Decision of the European Ombudsman closing the inquiry into complaint 1582/2014/PHP on the European Commission's handling of authorisation applications for genetically modified food and feed

Decision
Case 1582/2014/PHP - **Opened on** 17/10/2014 - **Decision on** 15/01/2016 - **Institution concerned** European Commission (Critical remark) |

The case concerned delays encountered in the authorisation of twenty applications for genetically modified food and feed. The complainants informed the Commission of their concerns on several occasions. In their view, the Commission's explanations and the persistent delays were unacceptable. Therefore, the complainants turned to the Ombudsman.

The Ombudsman inquired into the issue and found that the delays affecting the twenty applications were not justified. In the course of the inquiry, the Commission dealt with all the pending applications. The Ombudsman concluded, however, that the delays reflected a systemic problem rather than being the result of matters specific to the particular authorisation applications. In closing the inquiry, the Ombudsman found that the delays constituted maladministration on the part of the Commission.

The background to the complaint
1. The complainants are three associations representing companies which market genetically modified food and feed. [1] They repeatedly raised with the European Commission their concerns regarding delays in deciding on the authorisation of twenty genetically modified food and feed applications made between September 2012 and September 2014.

2. Regulation 1829/2003 ("FF Regulation") [2] and Regulation 182/2011 ("Comitology Regulation") [3] contain the rules for the authorisation of genetically modified food and feed. The FF Regulation prohibits genetically modified food and feed from being placed on the market without prior authorisation.

3. Under the FF Regulation, it is the Commission which authorises genetically modified food and feed. The Commission's decision on whether or not to issue an authorisation comes after the publication of a scientific opinion from the European Food Safety Authority (EFSA). The public has 30 days in which to submit comments to the Commission from the date of the publication of the EFSA opinion. The Commission must, within two months of the end of this consultation period (that is, within three months of receiving the EFSA's opinion), submit a draft decision on the application to the Standing Committee on Plants, Animals, Food and

Feed ("the Standing Committee"). This Committee is composed of representatives of all Member States and is chaired by a European Commission representative. [4]

4. When the vote in the Standing Committee does not produce a qualified majority in favour of or against the draft decision, the Standing Committee delivers no opinion . In that case, the Commission may either submit an amended version of that draft decision to the Standing Committee within two months of the vote, or submit the draft decision within one month of the vote to the Appeal Committee for further deliberation. [5]

5. The voting rules in the Appeal Committee are similar to those in the Standing Committee. If the Appeal Committee delivers no opinion , the Commission is nevertheless required to take a decision. However, the Comitology Regulation does not set out any time limit within which the Commission must take its decision after the vote of the Appeal Committee.

6. The complainants argued that, as regards their applications, the delays in the submission of the draft decisions to the Standing Committee amounted to approximately 16 months on average per product , well beyond the three months limit provided for in the FF Regulation. In addition, there were delays by the Commission of 3.5 months on average per product in taking decisions following the failure of the Appeal Committee to reach a qualified majority. The complainants argued that these delays were excessive when compared to the period between 2011 and 2013 when, in most cases, decisions were made within one month.

7. In the light of the foregoing, the complainants lodged a complaint with the European Ombudsman.

The inquiry

8. The Ombudsman opened an inquiry into the complainants' allegation that the Commission had failed to comply with the applicable time limits when dealing with the authorisation of twenty applications submitted under Regulation 1829/2003. The complainants argued that, as a result, the Commission breached its duties under Articles 4, 5 and 10 of the European Code of Good Administrative Behaviour. [6]

9. The claim made by the complainant was that the Commission should decide on the twenty pending applications and that it should avoid any such delays in the authorisation process in the future.

10. Following the submission of the complaint, five associations affected by similar delays sent a letter to the Ombudsman in support of the complainant's allegations.

