Ombudsman
Eorpach

Cinneadh maidir le cás 428/2016/LM faoi fhreagra Choimisiún na hEorpa ar iarratais ar athbhreithniú inmheánach ar a chinneadh údarú margaíochta a bhronnadh le haghaidh ráib ghéinmhodhnaithe

Cinneadh
Cás 428/2016/LM - **Tosaithe an** 18/08/2016 - **Moladh faoi** 12/12/2017 - **Cinneadh an** 11/07/2018 - **Institiúid ábhartha** An Coimisiún Eorpach (Moladh arna gcomhaontú ag an institiúid) |

Is ENR Gearmánach i réimse na biteicneolaíochta é an gearánach. D'iarr sé athbhreithniú ar chinneadh Choimisiúin na hEorpa chun táirgí ina bhfuil ráib ghéinmhodhnaithe a údarú. De bharr a bheith míshásta le freagra an Choimisiúin agus toisc nár fhreagair an Coimisiún laistigh den sprioc reachtúil 18 seachtain, chuaigh sé i muinín an Ombudsman.

Chinn an tOmbudsman gur ghlac an Coimisiún fad ama míréasúnach—35 seachtain seachas 18—le freagra a thabhairt ar iarratas an ghearánaigh. B'ionann é seo agus drochriarachán. Mhol sí dá réir go ndéanfadh an Coimisiún athbhreithniú ar a nósanna imeachta.

Mar fhreagra, rinne an Coimisiún athbhreithniú ar a nósanna imeachta agus nocht an tuairim go ligeann a nósanna imeachta dó cloí leis na spriocanna is infheidhme. Ghlac an Coimisiún freisin le moladh an Ombudsman sa chás nach mbeadh sé in ann cloí leis an sprioc chun freagra a thabhairt ar iarratas ar athbhreithniú, gur chóir go gcuirfeadh sé in iúl don ENR na cúiseanna ina leith seo agus an ceart chun imeachtaí dlí a thionscnamh.

Toisc gur ghlac an Coimisiún lena moltaí, cuireann an tOmbudsman deireadh leis an gcás.

Molann an tOmbudsman freisin gur chóir don Choimisiún a dhícheall a dhéanamh measúnú a dhéanamh ar ábhar breise a chuireann ENR isteach tar éis na sprice chun iarratas ar athbhreithniú a chur isteach agus gur chóir dó a chur in iúl go soiléir gur fearr leis iarratais ar athbhreithniú comhshínithe seachas go leor iarratas aonair ar an ábhar céanna.

Background to the complaint

1. The complainant, a German non-governmental organisation active in the area of biotechnology, disagrees with the European Commission's decision of April 2015 to authorise

the placing on the EU market of products containing the genetically modified oilseed rape “MON 88302” [1] . In June 2015, the complainant requested, under the Aarhus Regulation, an internal review of the Commission’s decision [2] . The request for internal review was later supported by eight other organisations [3] .

2. In February 2016, the Commission replied to the complainant’s request for internal review. Dissatisfied with the Commission’s response, the complainant turned to the Ombudsman in March 2016.

3. The complainant’s position was that (a) the Commission’s reply to the request for internal review of its decision to grant market authorisation for the genetically modified oilseed rape MON 88302 is flawed with respect to the environmental issues put forward in the request for review; and that (b) the Commission failed to respond to the request for internal review within the time limits of the Aarhus Regulation, which governs requests for internal review of administrative acts under environmental law.

4. Following a request from the Ombudsman, the Commission provided the complainant with additional explanations on the environmental concerns put forward in its request for review. The Ombudsman thus concluded that the Commission had resolved the first aspect of the complaint during the course of the inquiry. However, she made two recommendations to the Commission concerning the second aspect of the complaint on compliance with the time limits of the Aarhus Regulation [4] .

