**). The resolution also mentions the reference in the EFSA opinion of a study co-authored by an EFSA staff member and an industry-affiliated scientist, which has been subsequently removed (**recital I**), and the commitment from EFSA that staff members will no longer co-author scientific publications with industry-affiliated scientists, in order to avoid perceptions of inappropriate proximity to industry (**recital J**).

The resolution recalls the voting results on the draft implementing decision in the Standing Committee (**recital K**). Furthermore, the resolution recalls that the return of the draft

authorising decisions to the Commission for final decision, after not being supported by the Standing Committee on the Food Chain and Animal Health, has become the norm for decision-making on genetically modified food and feed authorisations and that this is not democratic (**recital L**). Finally, the resolution recalls the rejection by the Parliament of the Commission's legislative proposal of 22 April 2015 amending Regulation (EC) No 1829/2003, and the Parliament's call on the Commission to withdraw that proposal and submit a new one (**recital M**).

## **6. Responses to requests and overview of actions taken, or intended to be taken, by the Commission:**

The Commission would like to explain that the draft implementing decision at stake authorises the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87403, but not the cultivation of this maize.

With respect to **paragraphs 1 to 3** of the resolution, the Commission would like to point out that the draft decision has been processed in line with the procedural steps set out in Regulation (EU) 182/2011 on comitology and Regulation (EC) No 1829/2003 on genetically modified (GM) food and feed, as illustrated below:

- application for the authorisation of GM maize MON 87403 for food and feed uses in the EU was submitted by Monsanto Company on 26 June 2015;
- EFSA performed a comprehensive risk assessment of the product and published on 26 April 2018 a favourable opinion concluding that GM maize MON 87403 is as safe as its conventional counterpart and the tested non-genetically modified maize reference varieties;
- in its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003;
- the public commented on the EFSA opinion and the complementing statement, and all the scientific comments received were scrutinised by EFSA<sup>1</sup>;
- the draft decision was voted on 3 December 2018 in the Standing Committee with no qualified majority against or in favour;
- in accordance with the rules set in Regulation (EU) 182/2011 on comitology, the Commission proposed the draft decision to the Appeal Committee of 14 January 2019, where no qualified majority against or in favour was obtained either.

The Commission, therefore, considers that by adopting a decision that fully complies with the procedural steps set out by the co-legislators in the GMO legislation the Commission does not exceed its implementing powers. Consequently, there are no reasons to withdraw the draft decision for authorisation of the GM maize MON 87403. Furthermore, following the submission of an application and the respective opinion of EFSA, Article 7(3) and Article 19(3) of Regulation (EC) No 1829/2003 oblige the Commission to act, namely to adopt a final decision on the application.

At the meeting of the Committee on Environment, Public Health and Food Safety of the European Parliament on 21 January 2019, the Commission extensively explained the state of play of the authorisation procedure and why it had not exceeded its implementing powers.

With respect to the **other points of the resolution**, the Commission considers that they fall outside the remit of the right of scrutiny, which is limited to the question of whether the draft

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<sup>1</sup> [http://ec.europa.eu/food/plant/gmo/public\\_consultations/index\\_en.htm](http://ec.europa.eu/food/plant/gmo/public_consultations/index_en.htm)

implementing act exceeds the implementing powers provided for in the basic act. The Commission is not required to justify the draft implementing act as regards these points. Nevertheless, the Commission has carefully considered the positions expressed by the European Parliament and would like to make the following comments:

- regarding the comments in **recital M** on the Commission legislative proposal for a regulation amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, the Commission would like to recall that it regrets the decision of the European Parliament of 28 October 2015 to reject the proposal. The Commission maintains its original proposal, which, if adopted, would enable Member States to address at national level considerations, which are not covered by the EU decision-making process;
- furthermore, as regards to the lacking support of the Members States for any authorising decision of GMOs for food and feed uses (**recital K**) the Commission submitted a proposal to the Council and the European Parliament on 14 February 2017 for a regulation amending Regulation (EU) No 182/2011 to change the voting rules at the Appeal Committee, which if adopted by co-legislators, would increase transparency and accountability in GMO decision-making process;

in conclusion, the Commission would like to stress that as for any legislative procedure submitted under the ordinary legislative procedure, the rules in place continue to apply during the negotiations between the co-legislators and until a final agreement is found. Consequently, the Commission has to continue processing the applications for GM food and feed.

