**Follow up to the European Parliament non-legislative resolution of 24 October 2017 on   
the draft Commission implementing decision authorising the placing on the market   
of products containing, consisting of, or produced from genetically modified soybean**

**305423 × 40-3-2 (DP-3Ø5423-1 × MON-Ø4Ø32-6) pursuant to Regulation (EC)   
No 1829/2003 of the European Parliament and of the Council   
on genetically modified food and feed**

**2017/2906 (RSP)**

**1. Resolution tabled pursuant to Rule 106(2) and (3) of the European Parliament's Rules of procedure by the Committee on Environment, Public Health and Food Safety (ENVI)**

**2. EP reference number:** B8-0570/2017 / P8\_TA-PROV(2017)0397

**3. Date of adoption of the resolution:** 24 October 2017

**4. Subject:** Placing on the market of genetically modified soybean 305423 × 40-3-2 products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

**5. Competent Parliamentary Committee:** Committee on Environment, Public Health and Food Safety (ENVI)

**6. 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 applications for 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 it argues has proven to be inadequate (**Paragraph 4**). The resolution also calls on the legislators responsible to advance work on the Commission proposal amending Regulation (EU) No 182/2011 as a matter of urgency and to ensure that, inter alia, if no opinion is delivered by the Food Chain and Animal Health Standing Committee with respect to Genetically Modified Organisms (GMOs) approvals, the Commission will withdraw the proposal (**Paragraph 5**). Furthermore, the resolution calls on the Commission not to authorise any herbicide-tolerant genetically modified plants without full assessment of the specific cumulative effects of the residues from spraying with the complementary herbicides, and their commercial formulations, as applied in the countries of cultivation(**Paragraph 6**). In addition, the resolution calls on the Commission to request much more detailed testing of the health risks related to this stacked soybean (**Paragraph 7**). Finally, the resolution calls on the Commission to integrate the risk assessment of the application of the complementary herbicides and their residues into the risk assessment of herbicide-tolerant genetically modified plants (**Paragraph 9**), and to develop strategies for health risk assessment and toxicology, as well as post-market monitoring, that target the whole food and feed chain **(Paragraph 8**).

The resolution recalls the voting results on the draft Implementing Decision in Standing Committee (14 September 2017) (**Recital R**), and recalls the fact that the genetically modified soybean is tolerant to glyphosate-based herbicides and Aceto Lactate Synthase (ALS)-inhibiting herbicides and has an altered oil composition (**Recital D**). Furthermore, the resolution recalls that questions on the carcinogenicity of glyphosate remain and that gaps were identified in the risk assessment of one substance acting as ALS inhibitor (**Recitals I and L**).

The resolution also recalls that the return of the draft authorising decisions to the Commission for final decision, after not being supported by the Standing Committee on the Food Chain and Animal Health, has become the norm for decision-making on genetically modified food and feed authorisations (**Recital S**). The resolution further states that the Commission proposal to amend Regulation (EU) No 182/2011 is not sufficient in terms of addressing the lack of democracy in the GMO authorisation process, and suggests that when no opinion is delivered by the Food Chain and Animal Health Standing Committee, the Commission authorising decision should be withdrawn, a procedure which exists for some other standing committees (**Recitals V and W**). Furthermore, the resolution recalls the rejection by the Parliament of the Commission 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**).

**7. Responses to the EP 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 placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 × 40-3-2, pursuant to Regulation (EC) No 1829/2003.

With respect to **Paragraphs 1 to 4** of the resolution, the Commission would like to point out that the draft Implementing Decision for placing on the market of genetically modified soybean 305423 × 40-3-2 products has been processed in line with the procedural steps set out in Regulation (EU) No 182/2011 on comitology and Regulation (EC) No 1829/2003 on genetically modified food and feed, as illustrated below:

* + On 20 September 2007, Pioneer Overseas Corporation submitted to the competent authority of the Netherlands, an application for placing on the market of soybean 305423 × 40-3-2 for food/ feed uses.
  + The European Food Safety Authority (EFSA) performed a comprehensive risk assessment of the product, asking for additional scientific data compliant with its standards when needed, and published on 18 August 2016 a favourable opinion on this application, in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. EFSA concluded that genetically modified soybean 305423 × 40-3-2, as described in the application, is as safe as its conventional counterpart.
  + 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.
  + The draft Decision was voted on 14 September 2017 in the Standing Committee with no qualified majority against or in favour.
  + In accordance with the rules set in Regulation (EU) No 182/2011 on comitology, the Commission proposed the draft Decision to the Appeal committee of 19 October 2017, 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 authorisation of the GM soybean 305423 × 40-3-2. Furthermore, following the submission of an application and the respective opinion of the Authority, 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. Therefore, 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 specific concerns raised in **Recitals I-L** of the resolution as regards the fact that soybean 305423 × 40-3-2 is tolerant to glyphosate-based herbicides and ALS-inhibiting herbicides, the Commission would like to mention that the design of the field trials performed for this GM soybean involved the spraying with its respective intended herbicides. In addition, the Commission would like to point out that the risk assessment and authorisations of these herbicides and their residues are 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. These rules are applicable to all relevant crops and products whether they are GM or not, including this GM soybean. Likewise, future decisions concerning the authorisation/ renewal of the aforementioned herbicides and their MRL would also be applicable to this GM soybean. Based on the EFSA opinion, the intended use of soybean 305423 × 40-3-2 is safe and fully compliant with the requirements of the solely relevant Regulation (EC) No 1829/2003 for GMO authorisations.

* With respect to the voting results in the Standing Committee on 14 September 2017 (**Recital R**), the Commission would like to underline that the regular voting pattern – where Member States do not reach an opinion on GM food and feed authorisations – is the underlying factor of the Commission's legislative proposal, which once adopted by the co-legislators, would allow Member States to restrict or prohibit the use of GM food and feed on their territory, for reasons other than safety.
* With regards to the call in **Recital T** on the Commission to submit a new legislative proposal, the Commission would like to recall that it regrets the decision of the European Parliament of 28 October 2015 to reject the legislative proposal, in particular because it precisely aims at "*[taking] into account frequently expressed national concerns which do not only relate to issues associated with the safety of GMOs for health or the environment*". The Commission therefore maintains its original proposal, which, if adopted, would enable Member States to restrict or ban the use of GM food and feed, after the Commission has issued its decision, on the basis of national considerations.
* Furthermore, with regards to the lack of support of Members States for any authorising decision of GMOs for food and feed uses (**Recital S**), the Commission submitted a proposal (COM(2017) 85) 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 the 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.