**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 cotton GHB811
(BCS-GH811-4), 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 number:** 2021/3057 (RSP) / B9-0126/2022 / P9\_TA PROV(2022)0062

**3. Date of adoption of the resolution:** 9 March 2022

**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 recalls that the genetically modified (GM) cotton is tolerant to glyphosate-based herbicides and to hydroxyphenylpyruvate dioxygenase (HPPD) inhibiting active substances (**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 4**).

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 5**).

The resolution further calls on the European Food Safety Authority (EFSA) to request additional data for risk assessment (**paragraph 6**).

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 and the UN Sustainable Development Goals (**paragraph 7** and **recitals M** to **Q**).

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 (EC) 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 (**paragraph 8**).

The resolution recalls critical comments by Member States during the three-month consultation, regarding the comparative analysis and toxicology (**recital L**).

The resolution mentions that isoxaflutole is classified as toxic and that, while HPPD-inhibitors encompass a range of herbicides (including mesotrione), only isoxaflutole was used on the GM cotton for the purpose of the risk assessment and that mesotrione may be considered to have endocrine disrupting properties according to EFSA (**recital I**). The resolution also mentions that glyphosate is classified as probably carcinogenic to humans by the International Agency for Research on Cancer, while EFSA concluded it was unlikely to be carcinogenic (**recital G**) and that potentially higher quantity of residues from spraying with glyphosate and HPPD inhibitor herbicides may be present in the harvest (**recital F**). 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 K**).

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 (**recital S)**. Furthermore, the resolution recalls the numerous resolutions objecting to GMO authorisations adopted by the European Parliament in its eighth and ninth terms (**recital T**), 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 V**).

**6. 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 authorises the placing on the market of products containing, consisting of or produced from GM cotton GHB811 (BCS-GH811-4), but not the cultivation of this cotton.

With respect to **paragraphs 1** to **3**, as well as **Recital L** of the resolution, the Commission would like to point out that the draft decision has been prepared in line with and has undergone the procedural steps set out in Regulation (EC) No 1829/2003 on GM food and feed and in Regulation (EU) No 182/2011 on comitology, as illustrated below:

* On 19 September 2018, BASF Agricultural Solutions Seed US LLC submitted an application to the national competent authority of Germany in accordance with Articles 5 and 7 of Regulation (EC) No 1829/2003 for the authorisation of the placing on the market of GM cotton GHB811 for food/feed and other uses, except of cultivation.
* On 16 August 2021, EFSA published a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that GM cotton GHB811, as described in the application, is as safe as its conventional counterpart and the tested non-genetically modified cotton reference varieties with respect to the potential effects on human and animal health and the environment.
* 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.
* The public comments on the EFSA opinion and all scientific comments received were scrutinised by EFSA[[1]](#footnote-1).
* The draft decision was presented to the Standing Committee on 17 December 2021, with the outcome of no qualified majority against or in favour, by written procedure on 11 January 2021.
* In accordance with the rules set in Regulation (EU) No 182/2011 on comitology, the Commission presented the draft decision to the Appeal Committee on 10 February 2022, with no qualified majority against or in favour by written procedure on 21 February 2022.

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 authorisation of GM cotton GHB811. 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. As a result, the Commission adopted on 31 March 2021 the decision authorising the placing on the market of products containing, consisting of or produced from GM cotton GHB811.

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 theses 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 plan protection products (**recitals E** to **K** and **paragraph 4**), 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 is done in accordance with Regulation (EC) No 1107/2009 concerning the placing of plant production products on the market. The authorisation of GMOs is not linked to the authorisation of herbicides. The authorisation for herbicides and their respective ‘maximum residue levels’ under, respectively, Regulation (EC) No 1107/2009 and Regulation (EC) No 369/2005, apply to all the concerned uses whether GMO or not. 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 Farm to Fork Strategy, the EU will engage actively with trading partners, especially with developing countries, to accompany the transition towards a more sustainable use of pesticides to avoid disruptions in trade and promote alternative plant protection products and methods.

In relation to **paragraph 5**, the overall objective of the Commission’s upcoming proposal on a framework for sustainable food systems is to ensure that all foods placed on the EU market increasingly become sustainable. According to the action plan that accompanied the Farm to Fork strategy, the timing for this proposal is before the end of 2023. In the meantime, the Commission will continue assessing the submitted applications for genetically modified food and feed under the existing rules set out by the co-legislators, which provide for high standards of protection of human and animal health and the environment.

In relation to **paragraph 6**, the Commission would like to stress that the EFSA GMO Panel performed a very comprehensive risk assessment of this new GM cotton and concluded positively with respect to its potential effects on human and animal health, and the environment.

The Commission considers that it takes into account a scientific evaluation of the highest possible standard, relevant provisions of the EU law and other legitimate factors relevant to the matter in consideration in its decisions. Furthermore, regarding the concerns expressed in **paragraph 7** and **recitals M** to **Q**, 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 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 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.

Finally, with regards to the arguments concerning the decision-making process and the lack of support by Member States for any GMO authorisation for food and feed uses (**recitals R** to **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, the Commission continues to apply the procedures laid down in Regulation (EU) No 182/2011 on comitology and in Regulation (EC) No 1829/2003 on GM food and feed.

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