The time it took the Commission to reply to the request for internal review

The Ombudsman’s recommendations

5. Regarding the handling of requests for internal review of administrative acts adopted under environmental law, the Aarhus Regulation states that EU institutions shall provide a written reply as soon as possible, but no later than 12 weeks after the receipt of the request. When EU institutions are unable to do so, despite exercising due diligence, they must reply *“* **In any event** *(...) within 18 weeks from receipt of the request”* (emphasis added) [5] . It is clear from this wording that the legislature envisaged that an EU body dealing with a request for internal review should in principle always be able to reply to the request within 18 weeks.

6. The Ombudsman understands that requests for internal review of decisions on Genetically Modified Organisms (GMOs) can raise highly complex questions of science, which might require consultation with outside bodies responsible for the scientific assessment (for example EFSA or the European Chemicals Agency). However, in this case, the Commission took almost 35 weeks—that is, almost twice the time provided for in the Aarhus Regulation—to reply to the request.

7. The Ombudsman considered that to be an unacceptable overrun of the time limit, particularly given that the Commission's review decision was not made until four months after the European Food Safety Authority (EFSA) had provided its last input on the request. The Ombudsman thus found that the Commission's delay in dealing with the complainant's request for internal review constituted maladministration and made the following recommendations:

The Commission should, with a view to complying with the statutory time limits applicable to requests for internal review under the Aarhus Regulation, review its procedures for dealing with such reviews as well as the resources it requires in that regard. This review of procedures and resources should, in particular, take account of the fact that many such reviews will involve complex scientific assessments such as authorisations of products containing genetically modified organisms. In the event that the Commission concludes that the statutory time limits cannot, in many cases, be met, it should propose a legislative amendment of the time limits.

Where in exceptional cases the Commission is unable, despite exercising due diligence, to comply with the 18-week deadline for completion of reviews as provided for in the Aarhus Regulation, it should, as soon as possible (and at the latest within the 18-week period), inform the NGO which made the request of the reasons for the delay in concluding the review and of its right to institute proceedings before the Court of Justice in accordance with Article 12(2) of the Aarhus Regulation.

The Commission's response to the Ombudsman's recommendations

8. Regarding the first recommendation, the Commission stated that it had reviewed its internal procedures and concluded that these procedures do not prevent it from dealing with complex requests for review within the statutory deadlines.

9. However, review requests like the one at issue - concerning authorisations of GMOs, questioning the risk assessment made by the European Food Safety Authority (EFSA) - are those where it is most difficult to respect the statutory deadline because the Commission must also consult EFSA in order to provide a reply. For this kind of review, the Commission said that it will take measures so that it is possible to comply with the 18-week deadline.

10. The statutory deadlines laid down in the Aarhus Regulation apply to all requests for internal review. However, compliance with the deadlines is extremely difficult for one specific type of request only, namely, review requests questioning EFSA's risk assessment on the basis of which GMO authorisations were granted. The Commission said that any need to revise the deadline will be borne in mind in the context of a broader review of the Aarhus Regulation. However, the Commission considers that it is too early to conclude that such an amendment is necessary.

11. The Commission took into account the complainant's comments on EFSA's scientific

opinion, although the complainant submitted them after the deadline for sending a review request [6] . The Commission also decided, on its own initiative, to informally consult EFSA again on those comments. This contributed to a delay in the final reply by nearly a month. In the future, the Commission will not take into account further comments submitted after the 6-week deadline for introducing a request for review.

12. According to the Commission, several NGOs often send the same request for internal review, although the argumentation is identical in all of the requests. In this case, the Commission received nine identical review requests. The Commission thus had to examine if each of the NGOs was entitled to request an internal review [7] (unless it has already carried out this verification in the context of previous review requests submitted by the same NGO). The Commission considers that such a practice by NGOs has no added value. Since all requests are identical, the Commission's reply will also be identical. The Commission suggests that NGOs co-sign requests and designate one of the NGOs as a contact point, to which the reply of the Commission can be sent.

13. The Commission accepted the Ombudsman's second recommendation, stating that it will implement it systematically. Should the Commission not be able to comply with the 18-week deadline, it will, shortly before the deadline expires, or at the latest on the expiry date of the deadline, inform the NGO of the reasons of the delay and of its right to institute judicial proceedings.

