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 cotton LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Genetically modified cotton LLCotton25 (ACS-GHØØ1-3))

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

2. **Reference numbers:** 2019/2856(RSP) / B9-0170/2019 / P9_TA-PROV(2019)0054

3. **Date of adoption of the resolution:** 14 November 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)** 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) cotton is tolerant to glufosinate-based herbicides **(recital E)** 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)**.

Finally, the resolution urges the Commission to treat the Union's obligations under international agreements, such as the Paris Climate Agreement, the United Nations (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 9**).

The resolution recalls critical comments by Member States during the three-month consultation, regarding the monitoring reports produced by the applicant, and the allergenicity and toxicology assesment **(recital G)**.

The resolution also mentions that the use of glufosinate is no longer permitted in the Union **(recital J**) and that potentially higher quantity of residues from spraying with glufosinate will be present in the harvest **(recital I)**. The resolution states that it is problematic that the assessment of herbicides and

their residues is considered outside the remit of the European Food Safety Authority (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 refers to EFSA finding that the estimated operator exposure to glufosinate when used for weed control in GM maize exceeded the acceptable operator exposure level, even when personal protective equipment was used (**recital N**). The resolution also refers to a recent report by the United Nation's Special Rapporteur on the right to food stating that hazardous pesticides have catastrophic impacts on health, with pesticides responsible for an estimated 200 000 acute poisoning deaths each year, 99 per cent of which occur in developing countries **(recital O)**.

The resolution recalls the voting results on the draft implementing decision in the Standing and Appeal Committees **(recital P)**. 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 Q)**. Finally, the resolution recalls the numerous resolutions objecting to GMOs authorisations adopted by the European Parliament in its eight term (**recital R**), 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 S**).

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 renewal of placing on the market of products containing, consisting of or produced from genetically modified cotton LLCotton25, but not the cultivation of this cotton.

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 2 October 2017, the initial authorisation holder, Bayer CropScience AG, submitted to the Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for renewal of the authorisation for the placing on the market of GM cotton LLCotton25 for food/feed uses.
- On 14 November 2018, EFSA published a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that the renewal application did not contain evidence for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton LLCotton25, adopted by EFSA in 2006.
- In its opinion of 2018, 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.

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

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 renewal of the authorisation of the GM cotton LLCotton25. 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 I** to **O)**, 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.
- With respect to the concerns expressed in **recital D** and **paragraph 9**, the Commission would like to explain that it in its 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 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.
- With regards to the lack of support by Members States for any authorising decision of GMOs for food and feed uses **(recitals P** and **Q),** 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.