11. In the course of the inquiry, the Ombudsman received the opinion of the European Commission on the complaint and, subsequently, the comments of the complainants in response to the Commission's opinion. She also inspected the relevant files of the Commission. In conducting the inquiry, the Ombudsman has taken into account the arguments and opinions put forward by the parties.

12. While this inquiry was underway, nineteen out of the twenty applications were decided. [7] The complainants do not contest the outcome of the particular applications, but rather

the delays in the authorisation process. However, the complainants informed the Ombudsman of their desire to pursue their complaint with a view to ensuring that the Commission's administrative practice changes in the future and complies with the applicable rules.
Allegation of illegal and unreasonable delays in the authorisation process of genetically modified food and feed applications

Arguments presented to the Ombudsman

13. The complainants pointed out that the EU legislature had considered that, following the publication of the EFSA opinion, three months were sufficient for the Commission to submit a draft decision on an authorisation request to the Standing Committee. In their view, the procedural practices causing the delays in these cases were not provided by, or required by, the applicable rules. In particular, as examples of practices that delay the authorisation process, the complainants referred to two particular steps in the authorisation process: (i) a first meeting of the Standing Committee where the EFSA presents its opinion to the Member States and (ii) a second meeting where the Member States vote on the draft decision. The complainants argued that spreading the Standing Committee's deliberations over two separate meetings was not justified.

14. The complainants also said that while, in the past, the Commission drew up its draft decisions based on a written procedure, using an oral procedure seemed to be the rule at present. The complainants did not contest the use of the oral procedure as such, but rather the fact that the applications were being delayed unreasonably. Furthermore, the complainants referred to the disparities in the handling of authorisation applications in general, which in their view breached the principle of equality.

15. In its opinion, the Commission set out the various procedural steps followed in the authorisation process. It pointed out that some of the procedural steps are not compulsory. It also referred to some of the factors that may cause delays. [8] However, the Commission stressed that even though the two meetings mentioned in paragraph 13 (the meeting where the EFSA presents its opinion to the Member States and the meeting where the Member States vote on the draft decision) were not legally required, this did not imply that they were not essential and in the interest of good administration. [9] The Commission also stated that, where genetically modified food and feed authorisations are concerned, it always launches a written procedure in the first place.

16. As regards the alleged breach of the principle of equality, the Commission maintained that each application presents its own degree of complexity. It also rejected the complainants' view that the principle of legitimate expectations had been breached, arguing that in this case the applicants were duly informed of the problems and follow-up steps.

17. In its opinion, the Commission acknowledged that the three months deadline to submit the draft decisions to the Standing Committee had not been respected in these cases. However, the Commission concluded that, although it had taken more than three months to submit the draft decision as regards the twenty applications in question, this did not

automatically result in maladministration. In fact, the Commission often faces unexpected issues related to the scope of the applications and the need to gather the required scientific data. [10]

18. In its observations, the complainants repeated that the three months deadline must be respected in all instances. They thus concluded that the Commission's practice should be modified in order to comply with the binding rules.

The Ombudsman's assessment

19. By way of background, the Ombudsman notes that, in April 2015, the Commission made a proposal to the European Parliament and to the Council to amend the FF Regulation. The proposal, if acted upon, will not amend the authorisation process for genetically modified food and feed but will allow Member States to restrict or prohibit the use of genetically modified food or feed within their own territory. However, under the proposal, "[m] *ember States would have to justify that their opt-out measures are compatible with EU law and the principles of proportionality and non-discrimination between national and non-national products* **." [11]**

