European Ombudsman

Decision in case 1579/2018/KR on a request to review Commission Decisions authorising the import of three types of genetically modified soybeans

Decision
Case 1579/2018/KR - **Opened on** 25/03/2019 - **Decision on** 25/03/2019 - **Institution concerned** European Commission (No maladministration found) |

This complaint concerns the European Commission's decisions to authorise the importation of products containing, consisting of or produced from three genetically modified soybeans.

The complainant was of the view that the Commission wrongly authorised the importation. The arguments it presented to the Ombudsman were scientific in nature.

Given the Ombudsman's limited role in reviewing decisions involving complex scientific assessments, she asked the complainant to point out any manifest errors in the Commission's assessment. The complainant did not put forward evidence of a manifest error by the Commission. The Ombudsman also noted that the Commission had consulted the European Food Safety Authority (EFSA) on the matter and that it drew on the conclusions reached in EFSA's report in replying in substance to the complainant. On that basis, the Ombudsman found no maladministration.

The Ombudsman, however, takes note of the complainant's concerns about what it sees as inadequate post-market monitoring proposals of the genetically modified products at issue in this case. While the Ombudsman cannot assess whether they are adequate or not, she agrees with the complainant about the importance of post-market monitoring and urges the Commission, in cooperation with EFSA, to continue to monitor carefully the effects of these products.

Background to the complaint

1. On 24 April 2015, the European Commission authorised the import of three genetically modified soybeans [1] for use in food and feed [2] .

2. On 29 May 2015, the complainant, two NGOs that monitor developments in genetic technologies, asked the Commission to review the authorisations. The Commission replied by

declaring most of the request for review inadmissible and deciding that the remaining part did not justify the need to amend the decisions.

3. On 26 January 2016, the complainant brought an action before the General Court challenging the rejection of its request to review the authorisations.

4. On 14 March 2018, the General Court annulled the decision whereby the Commission refused to deal with the request for review.

5. As a result, on 19 July 2018, the Commission replied in substance to the complainant's request for review. It confirmed that its decisions authorising the import of the three genetically modified soybeans were valid.

6. On 7 September 2018, the complainant turned to the Ombudsman.

The inquiry

7. The Ombudsman opened an inquiry into the complainant's concern that the Commission wrongly authorised the importation of three genetically modified products.

8. Given the Ombudsman's limited role in reviewing decisions involving complex scientific assessments, the Ombudsman asked the complainant to point out any manifest errors in the Commission's assessment. The complainant did not reply to this request.

The Ombudsman's assessment

9. The arguments that the complainant presented to the Ombudsman are scientific in nature. The complainant:

· challenges the Commission's view that the three nutritionally-altered soybeans are "substantially equivalent" to existing conventional crops;

· is of the view that the Commission failed to take sufficient account of the health sensitivities of specific categories of consumers;

· argues that the Commission's "feed safety assessment" was inadequate. For example, the unintended effects of RNA interference (RNAi) [3] were not adequately assessed for one of the soybeans (MON 87705);

· disagrees with the Commission's view that the labelling and post-market monitoring proposals for the soybeans are adequate. For example, the labels do not describe in detail all the nutritional changes in the products.

10. The Commission consulted the European Food Safety Authority (EFSA) on the scientific issues that the complainant raised. In reply to this consultation, EFSA produced a report, which is public, containing an extensive analysis. [4] EFSA concluded that the complainant had " *not put forward new information that would invalidate [its] previous risk assessment conclusions* ".

11. The Commission's substantive reply to the complainant's request for review is based on the conclusions contained in EFSA's report.

12. It is not the role of the European Ombudsman to examine the merits of the scientific assessments underpinning a Commission decision. What the Ombudsman can assess is whether the Commission has carefully examined the information that the complainant has put forward and provided a reasoned reply to each of its arguments.

13. In the case at hand, the Commission has evaluated the information that the complainant put forward and provided the complainant with a reasoned reply.

14. Were evidence of a manifest error put forward, for example the fact of relevant information being overlooked, the Ombudsman could ask the Commission to clarify the matter. The complainant did not put forward evidence of a manifest error by the Commission.

15. The Ombudsman takes note of the complainant's concerns about what it sees as inadequate post-market monitoring proposals of the genetically modified products at issue in this case. While the Ombudsman cannot assess whether they are adequate or not, she agrees with the complainant about the importance of post-market monitoring and urges the Commission, in cooperation with EFSA, to continue to monitor carefully the effects of these products.

Conclusion

Based on the inquiry, the Ombudsman closes this case with the following conclusion [5] :

There was no maladministration by the Commission.

The complainant and the Commission will be informed of this decision.

Emily O'Reilly

European Ombudsman

Strasbourg, 25/03/2019

[1] These three GM products concern Monsanto's MON 87769 and MON 87705 soybeans, and Pioneer's 305423 soybean.

[2] Implementing Decisions 2015/686, 2015/696 and 2015/698

[3] The Commission, in its reply to the complainant's request for review, defined RNAi as " *a technique that can be used to down-regulate target genes in plants or in target pests* ." RNAi can be used to produce GM plants with altered agronomic, nutritional, industrial and food-processing traits. For more information, see for example EFSA's report on its international scientific workshop 'Risk assessment considerations for RNAi-based GM plants': http://www.efsa.europa.eu/en/supporting/pub/en-705 [Link].

[4] See: https://www.efsa.europa.eu/en/supporting/pub/en-862 [Link].