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 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9
and sub-combinations MON 89034 × NK603 × DAS-40278-9,
1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9)

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

2. **Reference numbers:** 2019/2859(RSP) / B9-0171/2019 / P9_TA-PROV(2019)0056

3. **Date of adoption of the resolution:** 14 November 2019

4. **Competent Parliamentary Committee:** 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)** on the ground that the draft measure exceeds the implementing powers provided for in Regulation (EC) No 1829/2003 **(paragraph 1)** and that it is not compatible with the aim of that Regulation 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)**. 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)**, and calls on the Commission, in the meantime, to stop authorising genetically modified organisms (GMO) when no opinion is delivered by Member States in the Appeal Committee **(paragraph 5)**.

The resolution recalls that the genetically modified (GM) maize is tolerant to glyphosate, glufosinate, 2,4-D and quizalofop containing herbicides **(recital C)** 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 8)**. Furthermore, it calls on the Commission not to authorise any herbicide-tolerant GM plant without full assessment of the residues from spraying with complementary herbicides, metabolites and any combinatorial effects **(paragraph 6**), 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 7)**. The resolution calls on the Commission not to authorise any sub-combinations of stacked events unless they have been evaluated by European Food Safety Authority (EFSA) based on complete data submitted by the applicant (**paragraph 9**), 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 10**). 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 11)**. Finally, the resolution urges the Commission to treat the Union's obligations under international agreements, such as the Paris Climate Agreement, the UN Convention on Biological Diversity and the UN Sustainable Development Goals, as 'relevant provisions of Union

law' and/or 'legitimate factors' under Regulation (EC) No 1829/2003, and to communicate on how they have been taken into account in the decision-making process (**paragraph 12**).

The resolution recalls that the applicant provided no experimental data for 3 sub-combinations in the scope of the application (**recital F**). The resolution also recalls critical comments by Member States during the three-month consultation, including that EFSA risk assessment is not sufficient and failed to properly assess the overall safety of the GM stack maize **(recital G)**. The resolution also states that an independent study concludes that EFSA risk assessment is not acceptable, that more detailed investigation was needed because the GM maize showed differences in composition, and that EFSA should have requested chronic feeding studies, to properly assess potential combinatorial and cumulative effects **(recitals H** to **J)**.

The resolution mentions that that the use of glufosinate is no longer permitted in the Union **(recital N**), that questions concerning the carcinogenicity of glyphosate remain **(recital L**), and that according to EFSA, toxicological data on metabolites relevant to GM glyphosate-tolerant crops are missing **(recitals M** and **T)**. The resolution refers to studies raising concerns on the safety of 2,4-D and its metabolites in GM crops **(recital O).** The resolution mentions that it can be expected that residues from spraying with these herbicides will be present in the harvest **(recital K).** The resolution states that it is problematic that the assessment of herbicides and their residues is considered outside the remit of the EFSA GMO Panel, as the formation of metabolites, as well as their composition and toxicity, and possible combinatorial effects, can be driven by the genetic modification itself (**recitals P** and **Q**). The resolution concludes that the safety of the stacked GM maize and its sub-combinations for human and animal health is not demonstrated (**recital R**).The resolution also mentions that the assessment of potential interactions of herbicide residues and their metabolites with Bt proteins is not undertaken (**recital Z**).

The resolution recalls the voting results on the draft implementing decision in the Standing and Appeal Committees **(recital AA)**. 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, which is not democratic **(recital AB)**. Finally, the resolution recalls the numerous resolutions objecting to GMOs authorisations adopted by the European Parliament in its eight term (**recital AC**), and states that no change of law is required for the Commission not to authorise GMOs in the absence of qualified majority of Member States in favour in the Appeal Committee (**recital AD**).

6. Responses to the 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 MON 89034 × 1507 × NK603 × 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 × NK603 × DAS-40278-9, and sub-combinations, for food and feed uses in the EU was submitted by Dow AgroSciences Europe on 11 January 2013.
- EFSA performed a comprehensive risk assessment of the product and published on 16 January 2019 a favourable opinion concluding that the GM maize MON 89034 × 1507 × NK603 × DAS-40278-9 and its sub-combinations, as described in the application, are as safe as its non-

GM comparator and the tested non-GM reference varieties with respect to the potential effects on human and animal health and the environment.

- 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.
- 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 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 89034 × 1507 × NK603 × 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.

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 European Parliament and would like to make the following comments:

With respect to the concerns about plant protection products (**recitals K** to **R)**, 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 is assessed for its 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. However, herbicides and their respective maximum residue levels (MRLs), authorised under Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 respectively, apply to all the concerned products, whether GMO or not. In addition, the existing MRLs for glufosinate-ammonium based herbicides, whose approval for use has expired in the EU, remain fully applicable, 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 four single events, (ii) the 4-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

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

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 respect to the concerns expressed in **recital E** and **paragraph 12**, the Commission would like to explain that it in taking decisions, it takes into account the scientific evaluation of the highest possible standard, relevant provisions of the EU law and other legitimate factors relevant to the matter in consideration. The Commission is highly committed to respect international commitments in the field of the environment. However, it does not consider that an individual Commission decision authorising the placing on the market of a given genetically modified food and feed, which does not present risks to health or to the Union environment, is the appropriate tool to achieving the objectives set out by international instruments quoted in the resolution. The international commitments of the EU under the United Nations Convention on Biological Diversity, the 2030 Agenda for Sustainable Development and Paris Agreement on climate change, relate to diverse objectives encompassing environment, education, fight against poverty, energy, innovation and many others.

With regards to the lack of support by Members States for any authorising decision of GMOs for food and feed uses **(recitals AA** and **AB),** the Commission submitted a proposal to the European Parliament and Council 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 European 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.