20. Also by way of background, the Ombudsman is aware of the unusual situation facing the Commission in this area, arising from the positions being adopted by the Member States in the Standing Committee and in the Appeal Committee. It appears to be the case that, in these two Committees, the Member States are systematically failing to deliver any opinions on the draft decisions being put forward by the Commission. In its Fact Sheet setting out the background to its proposal of April 2015, the Commission says: " *Since the entry into force of the EU legal framework on genetically modified food and feed, the results of the votes in Standing and Appeal Committees have systematically been "no opinion", whether the authorisation was for cultivation or GM food and feed. The final decision on authorisations is therefore always left to the Commission at the very end of the procedure. This situation of repeated "no opinion" results is unique compared to the thousands of implementing decisions adopted via comitology every year, where the Member States generally support the Commission's draft decision in the Standing Committee stage.* (...) *The reasons invoked by Member States to justify their abstentions or negative votes are sometimes scientific in nature, but in majority of the cases are based on other considerations, reflecting the societal debate in their country."*

21. As regards the delays in the authorisation process, there are two aspects to consider. First, the delay in submitting the draft decisions to the Standing Committee, and, second, the delay in taking decisions where the Appeal Committee has not reached a qualified majority.

22. As regards the delays which occurred when submitting draft decisions to the Standing Committee, it is clear that the existing rules do not confer on the Commission any discretion as regards when to submit such draft decisions. Articles 7(1) and 19(1) of the FF Regulation read as follows : [12]

" *Authorisation*

1. Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences ."

23. In these cases, the Commission recognised in its opinion that it had taken more than three months, from the dates of the EFSA's opinions, to submit the draft decisions to the Standing Committee. According to the information available to the Ombudsman, the time taken to submit the draft decisions significantly exceeded the deadline set out in the FF Regulation. [13] In fact, in these cases, the delays in question did not occur in one or two isolated instances, but were the norm rather than the exception. The Commission has put forward no convincing reasons to explain these delays. While the Ombudsman appreciates the difficult position in which the Commission finds itself, arising from the inability of the Member States to deliver an opinion either at Standing Committee or Appeal Committee stage, these difficulties do not absolve the Commission of its statutory responsibility to submit a draft decision to the Standing Committee within three months. In these circumstances, given the strict deadline laid down in Articles 7 and 19 of the FF Regulation, these delays constituted maladministration.

24. On the other hand, the Comitology Regulation does not set out a time limit for the adoption of a decision after the vote of the Appeal Committee. However, the Commission is bound by Article 41(1) of the Charter of Fundamental Rights and must therefore take the decision *within a reasonable time* . [14] The case law has established that compliance with the reasonable time requirement in the conduct of administrative procedures constitutes a general principle of EU law. Moreover, action within a reasonable time is required in all cases where the applicable texts are silent on the matter and the principles of legal certainty and protection of legitimate expectations prevent the institutions from acting without any restriction as to time. [15]

25. The Ombudsman takes the view that the assessment of what constitutes a reasonable time should be based on the specific circumstances of the case, such as its complexity, the conduct of the parties or supervening procedural matters. [16] In this case, the Ombudsman does not doubt the complexity, importance and sensitivity of decisions on the authorisation of genetically modified food and feed. In the absence of a specific requirement on the Commission to take a decision within a specific period of time, it is incumbent on the Commission to take only whatever time is necessary to allow it to conduct a final review of all the relevant facts and arguments.

26 The complainants suggest that it should have been possible for the Commission to take decisions within one month of the non-opinion of the Appeal Committee. The complainants claim that during the period between 2011 and 2013, the Commission generally took decisions within one month following the failure of the Appeal Committee to reach a qualified majority. In the cases concerned in this complaint, the Commission took, on

average, 3.5 months to take a decision following the Appeal Committee stage.

27. The Ombudsman is not satisfied that the Commission has given any reasonable explanation for an average delay of 3.5 months in taking its decision following the failure of the Appeal Committee to provide an opinion. In circumstances where, presumably, the substantive work on the individual case had already been done in advance of engaging with the Standing Committee and Appeal Committee, it is difficult to see why the Commission would need a further 3.5 months in which to take its decision. Given that a further delay at this stage might have adverse consequences for the complainants, and in the absence of any reasonable explanation for these delays, the Ombudsman finds that these delays by the Commission constituted maladministration.

