Cinneadh i gcás 1107/2020/NH ar sceitheadh faisnéise rúnda a líomhnaítear go ndearna Údarás Eorpach um Shábháilteacht Bia (EFSA) maidir le substaint ghníomhach a úsáidtear i lotnaidicídí

Cinneadh
Cás 1107/2020/NH - **Tosaithe an** 17/07/2020 - **Cinneadh an** 12/02/2021 - **Na hinstitiúidí lena mbaineann** An tÚdarás Eorpach um Shábháilteacht Bia (Ní bhfuarthas drochriarachán) | An tÚdarás Eorpach um Shábháilteacht Bia (Níl aon údar le fiosrúcháin bhreise) |

Bhain an cás le halt a foilsíodh i nuachtán Francach, inar mhaígh an t-iriseoir go raibh rochtain aige ar litir rúnda a chuir na gearánaigh chuig an Údarás Eorpach um Shábháilteacht Bia (EFSA) mar chuid de phróiseas athnuachana ar fhormheas substainte gníomhaí a úsáidtear i lotnaidicídí. D'áitigh na gearánaigh gur sceitheadh EFSA an litir sin chuig an bpreas, agus nach raibh cosaintí iomchuí i bhfeidhm aige i gcoinne nochtadh neamhúdaraithe faisnéise rúnda ag baill foirne. D'áitigh na gearánaigh freisin nach raibh EFSA oibiachtúil agus neamhchlaonta ina ráitis don phreas.

Fuair an tOmbudsman gur sheol na gearánaigh an litir atá faoi thrácht ní amháin chuig EFSA, ach chuig gníomhaithe eile freisin. Ó tharla nárbh é EFSA an t-aon chomhlacht a raibh an litir ina sheilbh aige, níorbh fhéidir a chinneadh go cinnte gur sceitheadh EFSA an litir chuig an bpreas. Rinne EFSA dhá fhiosrúchán inmheánach ar chásanna sceite a d'fhéadfadh a bheith ann agus tháinig siad ar an gconclúid nach raibh aon fhianaise ann gur tháinig aon sceitheadh ó bhall foirne EFSA. Níor aimsigh an tOmbudsman aon rud a thabharfadh le tuiscint nach raibh cosaintí cearta curtha i bhfeidhm ag EFSA i gcoinne sceite. Maidir le ráitis EFSA leis an bpreas, tháinig an tOmbudsman ar an gconclúid nár sháraigh EFSA a dhualgais oibiachtúlachta agus neamhchlaontachta.

Dhún an tOmbudsman an fiosrúchán agus cinneadh nach raibh aon drochriarachán i gceist ag EFSA sa chás seo.

Background to the complaint

1. The complainants are two producers of a pesticide with the active substance mancozeb. An active substance is the component in the pesticide that actually kills the pest or plant disease. The substance mancozeb is generally used against fungal diseases in a wide range of field

crops, in particular potatoes.

2. In the EU, each active substance in pesticides needs to be approved through a strict procedure before being sold and used. [1] The European Food Safety Authority (EFSA) and the national authorities in the EU countries are jointly responsible for carrying out a risk assessment of each active substance. Only substances for which there is objective evidence of safe use are approved.

3. The period during which active substances remain approved is, in general, 10 years, after which it is possible for producers of the substance to apply for renewal. [2] The renewal procedure involves a joint peer review of the risks of the substance by EFSA in collaboration with Member States.

4. The complainants applied for the renewal procedure of mancozeb in 2015. Between 2015 and 2019, EFSA carried out a peer review of the risk assessments with representatives of Member States. On 12 June 2019, EFSA sent its conclusions on the peer review to the complainants. The conclusions identified a number of critical areas of concern for mancozeb.

5. EFSA allows producers of active substances to redact confidential information in its conclusions before publication, in order to protect certain commercial interests. This process is called ' *sanitisation'* . [3] In this case, the complainants requested that EFSA publish a *sanitised* version of its conclusions on mancozeb. EFSA challenged the redactions requested by the complainants. The complainants then went to the EU courts to obtain an interim order to prevent EFSA from publishing the full version of its conclusions.

6. On 20 November 2019, EFSA published the *sanitised* conclusions on the peer review in the agency's online scientific journal - the "EFSA Journal". [4] EFSA indicated that it would publish a revised version of those conclusions as soon as the EU courts would settle the legal dispute on confidentiality between EFSA and the complainants.

7. On 2 December 2019, French newspaper *Le Monde* published an article entitled " *Scientific advice on a fungicide censored by its manufacturer* ". The article claimed to have had sight of an uncensored version of EFSA's conclusions on mancozeb and quoted two sentences from that version. The article also stated that an EFSA spokesperson regretted that the agency could not publish the full version of the conclusions, and that it hoped to do so soon.

