**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 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Commission Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

1. **Resolution tabled pursuant to Rule 112(2) and (3) of the European Parliament's Rules of Procedure**
2. **Reference numbers:** 2020/2836 (RSP) / B9-0346/2020 / P9\_TA-PROV(2020)0291
3. **Date of adoption of the resolution:** 11 November 2020
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)** on the grounds 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 also calls not to authorise sub-combination of stacked genetically modified (GM) events unless they have been thoroughly evaluated by the European Food Safety Authority (EFSA) on the basis of complete data submitted by the applicant **(paragraph 10)** and considers that approving varieties, for which no safety data have been provided, runs contrary to the principles laid down in Regulation (EC) No 178/2002 **(paragraph 11)**.

The resolution recalls that the GM maize is tolerant to glyphosate-based herbicides and produces three insecticidal proteins **(recital B)** and calls 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 9)**. The resolution calls on EFSA to further develop methods that permit the identification of unintended effects of stacked GM events, such as in relation to the adjuvant properties of Bt toxins **(paragraph 12)**.

The resolution calls on the Commission not to authorise the import for food and feed uses of any GM plant, which has been made tolerant to a herbicide, until the health risks associated with the residues have been comprehensively investigated on a case-by-case basis **(paragraph 8),** and also not to authorise genetically modified organisms (GMOs) if no opinion is delivered by Member States in the Appeal Committee on the Food Chain and Animal Health **(paragraph 7)**.

The resolution welcomes that the Commission recognises the need to take into account sustainability for GMO authorisation **(paragraph 4)** and calls the Commission to move forward with the development of those criteria with the involvement of the European Parliament and to indicate its process and timeframe **(paragraph 5)**.

The resolution urges the Commission to take into account the Union’s obligations to the sustainable development goals and obligations under the Paris Climate Agreement and the UN Convention on Biological Diversity (CBD) **(paragraph 6).**

The resolution recalls that the risk assessment of the four single events and four sub-combinations of the stacked GM maize were used as a basis for the assessment of the four-event stacked GM maize and the remaining six sub-combinations **(recital C)** and that no experimental data was provided by the applicant for six sub-combinations of the stacked GM maize **(recital H).**

The resolution also recalls critical comments by the Member States during the three-month consultation, including that EFSA risk assessment is not sufficient and failed to assess properly the overall safety of the GM stack maize **(recital F)** and states that an independent study concludes that EFSA risk assessment is not acceptable, that the risk assessment does not fulfil requirements for assessing risks to the immune system **(recital G)**.

The resolution mentions potentially higher quantities of residues from spraying with glyphosate and that according to EFSA, toxicological data on metabolites relevant to GM glyphosate-tolerant crops are missing **(recitals I** and **L)**. The resolution mentions that questions concerning the carcinogenicity of glyphosate remain **(recital J**). It states that it is problematic that the assessment of herbicides and their residues, along with their potential interaction with Bt proteins, 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 **(recital M)**.

The resolution mentions that exposure to Bt proteins may affect the immune system and that some of the Bt proteins may have adjuvant properties **(recital N).** The resolution also mentions a minority opinion adopted by a member of the EFSA GMO Panel on another stack GM maize, regarding unintended effects on the immune system of Bt proteins **(recital O)**.

The resolution recalls the voting results on the draft implementing decision in the Standing Committee **(recital R)**. 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 problematic **(recital S)**. Finally, the resolution recalls the numerous resolutions objecting to GMO authorisations adopted by the European Parliament in its eighth term **(recital T)**, and states that no change of law is required for the Commission not to authorise GMOs in the absence of a qualified majority of Member States in favour in the Appeal Committee **(recital U)**.

1. **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 authorises the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and its sub-combination, 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:

* On 15 February 2016, Monsanto Europe S.A./N.V submitted to the Commission an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the authorisation for the placing on the market of GM maize MON 87427 × MON 89034 × MIR162 × NK603 and its sub-combinations for food/feed uses.
* On 9 July 2019, EFSA published a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829. It concluded that genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and its sub-combinations, as described in the application, is as safe as and nutritionally equivalent to its conventional counterpart and the tested non-genetically modified maize 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]](#footnote-1).
* The draft decision was voted on 15 September 2020 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 12 November 2020, 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, it does not exceed its implementing powers. Consequently, there are no reasons to withdraw the draft decision for the authorisation of the GM maize MON 87427 × MON 89034 × MIR162 × NK603 and its 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:

In relation to **recital H** 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 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 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 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, authorised under respectively Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005, apply to all the concerned products, whether GMO or not. As announced in the Farm to Fork Strategy, the EU will engage actively with trading partners, especially with developing countries, to accompany the transition towards the more sustainable use of pesticides to avoid disruptions in trade and promote alternative plant protection products and methods.

With respect to concerns raised in **recitals N** to **P**, the Commission would like to stress that EFSA GMO Panel has discussed extensively the potential allergenic and adjuvant capacity of some Cry proteins considering all available information, including literature on the topic, and the GMO Panel has not identified safety concerns.

With regards to the lack of support by the Members States for any authorising decision of GMOs for food and feed uses **(recitals R** and **S)**, 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, in relation to **paragraphs 4** and **5**, while the Commission reflects on a new approach that is aligned to the political ambition set by the European Green Deal and the Farm to Fork Strategy, it will continue processing outstanding applications for GM food and feed under existing rules and until a different approach based on sustainability considerations is designed.

1. <http://ec.europa.eu/food/plant/gmo/public_consultations/index_en.htm> [↑](#footnote-ref-1)