**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 soybean MON 87751 (MON-87751-7), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

1. **Resolution tabled pursuant to Rules 106(2) and (3) of the European Parliament's Rules of Procedure**
2. **Reference numbers:** 2019/2603 (RSP) / B8-0216/2019 / P8\_TA-PROV(2019)0313
3. **Date of adoption of the resolution:** 27 March 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 states that Bt proteins have adjuvant properties and that Bt protein can enhance the immune system response of plant allergens produced from soybean **(recital D)** The resolution also recalls that 28-day repeated dose toxicity studies with mice were performed, one with Cry1a.105 and one with Cry2Ab2 **(recital H)**. The resolution states that those studies did not emulate exposure under practical condition **(recital I)** and that two toxicity studies do not fully comply with the requirements of the Organisation for Economic Co-operation and Development (OECD) **(recital J)**.

The resolution also states that many statistically significant differences in the 90-day feeding study should have been examined further, according to a Member State competent authority **(recital K)**. The resolution states its disagreement with the European Food Safety Authority (EFSA) assessment of the 90-day toxicity study with rats because the study did not use two different dosages of test material as required by Implementing Regulation (EU) 503/2013 **(recital L)** and with the use of defatted soybean meal as test material while soymilk was identified as main contributor in human diets **(recital M)**.

The resolution recalls the voting results on the draft implementing decision in Standing Committee on the Food Chain and Animal Health **(recital R)**. 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 it is not democratic **(recital S)**. 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 T)**.

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

The Commission would like to explain that the draft implementing decision at stake authorises the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87411, but not the cultivation of this soybean.

With respect to **paragraphs 1 to 5** 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:

* Application for the authorisation of GM soybean MON 87751 for food and feed uses in the EU was submitted by Monsanto Company on 26 September 2014.
* EFSA performed a comprehensive risk assessment of the product and published on 2 August 2018 a favourable opinion concluding that genetically modified (GM) soybean MON 87751 is as safe as and is nutritionally equivalent to its non-genetically modified comparator and other tested non-GM commercial varieties.
* In its opinion, 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]](#footnote-1).
* The draft decision was voted on 7 March 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 11 April 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 authorisation of the GM soybean MON 87751. 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 European Parliament on 14 March 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 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 concerns raised in **recitals D, E, F and G**, the Commission would like to stress that EFSA GMO Panel has discussed extensively the potential allergenic and adjuvant capacity of some Cry proteins considering all available information, including literature on the topic, and the GMO Panel has not identified safety concerns (for allergenicity, nor adjuvanticity). As soybean is considered to be a common allergenic food, EFSA carefully assessed potential changes in the GM soybean endogenous allergenicity, linked to the GM event, according to Implementing Regulation (EU) 503/2013 and its guideline. Based on the submitted mandatory studies, two additional studies also provided by the applicant, and on the current scientific knowledge EFSA concluded that there is no evidence of change in overall allergenicity of the GM soybean compared to its conventional counterpart.
* With respect to concerns raised in **recitals H, I and J**, the Commission would like to stress that both Cry proteins were already assessed by the GMO Panel (in the context of another application, maize MON 89034), which did not identify safety concerns for humans and animals health. In addition, EFSA carefully assessed all new data received from the applicant and concluded that no adverse effects are observed in mouse fed with each Cry protein.
* With respect to concerns raised in **recitals K, L and M**, the Commission would like to stress that ESFA performed a careful and complete assessment of the 90-day feeding study, according to Implementing Regulation (EU) 503/2013, and its own guideline documents. EFSA carefully assessed the statistically significant differences observed between the control and test groups and concluded that those observations are not an adverse effect as those differences are either minimal or not correlated by other endpoints.
* With regards to the comments in **recital T** on the Commission legislative proposal for a regulation amending Regulation (EC) No 1829/2003, 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.
* Furthermore, with regards to the lacking support of Members States for any authorising decision of GMOs for food and feed uses **(recital R)** the Commission submitted a proposal to the Council and the European 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.
* 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.
1. <http://ec.europa.eu/food/plant/gmo/public_consultations/index_en.htm> [↑](#footnote-ref-1)