**Follow up to the European Parliament non-legislative resolution on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize Bt 11 (SYN-BTØ11) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

1. **Resolution tabled pursuant to Rules 112(2) and (3) of the European Parliament's Rules of procedure**
2. **Reference numbers:** 2021/2761 (RSP) / B9-0375/2021 / P9\_TA-PROV(2021)0336
3. **Date of adoption of the resolution:** 7 July 2021
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 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. the protection of human life and health, animal health and welfare, the environment and consumer interests (**paragraph 2**).

The resolution welcomes that the Commission recognises the need to take sustainability into account for the authorisation of genetically modified organisms (GMOs) and expresses its disappointment that the Commission proceeds with GMO authorisations for import despite ongoing European Parliament objections and a majority of Member States voting against (**paragraph 4**), and calls on the Commission to move forward with the development of sustainability criteriawith the involvement of the European Parliament and to indicate its process and timeframe (**paragraph 5**).

The resolution recalls that the genetically modified (GM) maize is tolerant to glufosinate-based herbicides (**recital C**) and 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**).Furthermore, it reiterates its call on the Commission not to authorise the import for food or feed uses of any GM plant tolerant to herbicide that is not authorised for use in the EU (**paragraph 7**).

The resolution further calls on the European Food Safety Authority (EFSA) to review aspects of its risk assessment (**paragraphs 8-10**).

The resolution urges the Commission to take into account the EU’s obligations under international agreements, such as the Paris Climate Agreement, the UN Convention on Biological Diversity (CBD) and the UN Sustainable Development Goals (**paragraph 11**).

The resolution highlights the amendments adopted by the European Parliament on 17 December 2020 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 182/2011 and calls on the Council to proceed with its work on this file as a matter of urgency, and states that the Commission should not authorise GMOs when there is no qualified majority of Member States in favour of the authorisation decision (**paragraph 12**).

The resolution recalls critical comments by the Member States during the three-month consultation, regarding the literature search and shortcomings in the monitoring reports submitted by the applicant (**recital Q**).

The resolution also mentions that glufosinate is classified as toxic and its approval in the EU expired in 2018 (**recital E**) and that due to increase weed resistance, the GM maize will be potentially exposed to a higher dose of glufosinate anda higherquantity of residues may be present in the harvest (**recital D**). 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, can be driven by the genetic modification itself (**recital F**).

The resolution also refers to potential toxicity and adjuvant properties of Bt proteins and insufficient EFSA risk assessments (**recitals H - K**).

The resolution recalls the voting results on the draft implementing decision in the Standing Committee (**recital T**). 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 GM food and feed authorisations, which is problematic (**recital U**). Finally, the resolution recalls the numerous resolutions objecting to GMOs authorisations adopted by the European Parliament in its eighth and ninth terms (**recital V**), 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 X**).

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

The Commission would like to recall that the draft implementing decision at stake renews the placing on the market of products containing, consisting of or produced from GM maize Bt 11, 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 prepared and adopted in line with the procedural steps set out in Regulation (EC) No 1829/2003 on GM food and feed, and in Regulation (EU) 182/2011 on comitology, as illustrated below:

* On 24 September 2018, Syngenta submitted to the Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation for the placing on the market of GM maize Bt 11 for food/feed and other uses, except for cultivation.
* On 13 January 2021, EFSA issued a favourable opinion for this renewal application and concluded that no new hazards or modified exposure, and no new scientific uncertainties were identified that would change the conclusions of its initial risk assessment on maize Bt 11.
* In its opinion of 2021, 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.
* There were no scientific comments received during this public consultation on this renewal.
* The draft decision was presented to the Standing Committee on 17 May 2021 and no qualified majority against or in favour was obtained by the written procedure on 1 June 2021.
* In accordance with the rules set in Regulation (EU) 182/2011 on comitology, the Commission proposed the draft Decision to the appeal committee on 6 July 2021 and no qualified majority against or in favour was obtained by the written procedure on 14 July 2021.

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 the renewal of GM maize Bt 11. Furthermore, following the submission of an application for renewal 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 Parliament and would like to make the following comments:

With respect to the concerns about plant protection products (**recitals D** to **G**), 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. The environmental risk assessment of active substances and plant protection products itself is in accordance with Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. The authorisation of GMOs is not linked to the authorisation of herbicides. However, herbicides and their maximum residue levels, authorised under Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005, respectively, apply to all the concerned products, whether GMO or not.

As regards the concerns expressed in **recital S**, 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. However, as announced in the EU 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.

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 GM food and feed, which does not present risks to health or to the EU 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 UN CBD, 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 arguments concerning the undemocratic decision-making and the lack of support by Members States for any GMO authorisation for food and feed uses (**recitals T** and**V**), the Commission submitted a proposal to the Council and the Parliament on 14 February 2017 to amend Regulation (EU) No 182/2011, changing the voting rules at the Appeal Committee. If adopted by co-legislators, it would increase transparency and accountability in the GMO decision-making process. In the meantime, it continues to apply the procedures laid down in Regulation (EU) 182/2011 on comitology and in Regulation (EC) No 1829/2003 on GM food and feed.

In conclusion, in relation to **paragraphs 4** and **5**, the Commission’s planned upcoming proposal on a framework for sustainable food systems will provide the opportunity to consider how regulatory mechanisms could take into account the potential of certain products to contribute the sustainability goals of the European Green Deal and the Farm to Fork Strategy. In the meantime, the Commission will continue processing the applications for GM food and feed under existing rules set out by the co-legislators, which provide for high standards of protection of human and animal health and the environment.