8. The complainants wrote to EFSA on 6 December 2019 and expressed their surprise regarding the article published in *Le Monde* . The complainants contended that EFSA had leaked the uncensored version of its conclusions to *Le Monde* and therefore breached its duty of confidentiality. The complainants also said that EFSA had breached its duty of impartiality by stating to the newspaper that it regretted the redactions requested by the complainants. EFSA replied to the complainants that it would look into the alleged leak. On 20 April 2020, EFSA concluded that there was no evidence that one of its staff members may have disclosed the non-sanitised version of the conclusions on mancozeb, as the document had been shared with other actors (the European Commission and the national competent authorities).

9. On 10 April 2020, another French newspaper, *Le Parisien* , published an article entitled " *During the health crisis, the makers of a controversial pesticide shuffle their cards* " concerning the approval procedure for mancozeb. The journalist claimed to have had access to the content of a confidential letter sent by the complainants to EFSA on 19 August 2019, and quoted specific parts of that letter. The letter expressed, in particular, that the complainants were in "deep disagreement" with EFSA's conclusions on mancozeb, which they said were based on an "incomplete set of data". In this article, similar to *Le Monde* , an EFSA spokesperson also regretted that EFSA could publish only a redacted version of the conclusions.

10. On 20 May 2020, the complainants wrote to EFSA, expressing their surprise about the publication of the *Le Parisien* article and asking EFSA to publish a full retraction of the statements made in the article.

11. Having received no reply from EFSA, the complainants turned to the Ombudsman on 29 June 2020.

The inquiry

12. The Ombudsman opened an inquiry into the following aspects of the complaint:

1) how EFSA handled the complainants' concern regarding the leak of a letter written by the complainant's lawyer to French newspaper *Le Parisien* ;

2) whether EFSA has in place appropriate safeguards against the unauthorised disclosure of information by staff members;

3) whether EFSA breached its duty of impartiality and objectivity when an EFSA spokesperson expressed regrets to the press that EFSA could only publish a redacted version of its conclusions on mancozeb.

13. In the course of the inquiry, the Ombudsman asked EFSA to reply to the first two aspects of the complaint. The Ombudsman also offered the complainants the possibility to submit comments on EFSA's reply, but did not receive any comments.

Arguments presented to the Ombudsman

14. In their complaint, the complainants contended that EFSA had breached its duty of professional secrecy and confidentiality by leaking the confidential letter to *Le Parisien* . The letter had been sent by the complainants' lawyer and, therefore, contained privileged and confidential information. The complainants also argued that the article in *Le Parisien* included several hints that EFSA staff members were indeed the source of the information provided to the press, in particular because the journalist expressly states that he could consult the letter

sent to the " *agency's experts on behalf of these industrialists* ".

15. The complainants further argued that EFSA had failed to review, adapt or otherwise improve its internal safeguards against the unauthorised disclosure of information by its staff members, despite the concerns raised earlier by the complainants as regards the first leak to *Le Monde* newspaper on 2 December 2019.

16. The complainants also argued that EFSA had violated its duties of impartiality and objectivity, because an EFSA spokesperson had expressed regrets, both to *Le Monde* and to *Le Parisien* , that EFSA could publish only a redacted version of its conclusions on the substance. They alleged that the article in *Le Parisien* suggested that their request to redact the conclusions was unreasonable. In addition, they said that the journalist mentioned having talked solely to the EFSA spokesperson in the article, which proved that the leak of the letter had come from EFSA.

17. In its reply, EFSA informed the Ombudsman - and the complainants - that it had opened an internal investigation into the complainants' concerns regarding the alleged leak of the letter in order to assess the evidence provided. Three months later, while the Ombudsman inquiry was still ongoing, EFSA concluded the internal investigation and found that the facts collected did not point to any person who might have been involved in the disclosure of the concerned letter. Therefore, based on these findings, EFSA decided to close the case without any further action. EFSA also recalled that it had opened a similar internal investigation in the case of the alleged leak to *Le Monde* in December 2019, which had concluded that there was insufficient evidence to open an administrative inquiry.

18. EFSA explained that the wording used in the article in *Le Parisien* did not imply in any way that EFSA's experts disclosed the letter in question or that the journalist from *Le Parisien* spoke to them. In addition, EFSA said that there was no proven connection between the statements made by EFSA's spokesperson and the alleged leak of the letter.

19. EFSA also described the mechanisms in place to ensure the confidentiality of the documents handled by the agency. In particular, EFSA staff members are regularly trained on the obligation to refrain, including after leaving the service, from any unauthorised disclosure of information received in the line of duty, as well as on the principles of ethics and integrity. EFSA also has internal rules in place as regards records management and information security policies.

The Ombudsman's assessment

(i) Concerning the alleged leak of a letter to French newspaper Le Parisien

20. As a preliminary remark, the Ombudsman notes that the article in *Le Parisien* was published a few days before EFSA concluded that there had been no leak of information for the article published in *Le Monde* . As such, before EFSA was in a position to complete its first inquiry into

a possible leak, a second leak occurred, leaving the complainants with the impression that EFSA may have deliberately leaked information to the press on two occasions.

