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 soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Genetically modified soybean A2704-12 (ACS-GMØØ5-3))

- 1. Resolution tabled pursuant to Rule 112(2) and (3) of the European Parliament's Rules of procedure
- 2. **Reference numbers:** 2019/2828 (RSP) / B9-0105/2019 / P9_TA-PROV(2019)0029
- 3. Date of adoption of the resolution: 10 October 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), based on the grounds that the draft implementing decision at stake exceeds the implementing powers provided for in Regulation (EC) No 1829/2003 (paragraph 1) and that it is not compatible with the aim of Regulation (EC) No 1829/2003 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). In addition, the resolution calls on the Commission to suspend any implementing decision regarding authorisation of genetically modified organisms (GMO) until the authorisation procedure has been revised in such a way as to address the shortcomings of the current procedure, which has proven to be inadequate (paragraph 5). The resolution also calls for withdrawing proposals for GMO authorisations if no opinion is delivered by the Standing Committee (paragraph 6). 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).

The resolution calls on the Commission not to authorise the import for food or feed uses of any genetically modified (GM) plant tolerant to a herbicide that is not authorised for use in the Union, in this case glufosinate (**paragraph 9**). Furthermore, the resolution calls on the Commission not to authorise any herbicide-tolerant GM plants without full assessment of the residues from spraying with complementary herbicides, metabolites and commercial formulations, as applied in the countries of cultivation (**paragraph 7**). The resolution calls on the Commission 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 whether the GM plant concerned is to be cultivated in the Union or imported into the Union for food and feed uses (**paragraph 8**).

The resolution reiterates the European Parliament's alarm at the fact that the Union's high dependence on imports of animal feed in the form of soybeans causes deforestation in third countries (**paragraph 11**). The resolution calls on the Commission not to authorise the import of GM soybeans, unless it can be shown that their cultivation did not contribute to deforestation (**paragraph 12**).

The resolution refers to Regulation (EC) No 1829/2003, which states that GM food or feed must not have adverse effects on human health, animal health or the environment, and requires the Commission to take into account any relevant provisions of Union law and other legitimate factors relevant to the matter under consideration when drafting its decision. The resolution states that these legitimate factors should include the Union's obligations under the 2030 Agenda for Sustainable Development, the Paris Agreement on climate change and the United Nation Convention on Biological Diversity (CBD) (recital L and paragraph 13). The resolution also refers to a recent report by the United Nation's Special Rapporteur on the right to food stating that, particularly in developing countries, hazardous pesticides have catastrophic impacts on health and the potential to lead to human rights abuses against farmers and agricultural workers, communities living near agricultural lands, indigenous communities, and pregnant women and children (recital M).

The resolution recalls the voting results on the draft implementing decision in the Standing Committee on the Food Chain and Animal Health and the Appeal Committee (**recital T**). The resolution recalls that the return of the draft authorisation 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 and that this is not democratic. Finally, the resolution recalls the number of resolutions objecting to GMOs authorisations adopted by the Parliament in its eight term (**recital V**).

6. 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 at stake authorises the renewal of placing on the market of products containing, consisting of or produced from genetically modified soybean A2704-12, but not the cultivation of this soybean.

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 29 August 2017, 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 soybean A2704-12 for food/feed uses.
- On 14 January 2019, the European Food Safety Authority (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 soybean A2704-12, adopted by the Authority in 2007.
- In its opinion of 2019, EFSA considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- The public commented on the EFSA opinion and all the scientific comments received were scrutinised by EFSA¹.

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

- The draft Decision was voted on 11 June 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 12 July 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 renewal of the authorisation of the GM soybean A2704-12. 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.

At the meeting of the Environment, Public Health and Food Safety Committee of the Parliament on 25 September 2019, the Commission extensively explained the state of play of the authorisation procedure and why it had not exceeded its implementing powers. At the plenary session of the Parliament on 9 October 2019, the Commission participated in the debate on authorisation of GMOs and explained how it processes authorisations for placing on the market of GMOs in full compliance with the EU legislation and in full respect of the scientific assessment performed by EFSA.

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 specific concerns raised in recitals G to I of the resolution, 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 are assessed for their 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. Herbicides are authorised by the procedures set out in Regulation (EC) No 1107/2009, and Regulation (EC) No 396/2005 on maximum residue levels (MRLs). In addition, the existing MRLs for glufosinate-ammonium based herbicides remain fully applicable after the expiry of approval of glufosinate in the EU, 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 authorization of herbicides.

With respect to the concerns expressed in **recitals L, N, O, P, Q,** and **S**, the Commission would like to explain that it takes its decision taking 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.

At this point, the Commission would like to recall that, at present, the volume of imports of soybean depends on the high protein feed demand in the EU. In this regard, a reflection on possible action based on the report of the Commission on the development of plant proteins in the EU of November 2018 has been launched.

With regard to deforestation, in its Communication on Stepping up EU Action to Protect and Restore the World's Forests of 23 July 2019², the Commission proposed a framework of actions to reinforce the EU's contribution to the protection of forests, in particular primary forests in tropical countries, and regenerate forests in a sustainable and responsible way at the global level. The actions proposed include reducing the EU consumption footprint on land and encouraging the consumption of products from deforestation-free supply chains in the EU. In particular, the Commission will encourage the strengthening of standards and certification schemes that help to identify and promote deforestation-free commodities through, among other things, studies on their benefits and shortcomings and by developing guidance, including assessment based on certain criteria to demonstrate the credibility and solidity of different standards and schemes. The Commission will also assess additional demand side regulatory and non-regulatory measures to ensure a level playing field and a common understanding of deforestation-free supply chains, in order to increase supply chain transparency and minimise the risk of deforestation and forest degradation associated with commodity imports in the EU.

Furthermore, with regards to the lacking support of the Member States for any authorising decision of GMOs for food and feed uses (**recitals T** and **U**) the Commission submitted a proposal to the Council and the Parliament on 14 February 2017 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 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.

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² EU Communication on stepping up EU action to protect and restore the world's forests, COM(2019) 352 final.