**Follow up to the European Parliament non-legislative resolution of 30 May 2018
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 maize GA21 (MON-ØØØ21-9) pursuant
to Regulation (EC) No 1829/2003 of the European Parliament and of the Council
on genetically modified food and feed**

**2018/2698 (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**

**2. EP reference number:** B8-0232/2018 /P8\_TA-PROV(2018)0221

**3. Date of adoption of the resolution:** 30 May 2018

**4. Subject:** Renewal of the authorisation for placing on the market of genetically modified maize GA21 products

**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 this draft Implementing Decision 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 until the authorisation procedure has been revised in such a way as to address the shortcomings of the current procedure, which it states has proven to be inadequate (**Paragraph 4**). The resolution reiterates the Parliament’s commitment to advancing work on the Commission proposal amending Regulation (EU) No 182/2011 in order to ensure that, inter alia, if no opinion is delivered by the Standing Committee on the Food Chain and Animal Health with respect to the approvals of genetically modified organisms (GMOs), the Commission will withdraw the proposal; it also calls on the Council to move forward with its work on that Commission proposal as a matter of urgency (**Paragraph 8**). Furthermore, the resolution calls on the Commission not to authorise any herbicide-tolerant genetically modified plants without full assessment of the residues from spraying with the complementary herbicides, and their commercial formulations, as applied in the countries of cultivation (**Paragraph 6**). Moreover, 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, regardless of whether the genetically modified plant concerned is to be cultivated in the Union or for import for food and feed (**Paragraph 7**). Finally, the resolution calls on the Commission to uphold its commitments under the UN Convention on Biological Diversity by suspending all imports of glyphosate-tolerant genetically modified plants **(Paragraph 5)**.

The resolution recalls the fact that the genetically modified maize is tolerant to glyphosate (**Recital E**). The resolution states that questions concerning the carcinogenicity of glyphosate remain (**Recital J**), refers to risks and negative impacts of the use of glyphosate on biodiversity (**Recital R**) and recalls the fact that the Parliament has established a special committee on the Union’s authorisation procedure for pesticides (**Recital K**). The resolution recalls that conclusions on the safety of residues from spraying genetically modified crops with glyphosate formulations cannot be drawn, and that additive and mixtures used in commercial formulations can show a higher toxicity than glyphosate alone (**Recital L**). The resolution states that herbicide-tolerant genetically modified crops result in a higher use of complementary herbicides than their conventional counterparts (**Recital F**), and that this re-authorisation decision will continue to create demand for cultivation of maize GA21 in third countries (**Recital S**). The resolution mentions that it is expected that this maize will be exposed to higher and repeated doses of glyphosate, leading to a higher burden of residues in the harvest, and that the herbicide may also influence the composition of the plant and its characteristics (**Recital G**). The resolution states that the impacts of spraying maize GA21 with glyphosate have not been assessed (**Recital N**). The resolution recalls that Member States are not currently required by the Commission to measure glyphosate residues on maize imports in order to ensure compliance with maximum residue levels as part of the coordinated multiannual control programme for 2018, 2019 and 2020 (**Recital O**). The resolution recalls that Member States submitted critical comments during the consultation on the application (**Recital H**), and the fact that the GMO Panel considers that further discussion is needed on the practical implementation of the post-marketing environmental monitoring plans (**Recital I**).

The resolution recalls that the Union has signed up to the UN’s Sustainable Development Goals (SDGs), which includes a commitment to reduce the number of deaths and illnesses from hazardous chemicals, and air, water and soil pollution and contamination (**Recital P**). Furthermore, the resolution recalls that the Commission is committed to Policy Coherence for Development (**Recital Q**) and that the Union is party to the UN Convention on Biological Diversity (**Recital T**).

The resolution recalls the voting results on the draft Implementing Decision in the Standing Committee (**Recital V**). Furthermore, the resolution states 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 and that this is not democratic (**Recital W**). 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 X**).

**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 this draft Implementing Decision authorises the renewal of the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21, 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 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 6 October 2016, Syngenta Crop protection NV/SA 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 maize GA21 for food/ feed uses.
* Based on the data provided, EFSA concluded that no new hazards or modified exposure and no new scientific uncertainties were identified that would change the conclusions of the original risk assessment on maize GA21. EFSA published on 4 October 2017 a favourable opinion on this application, in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003.
* 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 had the opportunity to comment on the EFSA opinion, but no scientific comments have been made on this opinion.
* The draft Decision was voted on 23 April 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 15 May 2018, 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 maize GA21. Furthermore, following the submission of an application and the respective opinion of EFSA, Articles 7(3) and 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 16 May 2018, the Commission extensively explained the state of play of the authorisation procedure, including 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 the specific concern raised in **Recitals J, L and R** 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 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
* Regarding **Recital N**, the Commission would like to stress that, during the risk assessment, herbicide-tolerant crops sprayed with the intended herbicide(s) are assessed and checked for intended and unintended effects regarding composition, agronomic and phenotypic characteristics.
* Regarding the Sustainable Development Goals (SDGs) (**Recital P**), the EU has played an active role throughout the process and is committed to implementing the 2030 Agenda for Sustainable Development and the SDGs within the EU and in development cooperation with partner countries. All countries, developed and developing alike, have a shared responsibility to achieve the SDGs.
* With respect to the comments in **Recitals S and T**, the Commission would like to underline that the decision on whether to allow cultivation of GMOs in a third country is sovereign and exclusive to that country.
* With regards to the comments in **Recital T** 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.
* Furthermore, with regards to the lack of support of Members States for any authorising decision of GMOs for food and feed uses (**Recital X**), 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.