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 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

1. **Resolution tabled pursuant to Rule 106(2) and (3) of the European Parliament's Rules of Procedure**

2. **Reference numbers:** 2019/2522 (RSP) / B8-0074/2019 / P8_TA-PROV(2019)0058

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 the genetically modified maize is resistant to insects through the production of a Bt protein (**recital B**) and mentions that Bt proteins may have toxic effects (**recitals F and G**). The resolution recalls that the European Food Safety Authority (EFSA), in its opinion of 2015, was not able to complete its food and feed risk assessment owing to inadequacies in the 28-day toxicity study provided by the applicant (**recital C**). The applicant provided later a new 28-day toxicity study (**recital D**) and EFSA adopted a favourable opinion for this GM maize in 2018 (**recital E**). The resolution points out shortcomings in the 28-day toxicity study (**recitals D and G**) and to similarities between the Bt protein and other cytotoxic proteins, which have not been investigated further by EFSA (**recital H**). Finally, the resolution refers to one Member State's comment on the application, that the Bt protein expressed in the GM maize exceeds the default maximum residue levels (MRL) permitted, as set out in Regulation (EC) No 396/2005 (**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 5307, 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 5307 for food and feed uses in the EU was submitted by Syngenta Crop Protection AG on 7 April 2011;
- in 2015, EFSA published an opinion for this application, but was not able to reach an overall conclusion on GM maize 5307 due to an inadequate toxicity study provided for the new protein produced by this maize. In December 2016, the applicant provided a new toxicity study on the protein, which has since been assessed by EFSA. On 11 April 2018, EFSA published a statement complementing its opinion and concluded that maize 5307, as assessed in the initial opinion and in the supplementary toxicity study, is as safe and nutritious as its non-GM conventional counterpart;
- 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[1];
- 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 5307. 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.

[1] http://ec.europa.eu/food/plant/gmo/public_consultations/index_en.htm

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 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 comment in **recital J** about the Bt protein expressed by the GM maize exceeding the default MRL as set out in Regulation (EC) No 396/2005, the Commission would like to mention that the default MRL for 'delta endotoxin of *Bacillus thuringiensis*' set out in that regulation is not applicable to Bt toxins produced by GM crops. In the case of GM crops, the Bt protein is not a substance to be applied on the plants, but it is part of the GM plant itself. Therefore, the protein levels in the GM maize were known and taken into account by EFSA during the assessment of the Bt protein, and the whole GM maize, and EFSA concluded positively on the safety of the GM maize;
- 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 the Member States to address at national level considerations, which are not covered by the EU decision-making process;
- furthermore, as regards 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.