European Commission

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Brussels, 20. 05. 2019
ARES(2019)

Dear Dr Then,

On 28 January 2019, you lodged a request for internal review, under Article 10 of Regulation (EC) No 1367/2006 ("the Aarhus Regulation")[1], of Commission Implementing Decision (EU) 2018/2046, of 19 December 2018, authorising the placing on the market of products containing, consisting of or produced from genetically modified ("GM") maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and sub-combinations[2] under Regulation (EC) No 1829/2003 on GM food and feed[3] ("the Commission Implementing Decision").

The Commission considers that your organisation complies with the criteria set out in Article 11 of the Aarhus Regulation and is therefore entitled to lodge 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(1) of the Regulation.

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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) 2018/2046 of 19 December 2018 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, and genetically modified maize combining two, three or four of the single events MON 87427, MON 89034, 1507, MON 88017 and 59122 and repealing Decision 2011/366/EU (OJ L 327, 21.12.2018, p. 70–76).

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).

In your request, you claim that the adoption of the Commission Implementing Decision was not in accordance with Union law due to inadequacies in the risk assessment carried out by the European Food Safety Authority (EFSA) on the application for authorisation. In particular, you base your claim on the following allegations regarding EFSA's assessment:

1. Inadequate food and feed safety assessment (allergenicity, adjuvanticity and synergistic or antagonistic effects)

2. Inadequate field trials design/experiments (with regard to agricultural practices and to meteorological and agronomic conditions)

3. Inadequate protein expression dataset (for the GM maize and its sub-combinations)

4. Inadequate environmental risk assessment (gene flow to other plant species)

You also claim that the applicant did not provide a specific detection method for the GM maize and that public access to the methods for quantifying protein expression levels should be ensured.

Based on all these allegations, you claim that the Commission Implementing Decision was adopted in breach of EU law as, in your view, the Commission and EFSA would have failed to demonstrate the safety of the GM stack maize.

Against this background, you request that the authorisation is revoked and that the process of risk assessment is re-started.

The Commission would like to stress that the authorisation for the GM stack maize was granted in accordance with the requirements laid down by Regulation (EC) No 1829/2003 and on the basis of a favourable assessment of the EFSA[4], which concluded that the GM stack maize is as safe and nutritious as the non-GM comparator and the tested non-GM reference varieties in the context of the scope of the application.

The Commission has carefully assessed your allegations and considers that your request is unfounded as regards its criticisms on the way EFSA has performed the risk assessment of the GM stacked maize as well as on the access to the methods for quantifying protein expression levels.

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[4] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messéan A, Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Álvarez F, Lanzoni A and Paraskevopoulos K, 2017. Scientific Opinion on application EFSA-GMO-BE-2013-118 for authorisation of genetically modified maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 and subcombinations independently of their origin, for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Company. EFSA Journal 2017;15(8):4921, 32 pp. https://doi.org/10.2903/j.efsa.2017.4921

You will find in annex the detailed Commission's assessment of your allegations and a reply to your claim as regards question of public access to the methods for quantifying protein expression levels, which is independent from the question of whether the Commission Implementing Decision was adopted in accordance with the conditions of Regulation (EC) No 1829/2003.

The Commission has consulted EFSA on the scientific aspects of the technical dossier on which you base your request for internal review. In reply to the Commission's consultation, EFSA has published a technical report[5] in which it concluded that you did not put forward new information that would invalidate the previous risk assessment conclusions and risk management recommendations made by its GMO Panel for the GM stack maize. Therefore, EFSA considers that the previous risk assessment conclusions on the GM stack maize remain valid.

The Commission's reply to your scientific claims is based on 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 the grounds you provided in your request do not justify the need to revoke nor amend the Commission Implementing Decision as a result of the comprehensive administrative review carried out following your request.

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 Decision authorising the placing of the market of products containing, consisting of or produced from GM maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and sub-combinations

5 EFSA, Scientific advice on the internal review under Regulation (EC) No 1367/2006 of the Commission's decision authorising the placing on the market of genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and subcombinations. EFSA supporting publication 2019:EN-1603.