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Brussels, 8 July 2021

Dear Dr Then,

On 8 March 2021, you submitted a request for internal review under Article 10 of Regulation (EC) No 1367/2006[1] ('Aarhus Regulation') of the following Commission Implementing Decisions, adopted on 22 January 2021 pursuant to Articles 7(3) and 19(3) of Regulation (EC) No 1829/2003[2] ('Commission Implementing Decisions'):

- Commission Implementing Decision (EU) 2021/66 authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87751 × MON 87701 × MON 87708 × MON 89788[3];
- Commission Implementing Decision (EU) 2021/61 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two, three or four of the single events MON 87427, MON 87460, MON 89034, MIR162 and NK603[4];
- Commission Implementing Decision (EU) 2021/65 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and MON 87411[5].

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, p. 13).
2 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).
3 OJ L 26, 26.1.2021, p. 44.
4 OJ L 26, 26.1.2021, p. 12.
5 OJ L 26, 26.1.2021, p. 37.

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In your request, you claim that the Implementing Decisions do not fulfil the requirements of EU legislation, for the following reasons:

1) the risk assessments (risk characterisations) carried out by the European Food Safety Authority (EFSA) and the applicants, on which the Implementing Decisions rely, do not clearly demonstrate that the GM food and feed derived from the GMOs in question have no adverse effects on human and animal health or the environment;
2) the Implementing Decisions should have required method(s) for post-market monitoring specific to the authorised GMO which are only functional with that GMO and not with other already authorised transformation events.

The Commission has considered the admissibility of your request in the light of the provisions of Title IV of the Aarhus Regulation, and its Articles 10 and 11 in particular. The Commission considers that your organisation complies with the criteria set out in Article 11 of the Aarhus Regulation and that is therefore entitled to make a request for internal review. Your request has been lodged within the applicable time limit and with indication of the grounds for the review in which you base your request, in accordance with Article 10(1) of the Aarhus Regulation.

The Commission has consulted EFSA on the scientific aspects of your request for internal review. In reply to the Commission's consultation, EFSA has concluded that the technical backgrounds you provided do not justify a re-examination of the conclusions and risk management recommendations made by the EFSA GMO Panel for GM soybean MON 87751 × MON 87701 × MON 87708 × MON 89788, GM maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and its subcombinations and GM maize MON 87427 × MON 89034 × MIR162 × MON 87411 and its subcombinations. Therefore, EFSA considers that the previous risk assessment conclusions on these GM stacks remain valid.

The Commission has carefully assessed your allegations and considers that your request is unfounded. The detailed Commission's assessment of the grounds for the review is enclosed in the annexes to this letter.

On this basis, the Commission considers that the three Commission Implementing Decisions in question are in accordance with the applicable EU legislation.

Should you disagree with this reply, you may bring the matter before the Ombudsman or before the General Court in accordance with the conditions laid down in Articles 228 or 263, respectively, of the Treaty on the Functioning of the European Union.

Yours sincerely,

D. Kyprakides

Enclosures: Annex I - Assessment of the grounds for the review in request for internal review of Commission Implementing Decision (EU) 2021/66 authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87751 × MON 87701 × MON 87708 × MON 89788 pursuant to Regulation (EC) No 1829/2003

Annex II - Assessment of the grounds for the review of Commission Implementing Decision (EU) 2021/61 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two, three or four of the single events MON 87427, MON 87460, MON 89034, MIR162 and NK603 pursuant to Regulation (EC) No 1829/2003

Annex III - Assessment of the grounds for the review of Commission Implementing Decision (EU) 2021/65 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and MON 87411 pursuant to Regulation (EC) No 1829/2003