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 MZHG0JG (SYN-ØØØJG-2), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Genetically modified maize MZHG0JG (SYN-ØØØJG-2))

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

2. **Reference numbers:** 2019/2830 (RSP) / B9-0107/2019 / P9_TA-PROV(2019)0028

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 ground 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 for withdrawing proposals for GMO authorisations if no opinion is delivered by the Standing Committee **(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 the fact that the genetically modified maize is tolerant to glyphosate- and glufosinate ammonium-containing herbicides, and resistant to corn rootworms **(recital D)**. It calls on the Commission not to authorise any herbicide-tolerant genetically modified (GM) plant without full assessment of the residues from spraying with complementary herbicides, metabolites and commercial formulations as applied in countries of cultivation **(paragraph 7)**. Furthermore, the resolution calls on the Commission 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 also calls on the Commission not to authorise imports of any GM plant for food or feed uses which has been made tolerant to a herbicide not authorised in the Union (**paragraph 9**). In addition, the resolution calls on the Commission to suspend any implementing decision regarding the 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)**. The resolution also calls for withdrawing proposals for GMO authorisations if no opinion is delivered by the Standing Committee **(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 also recalls critical comments by the Member States during the three-month consultation, particularly regarding the toxicology assessment, which some Member States considered insufficient, and regarding the comparative analysis and the lack of equivalence of ferulic acid **(recital E)**. The resolution also states that an independent study concludes that EFSA risk assessment does not properly assess toxicity, because of a lack of reliability of the data, the environmental risk assessment by the European Food Safety Authority (EFSA) is deemed not acceptable, as it does not consider potential gene transfer between the GM maize and its wild relative teosinte **(recital F)**.

The resolution states that questions concerning the carcinogenicity of glyphosate remain **(recital J),** that the use of glufosinate is no longer permitted in the Union **(recital I)** and that it can be expected that the herbicide-resistant plants will be exposed to higher and repeated doses of the complementary herbicide which will lead to a higher level of residues **(recital G)**. The resolution also states that toxicological data allowing a consumer risk assessment to be performed for several break-down products of glyphosate are missing (**recital K**) and that the way complementary herbicides are broken down, the composition and the toxicity of those break-down products may be driven by the genetic modification itself (**recital L**).

The resolution recalls the voting results on the draft implementing decision in Standing Committee on the Food Chain and Animal Health and of the Appeal Committee **(recital N)**. 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 that this is not democratic **(recital O)**. Finally, the resolution recalls that the European Parliament has adopted numerous resolutions against placing on the market of GMOs for food and feed and for cultivation in its eighth term **(recital P)**.

6. Responses to requests and overview of actions 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 MZHG0JG, but not the cultivation of this maize.

With respect to **paragraphs 1, 2, 3, 6** and **8** 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 MZHG0JG for food and feed uses in the EU was submitted by Syngenta Crop Protection on 1 September 2016.
- EFSA performed a comprehensive risk assessment of the product and published on 14 November 2018 a favourable opinion concluding that the GM maize MZHG0JG is as safe as and is nutritionally equivalent to its non-genetically modified comparator and other tested non-GM commercial 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 all the scientific comments received were scrutinised by EFSA[1].
- The draft decision was voted on 30 April 2019 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 5 June 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 MZHG0JG. 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 concerns raised in **recitals E** and **F**, the Commission would like to stress that ESFA performed a careful and complete assessment of the 90-day feeding study, environmental risk assessment and comparative analysis according to Implementing Regulation (EU) 503/2013 and its own guideline documents. EFSA carefully assessed potential gene transfer between the maize MZHG0JG and its close relative teosinte, and concluded that the spread of genes from occasional feral maize MZHG0JG plants in Europe will not differ from that of conventional maize varieties.

With respect to concerns about plant protection products (**recitals I** to **M),** 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 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

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

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.

Furthermore, with regards to the lacking support of the Member States for any authorising decision of GMOs for food and feed uses **(recitals N** and **O)** the Commission submitted a proposal to the Council and the Parliament on 14 February 2017 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.