14. The complainant considers that the measures taken, and proposed to be taken, by the Commission are not effective. A revision of the internal procedures should not only deal with procedural aspects but also aim to significantly improve the discussion on the scientific questions underlying review requests. While meeting the statutory deadlines, the Commission should not neglect the scientific content of the requests for internal review.

The Ombudsman's assessment after the recommendations

15. The Ombudsman welcomes the fact that the Commission has reviewed its procedures and that it is confident that it can meet the statutory deadlines so that, at least currently, there is no need for it to propose a change to the time limits in the Aarhus Regulation.

16. The Commission says it has decided not to take into account further material or comments sent by the requester after the expiry of the 6-week deadline to request a review. The Ombudsman would suggest a more nuanced approach in this regard. In some cases it will be clear that the review will benefit from proper consideration being given to the additional material now provided. In such cases, the obligation on the Commission to ensure that the decision to grant authorisation is well-founded [8] , and based on all relevant considerations, may outweigh the requirement to conclude the review within the deadline. The quality of the scientific analysis of the substantive issues raised in the review request should be the Commission's priority. An approach which may be acceptable in such cases is for the Commission to inform the requester that it is willing to consider the new material but on the basis that the requester will accept that

the review decision will be delayed as a result. Where the requester does not agree to an appropriate extension to the review deadline, it will be reasonable for the Commission to decline to take account of the new material. The Ombudsman will make a suggestion for improvement in this regard.

17. The Ombudsman welcomes the Commission's acceptance of her recommendation that it inform an NGO, in case of exceptional non-compliance with the 18-week deadline, giving reasons for the delay, and that it also informs the NGO of its right to institute judicial proceedings.

18. On the basis of the above, the Ombudsman considers that the Commission has followed her recommendations.

19. To allow the Commission to focus even more of its time on the substantive issues in review requests, the Ombudsman encourages the Commission to explain and give appropriate visibility (such as on its dedicated website) to its preference that, where possible, NGOs co-sign a single review request rather than submitting many individual but identical requests. The Ombudsman will make a suggestion for improvement in this regard.

Conclusion

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

The Commission has followed the Ombudsman's recommendations.

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

Suggestions for improvement

The Ombudsman encourages the Commission to explain and give appropriate visibility (such as on its dedicated website) to its preference that NGOs co-sign a single review request rather than submitting many individual but identical requests.

Where an NGO, which has already requested an internal review, provides further relevant material after the expiry of the deadline to request a review, the Commission should do its utmost to examine that material in the course of its review. In such situations, it would seem reasonable for the Commission to seek the agreement of the review requester to an appropriate extension of the deadline for the completion of its review.

Emily O'Reilly

European Ombudsman

Strasbourg, 11/07/2018

[1] Commission Implementing Decision (EU) 2015/687 of 24 April 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rape MON 88302 (MON-883Ø2-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, OJ 2015 L 112, p. 22, available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0022.01.ENG [Nasc]

[2] This request was made according to Article 10 of 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, which states that " *any non-governmental organisation which meets the criteria set out in Article 11* [[2]] *is entitled to make a request for internal review to the Community institution or body that has adopted an administrative act under environmental law* ".

[3] More information available at: http://ec.europa.eu/environment/aarhus/requests.htm [Nasc]

[4] For further information on the background to the complaint, the parties' arguments and the Ombudsman's inquiry, please refer to the full text of the Ombudsman's recommendation available at: https://www.ombudsman.europa.eu/cases/recommendation.faces/en/87311/html.bookmark [Nasc]

[5] Article 10(3) of the Aarhus Regulation.

[6] Article 10(1) of the Aarhus Regulation states that requests for review must be made " *within a time limit not exceeding six weeks after the administrative act was adopted* ".

[7] Article 11 of the Aarhus Regulation lays down the criteria according to which NGOs are entitled to make requests for internal review.

[8] See, for instance, Article 168(1) of the Treaty on the Functioning of the EU: " *A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities* ".