Conclusion

On the basis of the inquiry into this complaint, the Ombudsman closes it with the following critical remark:

The Commission failed in these cases to meet the three months legally binding deadline for submitting draft decisions to the Standing Committee on Plants, Animals, Food and Feed. The Commission failed also to take its decisions within a reasonable time following the failure of the Appeal Committee to deliver an opinion. These failures constituted maladministration.

Given that the decision-making process in relation to genetically modified food and feed is currently being reviewed, the Ombudsman feels it is unnecessary to make a recommendation to the Commission in this case. However, pending the conclusion of the review and the adoption of new legislation, the Ombudsman trusts that the Commission will seek to comply with the existing legal requirements regarding the timescales for dealing with applications for the authorisation of genetically modified food and feed.

If the Commission believes that the existing timescale for bringing a draft decision to the Standing Committee is not adequate, it could consider dealing with this issue as part of its current review of the decision-making process on genetically modified food and feed in the EU. Similarly, if the Commission believes that there should be a specific statutory timescale within which it must take a decision following the failure of the Appeal Committee to reach a qualified majority, this also could be raised in the context of the current review .

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

Emily O'Reilly

Strasbourg, 15/01/2016

[1] EuropaBio, COCERAL and FEFAC.

[2] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

[3] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

[4] http://ec.europa.eu/food/plant/standing_committees/index_en.htm

[5] The Appeal Committee is also composed of representatives of Member States.

[6] Article 4 (Lawfulness), Article 5 (Absence of discrimination) and Article 10 (Legitimate expectations, consistency and advice).

[7] On 18 September 2015, the complainant informed the Ombudsman that as regards the last remaining application, the company concerned had requested its withdrawal, although that application still appeared in the Commission's registry as "ongoing".

[8] For example, the Commission explained that, as regards the public consultation, some comments need to be translated, and the EFSA is given an additional month to assess them. The draft decision cannot be finalised until the EFSA's final assessment of public comments is received.

The Commission also referred to other reasons that, in practice, could cause delays (e.g., the extension of the inter-service consultation process during the summer holidays, consultation with the applicants).

[9] The current practice is to hold a first meeting of the Standing Committee where EFSA presents its opinion to Member States and a second meeting where Member States vote on the draft decision. The Commission argues that, even if not required by law, the presentation by EFSA is a very relevant step in the authorisation process.

[10] In its opinion, the Commission offered a full overview of the process followed and the difficulties encountered as regards each application. Some of the explanations provided have a confidential character. Therefore, this decision will only mention the arguments put forward by the Commission which are of a general nature and can be disclosed.

[11] MEMO/15/4779 " *Review of the decision-making process on GMOs in the EU: Questions and Answers".*

[12] Article 7 refers to genetically modified food and Article 19 to genetically modified feed.

[13] For instance, at the date of the submission of the complaint (September 2014) the following delays, following the delivery of an opinion by EFSA, were recorded with regard to 4 product applications:(a) "Maize -MON863 (ffip renewal)" - 53 months, (b) "Cotton - MON531

(ffip renewal) - 35 months, (c) Cotton -MON1445 (ffip renewal) - 32 months, and (d) "Cotton - MON531 x MON1445 - ff renewal" - 29 months.

[14] Note that when the Commission made public its intention to review the decision-making process concerning genetically modified food and feed authorisation applications, it stated that: " *If the result of the vote is "No opinion", the Commission is required by the GMO legal framework* and by the Charter of Fundamental Rights to adopt a decision on the application so, in practice, has little choice but to give the authorization ." (MEMO/15/4779 " *Review of the decision-making process on GMOs in the EU: Questions and Answers* ").

[15] Judgment of the Court of Justice of 13 November 2014, *Nencini v Parliament,* C-447/13 P ECLI:EU:C:2014:2372

[16] See, for example, Decision of the European Ombudsman closing the inquiry into complaint 1561/2014/MHZ.