21. The Ombudsman has examined the letter sent by the complainants' lawyer to EFSA on 19 August 2019, to which the journalist of *Le Parisien* had access. It appears that the lawyer did not send the letter to EFSA only, but also to other actors involved in the renewal procedure for mancozeb, including a national research institute, a national official and a staff member of another EU institution. This means that EFSA was not the only body in possession of the document at the time when *Le Parisien* published the article. According to EU case law, if a document has already been made available to a number of other actors prior to the leak, it cannot be presumed that the issuing authority is the source of the leak. [5]

22. Following the expression of concerns by the complainants about the leak, EFSA opened an internal investigation in order to assess the evidence provided. The investigation concluded, after three months, that there was no evidence that an EFSA staff member may have disclosed the letter to the press. This shows that EFSA took the matter seriously and was sufficiently diligent in following up on the complainant's concerns. The Ombudsman, for her part, has found no evidence to suggest that EFSA committed any maladministration in its handling of the case.

(ii) Concerning the safeguards in place against the unauthorised disclosure of information

23. It follows from this finding that there is no reason to believe that the measures in place at EFSA to prevent unauthorised disclosure of information by staff members are not appropriate. EFSA has described the extensive safeguards in place, and the Ombudsman finds that no further inquiries are justified in this regard.

(iii) Concerning the regrets expressed by EFSA to the press that it could publish only a redacted version of its conclusions on mancozeb

24. The complainants contend that the statements made by an EFSA spokesperson to the press, expressing regrets that the agency could publish only a redacted version of the conclusions on mancozeb, imply that EFSA was not impartial and objective.

25. The Ombudsman notes that, in line with the applicable rules, [6] EFSA is responsible for the assessment of confidentiality requests pertaining to applications submitted under the procedure for the renewal of the approval of an active substance. The same rules clearly lay down that requests for confidential treatment of information in this field are an exception to the principle of proactive public disclosure. It is therefore entirely reasonable for EFSA to seek to ensure maximum transparency when it comes to publishing the conclusions on active substances. The fact that EFSA, through a spokesperson, made public its regrets that the conclusions in one case were not fully transparent cannot be considered as a breach of its duties of impartiality and objectivity. The complainants later brought the case before the EU courts, [7] which means the disagreement between EFSA and the complainants concerning the publication of the conclusions on mancozeb was a matter of public record.

26. The Ombudsman notes that the document in question serves as a basis for the process regarding the renewal of the approval for a pesticide with a high potential impact on public health and environment. It is vital for the public in a democratic society to follow the process for the approval of such substances. While companies have the right to request that some information remains confidential for reasons of commercial interests, it would be damaging for transparency and EU citizens' participation in the democratic life of the EU if companies were in a position to redact documents without an objectively justifiable reason for doing so.

27. A review of other conclusions on pesticides available on the EFSA website shows that, generally, almost no information is redacted. In the case of mancozeb, the complainants largely redacted the substantive part of the conclusions. As the EFSA spokesperson explained to the press, " *this happens rarely* ".

28. The Ombudsman concludes that there was therefore no maladministration by EFSA when it declared to the press that it regretted that it could publish only a redacted version of the conclusions on mancozeb.

Conclusions

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

There was no maladministration by EFSA in this case. No further inquiries are justified regarding the complainants' argument about the adequacy of the safeguards in place against unauthorised disclosure of confidential information.

The complainants and EFSA will be informed of this decision **.**

Emily O'Reilly European Ombudsman

Strasbourg, 12/02/2021

[1] This is laid down in Regulation (EC) No 1107/2009 [Nasc] of the European Parliament and of the Council concerning the placing of plant protection products on the market.

[2] As laid down in the Commission Implementing Regulation (EU) No 844/2012 [Nasc] setting out the provisions necessary for the implementation of the renewal procedure for active substances.

[3] See EFSA's " Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances [Nasc]", adopted 27 March 2019, section 2.5:

" *Before publication, the applicant can submit a request for removal of information deemed confidential from such documents in line with Article 63(2) of Regulation (EC) No 1107/2009 ("sanitisation")* ".

[4] See " *Peer review of the pesticide risk assessment of the active substance mancozeb* ", available at https://www.efsa.europa.eu/en/efsajournal/pub/5755 [Nasc].

[5] See Judgment of the General Court of 8 July 2008, *Franchet and Byk* v [Nasc]*European Commission* , case T-48/05, paragraphs 202 to 206.

[6] Regulation (EC) No 1107/2009 [Nasc] of the European Parliament and of the Council concerning the placing of plant protection products on the market.

[7] In the course of the Ombudsman's inquiry, on 12 August 2020, the General Court dismissed the application for interim relief made by the complainants on the ground that there was no prima facie case (see order of the President of the General Court of 12 August 2020, *Indofil Industries* v [Nasc]*EFSA* , case T-162/20 R). As a result, EFSA published the full, unredacted, version of the conclusions on mancozeb on its website.