

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 cotton GHB614 × LLCotton25 × MON 15985 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:** 2019/2524 (RSP) / B8-0076/2019 / P8_TA-PROV(2019)0060
- 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 2**), based on the ground that the draft implementing decision at stake exceeds the implementing powers provided for in Regulation (EC) No 1829/2003 (**paragraph 1**). The resolution calls to not authorise the import, for food or feed, of any genetically modified (GM) plant which has been made tolerant to a herbicide which is not authorised for use in the Union, in this case glufosinate (**paragraph 3**). The resolution calls to not authorise any herbicide-tolerant GM plant without full assessment of the residues from spraying with complementary herbicides, metabolites and commercial formulations as applied in countries of cultivation (**paragraph 4**), 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 5**). The resolution also calls to not authorise any GM plants, which contain antimicrobial resistant genes (**paragraph 6**). 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 also calls for withdrawing proposals for genetically modified organisms. (GMO) authorisations if no opinion is delivered by the Standing Committee (**paragraph 9**). Finally, the resolution reiterates the Parliament's commitment to advancing work on the Commission proposal amending Regulation (EU) No 182/2011 and calls on the Council to move forward with its work in relation to that Commission proposal as a matter of urgency (**paragraph 7**).

The resolution recalls the fact that the genetically modified cotton is made tolerant to glyphosate-containing and glufosinate-ammonium-containing herbicides, resistant against certain lepidopteran pests and is resistant to antibiotic (**recital C**) and that the use of glufosinate is no longer permitted in the Union (**recital G**). The resolution states that questions concerning the carcinogenicity of glyphosate remain (**recital H**) and 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 characteristic (**recital F**) and that information on residue levels of herbicides and their metabolites is essential for the risk assessment of herbicide-tolerant GM plants (**recital K**). The resolution also states that conclusion on the

safety of residues of glyphosate cannot be drawn, that herbicides additives can be toxic (**recital I**) and that an additive no longer permitted in the Union is still permitted in countries cultivating this GM cotton (**recital J**). The resolution also points out that the Member States are not required to measure glufosinate and glyphosate residues on cotton 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 L**).

The resolution recalls that gossypol is a naturally occurring toxic constituent of cotton, that the GM cotton has a higher content of gossypol (**recital M**) and that it is described as an undesirable substance in animal feed (**recital N**). The resolution also states that the legal limits of gossypol regulated by the Union legislation (Directive 2002/32/EC) does not provide sufficient assurances that the GM cotton is safe for consumption (**recital O**). The resolution also states that Cry proteins (Bt toxins) can reinforce allergenicity of other foodstuffs (**recital P**) and that specific attention should be made on interaction between Bt toxins and herbicide residues (**recital Q**).

The resolution recalls that this GM cotton contains two antibiotic resistance genes, including *aadI*, conferring resistance to antimicrobials that are classified as “critically important” (**recital R**) and that Directive 2001/18/EC aims to phase out antibiotic resistance marker genes in GMOs, which may have adverse effects in human health or on environmental safety (**recital S**). The resolution also recalls that the European Food Safety Authority (EFSA) recommended, in a 2004 opinion, that *aadI* gene should be restricted to field trial purposes (**recitals T and U**). The resolution refers to many critical comments from the Member States on this GM cotton application (**recital V**).

The resolution recalls the voting results on the draft implementing decision in the Standing Committee (**recital W**). 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 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 X**). 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 Y**).

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 placing on the market of products containing, consisting of or produced from genetically modified cotton GHB614 × LLCotton25 × MON 15985, but not the cultivation of this cotton.

With respect to **paragraphs 1, 2, 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:

- application for the authorisation modified cotton GHB614 × LLCotton25 × MON 15985 for food and feed uses in the EU was submitted by Bayer CropScience AG on 11 February 2011;
- EFSA performed a comprehensive risk assessment of the product and published on 5 September 2017 a favourable opinion concluding that GM modified cotton GHB614 ×

LLCotton25 × MON 15985 is safe and is expected to have the same nutritional impact as its non-genetically modified comparator and other tested non-GM commercial varieties;

- in its opinion, 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 public had the opportunity to comment on the EFSA opinion but no comments were received during this public consultation;
- 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 authorisation of the GM modified cotton GHB614 × LLCotton25 × MON 15985. 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 21 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 concerns about plant protection products (**recitals G, I and K**), 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 maximum residue levels (MRLs) are set under Regulation (EC) No 396/2005;
- with respect to concerns raised in **recital F**, the Commission would like to point 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 the 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 the specific concern raised in **recital L**, 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, the 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 cotton, and to define their National Control Plan accordingly;

- with respect to specific concerns raised in **recitals M, N and O** the Commission would like to point that Directive 2002/32/EC has introduced limits to the maximum contents of free gossypol for feed. These limits cannot be exceeded in order to protect target species and consumers of animal products derived from animals fed gossypol-containing feed. In addition, the feed operators must comply with the maximum limit of free gossypol and the Member States have the responsibility to ensure that those limits are respected. In addition, EFSA assessed the risks of presence of higher gossypol content in food. Because cotton products that may be directly consumed by humans are essentially free from gossypol, EFSA concluded that there are no toxicological concerns as regards as the changes in levels of gossypol observed in this GM cotton;
- with respect to specific concerns raised in **recitals R, S, T and U**, the Commission would like to stress that EFSA concluded^{1,2,3} that the two antibiotic resistance marker genes present in this GM cotton are safe for human and animal health, and the environment. In addition, there is no risk linked to these genes of increasing environmental prevalence of these antimicrobial resistance genes within bacteria;
- regarding the comments in **recitals X and Y** 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 the Member States to address at national level considerations that are not covered by the EU decision-making process;
- furthermore, as regards the lacking of support of the Members States for any authorising decision of GMOs for food and feed uses (**recital W**), 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;
- 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 EFSA GMO Panel, EFSA BIOHAZ Panel, 2009. Scientific Opinion on Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants. EFSA Journal 2009; 1034, 1-82

² EFSA GMO Panel, 2014. Scientific Opinion on applications (EFSA-GMO-UK-2008-57 and EFSA-GMO-RX-MON15985) for the placing on the market of insect-resistant genetically modified cotton MON 15985 for food and feed uses, import and processing, and for renewal of authorisation of existing products produced from cotton MON 15985, both under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2014;12(7):3770

³ EFSA GMO Panel, 2018. Scientific opinion on the assessment of genetically modified cotton GHB614 x LLCotton25 x MON 15985 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-94). EFSA Journal 2018;16(4):5213