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 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9)

1. **Resolution tabled pursuant to Rule 112(2) and (3) of the European Parliament's Rules of procedure**

2. **Reference numbers:** 2019/2829 (RSP) / B9-0106/2019 / P9_TA-PROV(2019)0030

3. **Date of adoption of the resolution:** 10 October 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 (GMO) 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)**. The resolution also calls on the Commission to withdraw proposals for GMO authorisations if no opinion is delivered by the Standing Committee on the Food Chain and Animal Health **(paragraph 6)**. The resolution calls on the Council to move forward with its work in relation to the Commission proposal amending Regulation (EU) No 182/2011 **(paragraph 4)**.

The resolution recalls that the stacked genetically modified (GM) maize is tolerant to glyphosate, glufosinate and 2,4-D herbicides (**recital D**) and calls on the Commission not to authorise the import for food or feed uses of any GM plant tolerant to an herbicide that is not authorised for use in the Union **(paragraph 9)**. Furthermore, it calls on the Commission not to authorise any herbicide-tolerant GM plants without full assessment of the residues from spraying with complementary herbicides, metabolites and commercial formulations, as applied in the countries of cultivation **(paragraph 7**), and to 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 where the GM plant is cultivated **(paragraph 8)**. The resolution calls on the Commission not to authorise any sub-combinations of stacked events unless they have been evaluated by the European Food Safety Authority (EFSA) based on complete data submitted by the applicant (**paragraph 10**), and considers that approving sub-combinations for which no safety data have been provided runs contrary to the principles of Regulation (EC) No 178/2002

(**paragraph 11**). Finally, the resolution calls on EFSA to further develop and systematically use methods for identifying unintended effects of stacked GM events, including in relation to the adjuvant properties of Bt toxins **(paragraph 12)**.

The resolution recalls that the applicant provided no experimental data for 14 sub-combinations in the scope of the application (**recital F**). The resolution mentions that that the use of glufosinate is no longer permitted in the Union **(recital L)** and refers to studies raising concerns on the safety of 2,4-D and its metabolites in GM crops **(recitals M** and **N).** The resolution states that questions concerning the carcinogenicity of glyphosate remain **(recital I**), and that according to EFSA, toxicological data on metabolites relevant to GM glyphosate-tolerant crops are missing **(recitals J** and **K)**. The resolution mentions that it can be expected that residues from spraying with these herbicides will be present in the harvest **(recital G).**

The resolution recalls the voting results on the draft implementing decision in the Standing and Appeal Committees, **(recital S)**. 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, has become the norm for decision-making on genetically modified food and feed authorisations and it is not democratic **(recital M)**. Finally, the resolution recalls the numerous resolutions objecting to GMOs authorisations adopted by the European Parliament in its eight term **(recital U**).

6. Response to the requests and overview of the action taken, or intended to be taken, by the Commission:

The Commission would like to recall 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 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and sub-combinations, but not the cultivation of these 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:

- An application for the authorisation of GM maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9, and sub-combinations, for food and feed uses in the EU was submitted by Dow AgroSciences Europe on 6 February 2013.
- EFSA performed a comprehensive risk assessment of the products and published on 14 January 2019 a favourable opinion concluding that GM maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 is as safe as its non-genetically modified comparator and the tested non-genetically modified reference varieties. As regards the sub-combinations for which no experimental data were provided, EFSA concluded that they are expected to be as safe as the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9, the previously assessed sub-combinations and the stacked GM maize.
- 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 all the scientific comments received were scrutinised by EFSA[1].
- The draft Decision was voted on 12 July 2019 in the Standing Committee with no qualified majority against or in favour.

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

- In accordance with the rules set in Regulation (EU) 182/2011 on comitology, the Commission proposed the draft Decision to the Appeal Committee of 16 September 2019, where no qualified majority against or in favour was obtained either.

The Commission, therefore, considers that by adopting a decision, which 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 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and sub-combinations. 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 Environment, Public Health and Food Safety Committee of the Parliament on 25 September 2019, the Commission extensively explained the state of play of the authorisation procedure and why it had not exceeded its implementing powers. At the plenary session of the Parliament on 9 October 2019, the Commission participated in the debate on authorisation of GMOs and explained how it processes authorisations for placing on the market of GMOs, in full compliance with the EU legislation and in full respect of the scientific assessment performed by EFSA.

With respect to the **other provisions 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 Parliament and would like to make the following comments:

With respect to the specific concerns raised in **recitals I** to **N** of the resolution, the Commission would like to point out that the risk assessment in the context of an application for food and feed uses of a herbicide-tolerant GM crop is focused on the potential impact of the genetic modification on human and animal health and on the environment. Considerations on environmental protection in the area of pesticides are within the scope of Regulation (EC) No 1107/2009 concerning the placing on the market of plant protection products according to which each active substance and each plant protection product are assessed for their environmental safety before a risk management decision to approve a substance or authorise the use of a product is made. The authorisation of GMOs is not linked to the authorisation of herbicides. Herbicides are authorised by the procedures set out in Regulation (EC) No 1107/2009, and Regulation (EC) No 396/2005 on maximum residue levels (MRLs). In addition, the existing MRLs for glufosinate-ammonium based herbicides remain fully applicable after the expiry of approval of glufosinate in the EU, and imported food and feed, whether GM or not, have to comply with those MRLs. It is important to recall that the EU has no power to interfere with the environmental law and standards established in third countries, including the authorisation of herbicides.

In relation to **recital F** and the assessment of sub-combinations for which no experimental data was provided, the EFSA GMO Panel used a weight of evidence approach to conclude positively on their safety, based on the assessment of (i) the five single events, (ii) the 5-event stacked GM maize (with all proteins), and (iii) other sub-combinations previously assessed. In addition, as current control procedures do not allow identifying the origin of sub-combinations, applications for GM maize have to include all possible sub-combinations, in order to ensure that authorisations are coherent with the products of which the placing on the market is unavoidable and for the feasibility of controls.

With regards to the lack of support by the Members States for any authorising decision of GMOs for food and feed uses **(recitals S** and **T)** the Commission submitted a proposal to the Council and the 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. The Commission would also like to recall that it regrets the decision of the Parliament of 28 October 2015 to reject the proposal of 22 April 2015 amending Regulation (EC) No 1829/2003, which, if adopted, would enable Member States to address at national level considerations, which are not covered by the EU 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 under existing rules.