European Commission

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Brussels, 19/07/2018
ARES(2018) 3838490

Dear Dr Wallace, Dr Then,

On 29 May 2015 you lodged a request for internal review, under Article 10 of Regulation (EC) No 1367/2006 ("the Aarhus Regulation")[1], of Commission Implementing Decisions 2015/686, 2015/696 and 2015/698, of 24 April 2015, authorising the placing on the market of products containing, consisting of or produced from genetically modified ("GM") soybeans MON 87769, MON 87705 and 305423[2], under Regulation (EC) No 1829/2003 on genetically modified food and feed[3] ("the Commission Implementing Decisions").

In your request, you claimed a violation of Union law due to the adoption of the Commission Implementing Decisions, based on the following allegations:

1. lack of EFSA guidance for health impacts of GM crops with significantly altered nutritional content;

[1] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006).
[2] Commission Implementing Decision (EU) 2015/686, Commission Implementing Decision (EU) 2015/696 and Commission Implementing Decision (EU) 2015/698 of 24 April 2015 (OJ L 1 12, 30.04.2015, p. 16, 60 and 71).
[3] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003, L 268, p. 1).

2. inadequate and inconsistent nutritional risk assessment;

3. inadequate and inconsistent labelling for GM food with altered nutritional composition;

4. inadequate and inconsistent post-market monitoring proposals for GM food with altered nutritional composition;

5. herbicide residues are not considered in the health impacts of the GM food and feed consumption regarding MON 87705 and 305423;

6. inadequate assessment of the unintended effects of Ribonucleic acid (RNA) interference regarding MON 87705.

By letter dated 16 November 2015[4], the Commission replied to your request and concluded that:

- your organisations comply with the criteria set out in Article 11 of the Aarhus Regulation and are therefore entitled to make a request for internal review. Your request has been lodged on the basis of Title IV of the Aarhus Regulation, within the specified time limit and with indication of the grounds of review in which you base your request, in accordance with Article 10(2) of the Regulation;

- allegations 1 to 5 and part of allegation 6 were not admissible because they related to health effects of consumption of the GM soybeans, which were outside the scope of Article 10 of the Aarhus Regulation;

- part of allegation 6 fell under the scope of internal review but did not justify the need to amend the Commission Implementing Decisions.

As a result of an action brought by TestBiotech e.V against the Commission's reply, in its judgement of 14 March 2018 in case T-33/16 (*TestBiotech eV* v *Commission*[5]) the General Court found that the allegations submitted in the request for internal review fell under the scope of Article 10 of the Aarhus Regulation and, in consequence, annulled the Commission's letter.

[4] Ref. Ares(2015)5145741.
[5] Judgement of the General Court of 14 March 2018, *TestBioTech* v *Commission*, T-33/16, ECLI:EU:T:2018:135.

To comply with the obligations deriving from that judgement, and in accordance with Article 266 TFEU, the Commission is bound to review in substance all your allegations.

Please find in annex the Commission's assessment of your allegations.

We would like to recall that the authorisation decisions for the GM soybeans were granted in accordance with the requirements laid down by Regulation (EC) No 1829/2003, and on the basis of a favourable assessment of the European Food Safety Authority ("EFSA")[6], which concluded that the soybeans are as safe as their conventional counterparts with respect to potential effects on human and animal health and the environment in the context of their intended uses.

The Commission consulted EFSA on the scientific aspects of the technical dossier on which you base your request for internal review. In reply to Commission's consultation, EFSA published a technical report[7] in which it concluded that you did not put forward new information that would invalidate the previous risk assessment conclusions made by its GMO Panel for the GM soybeans 305423, MON 87705 and MON 87769. Therefore, EFSA considers that the previous risk assessment conclusions on the three GM soybeans remain valid.

The Commission's reply to your scientific claims is based in the conclusions of the mentioned EFSA's technical report.

Based on these considerations and on the assessment set out in the annex to this letter, the Commission considers that your allegations must be rejected.

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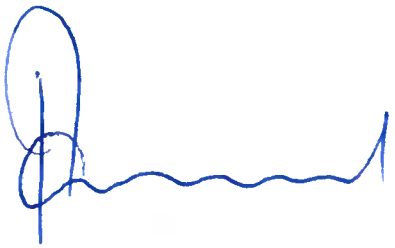
[6] EFSA Panel on Genetically Modified Organisms (GMO), 2012. Scientific Opinion on application EFSA-GMO-NL-2010-78 for the placing on the market of herbicide tolerant genetically modified soybean MON 87705 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2012; 10(10):2909, 34 pp. doi:10.2903/j.efsa.2012.2909; EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2013. Statement complementing the scientific opinion on application EFSA-GMO-NL-2010-78 to cover the safety of soybean MON 87705 oil for commercial frying. EFSA Journal 2013; 11(12):3507, 9 pp. doi:10.2903/j.efsa.2013.3507;
EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2013. Scientific Opinion on application EFSA-GMO-NL-2007-45 for the placing on the market of herbicide-tolerant, high-oleic acid, genetically modified soybean 305423 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer. EFSA Journal 2013; 11(12):3499, 35 pp. doi:10.2903/j.efsa.2013.3499.
EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on application EFSA-GMO-UK-2009-76 for the placing on the market of soybean MON 87769 genetically modified to contain stearidonic acid, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2014; 12(5):3644, 41 pp. doi:10.2903/j.efsa.2014.3644.

[7] EFSA (European Food Safety Authority), 2015. EFSA scientific assistance to EC on the internal review submitted under Regulation (EC) No 1367/2006 on the application of the provisions of the Aarhus Convention against Commission Decisions to authorise genetically modified soybeans 305423, MON 87705 and MON 87769. EFSA supporting publication 2015: EN-862. 16 pp.

Therefore, the Commission concludes that the elements you provided in your request do not justify the need to amend the Commission Implementing Decisions.

Should you disagree with this reply, you may bring the matter before the Ombudsman or before the General Court if you have a complaint which falls within the conditions laid down in Article 228 or 263 respectively of the Treaty on the Functioning of the European Union.

Yours sincerely,



Enclosure: Annex - Assessment of the allegations included in the request for internal review of Commission Implementing Decisions on GM soybeans MON 87769, MON 87705 and 305423