Follow up to the European Parliament non-legislative resolution on the draft Commission implementing decision amending Implementing Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

1. **Resolution tabled pursuant to Rule 106(2) and (3) of the European Parliament's Rules of Procedure**

2. **Reference numbers:** 2019/2521 (RSP) / B8-0073/2019 / P8_TA-PROV(2019)0057

3. **Date of adoption of the resolution:** 31 January 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)**. The resolution also calls for withdrawing proposals for genetically modified organisms (GMO) authorisations if no opinion is delivered by the Standing Committee **(paragraph 9)**. In addition, the resolution calls on the Commission to suspend any implementing decision regarding authorisation of genetically modified organisms 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 8)**. 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 7)**. The resolution calls to not authorise the import, for food or feed, of any genetically modified plant which has been made tolerant to a herbicide which is not authorised for use in the Union, in this case glufosinate **(paragraph 4)**. The resolution also calls to not authorise any herbicide-tolerant genetically modified (GM) plant without full assessment of the residues from spraying with complementary herbicides, metabolites and commercial formulations as applied in countries of cultivation **(paragraph 5)** 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 6)**.

The resolution refers to amending Decision 2013/327/EU to cover the scope of products in one decision and questions the legitimacy of such an approach **(recital D)**.

The resolution refers to the comments, e.g. on the monitoring approach and concerns related to the metabolite N-acetyl-glufosinate, that were submitted by the Member States **(recitals E and K)**. The resolution points out that the GM oilseed rapes are resistant to glufosinate **(recital F)** and that the use of glufosinate is no longer permitted in the Union **(recital H)**. The resolution also states that it can be expected that the herbicide-resistant plants will be exposed to higher and repeated doses of the complementary herbicide, which will lead to a higher

burden of residues and influence the composition of the GM plant and its agronomic characteristics **(recital G)**, and that information on residue levels of herbicides and their metabolites is essential for the risk assessment of herbicide-tolerant GM plants **(recital I)**. The resolution also points out that the Member States are not required to measure glufosinate residues on oilseed rape imports in order to ensure compliance with maximum residue levels as part of the coordinated multiannual control programme of the Union for 2019, 2020 and 2021 **(recital J)**.

The resolution recalls the voting results on the draft implementing decision in the Standing Committee **(recital L)**. 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 and that this is not democratic **(recital M)**. Finally, the resolution recalls the rejection by the Parliament of the Commission's legislative proposal of 22 April 2015 amending Regulation (EC) No 1829/2003, and the Parliament's call on the Commission to withdraw that proposal and submit a new one **(recital N)**.

6. Responses to requests and overview of actions taken, or intended to be taken, by the Commission:

The Commission would like to explain that the draft implementing decision at stake authorises the renewal of the placing on the market of feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3, pursuant to Regulation (EC) No 1829/2003.

With respect to **paragraphs 1 to 3 and paragraphs 8 and 9** 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 20 May 2016, Bayer CropScience AG submitted to the Commission an application, in accordance with Article 11 and Article 23 of Regulation (EC) No 1829/2003, for the renewal of the authorisation for the placing on the market of the products covered by Decision 2007/232/EC;
- on 28 November 2017, the European Food Safety Authority (EFSA) issued 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 oilseed rapes Ms8, Rf3 and Ms8 × Rf3, adopted by EFSA in 2005;
- in its opinion of 28 November 2017, EFSA considered all the comments 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 draft decision was voted on 3 December 2018 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 14 January 2019, where no qualified majority against or in favour was obtained either.

The Commission, therefore, considers that by adopting a decision, which 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 oilseed rapes Ms8, Rf3 and Ms8 × Rf3. 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 Committee on Environment, Public Health and Food Safety of the European Parliament on 22 January 2019, the Commission extensively explained the state of play of the authorisation procedure and why it had not exceeded its implementing powers.

With respect to the **other points 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 raised in **recital D**, the Commission would like to point out that the different uses of oilseed rapes are merged into a single authorisation for simplification and that all these uses are subject to the conditions of authorisation set out in Implementing Decision 2013/327/EC;
- with respect to the specific concern raised in **recital J**, the Commission would like to mention that, in addition to the Multi-Annual Control Programme of the Union for pesticide residues required by Article 29 of Regulation (EC) 396/2005, and as provided for by Article 15(1) of Regulation 882/2004, Member States are also obliged to establish multi-annual National Control Plans. It is therefore the responsibility of the Member States to evaluate the potential risk of those herbicides on imported oilseed rape, and to define their National Control Plan accordingly;
- with respect to concerns raised in **recitals G and I and paragraphs 4 to 6**, 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 crop is focused on the potential impact of the genetic modification on human and animal health and on the environment. The risk assessment and authorisation of herbicides is subject to the procedures set out in Regulation (EC) No 1107/2009, and the maximum residue levels (MRLs) are set under Regulation (EC) No 396/2005. Additionally, the Commission points out that the potential influence of herbicides on the composition of herbicide-tolerant GM crops is taken into account in EFSA's risk assessment because GM crops sprayed with the intended herbicides are assessed for potential changes in composition, agronomic and phenotypic characteristics. In case of significant changes, additional studies, including toxicity studies, would be required, on a case-by-case basis, during the risk assessment;
- with respect to concerns raised in **recital K**, the Commission would like to point out that the metabolite N-acetyl-glufosinate is explicitly included in the residue definition for the calculation of the MRL for glufosinate-ammonium;
- with regards to the lacking support of Members States for any authorising decision of GMOs for food and feed uses **(recitals L and M)** the Commission submitted a proposal to the Council and the European Parliament 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;

- with regards to the comments in **recital N** on the Commission legislative proposal for a regulation amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, the Commission would like to recall that it regrets the decision of the European Parliament of 28 October 2015 to reject the proposal. The Commission maintains its original proposal, 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.