



Decisione nel caso 747/2016/PL sull'uso da parte dell'Autorità europea per la sicurezza alimentare della soglia di allarme tossicologico

Decisione

Caso 747/2016/PL - Aperto(a) il 29/08/2016 - Decisione del 17/12/2018 - Istituzione coinvolta Autorità europea per la sicurezza alimentare (Cattiva amministrazione non riscontrata) |

Il caso riguardava il modo in cui l'Autorità europea per la sicurezza alimentare (EFSA) utilizza la soglia di allarme tossicologico (TTC). La TTC è uno strumento di valutazione del rischio basato sul principio che vi sono livelli di esposizione al di sotto dei quali le sostanze chimiche non presentano un rischio significativo per la salute umana.

Nel 2014 l'EFSA e l'Organizzazione mondiale della sanità (OMS) hanno ospitato un seminario di esperti finalizzato a esaminare i fondamenti scientifici alla base del concetto di TTC. Le conclusioni del seminario sono state oggetto di una consultazione pubblica e sono state pubblicate nel marzo 2016.

Il denunciante, una ONG, ha messo in discussione l'utilizzo da parte dell'EFSA del concetto di TTC, ritenendo che non rispecchi le evidenze scientifiche attuali. Ha affermato inoltre che molti degli esperti che hanno partecipato al seminario avevano conflitti di interesse.

L'Ufficio del Mediatore europeo non è un organo scientifico e non può pertanto esprimere il proprio parere in merito a uno strumento di valutazione dei rischi specifico come la TTC. Sulla base della revisione effettuata in questo caso, la Mediatrice ha ritenuto che le spiegazioni dell'EFSA relative all'uso della TTC fossero ragionevoli.

Per quanto riguarda gli esperti che hanno partecipato al seminario, la Mediatrice ha concluso che, nel caso specifico, l'EFSA non era tenuta a verificare se avessero conflitti di interesse, dal momento che era ragionevole per l'EFSA affidarsi all'esame preventivo di tali esperti da parte dell'OMS.

La Mediatrice ha concluso che non vi è stata cattiva amministrazione da parte dell'EFSA.

Tuttavia, la Mediatrice ha suggerito che l'EFSA si assicuri del fatto che gli esperti partecipanti a conferenze o riunioni non abbiano conflitti di interesse, se la conferenza o la riunione — come quella in questione — è organizzata per ispirare il processo decisionale dell'EFSA o potrebbe essere percepita come tale.



Background to the complaint

- 1.** The complainant, PAN Europe, is a network of civil society organisations, which seeks to bring about a substantial reduction in pesticide use throughout Europe.
- 2.** The Threshold of Toxicological Concern (TTC) is a risk assessment tool based on the principle that there are exposure levels below which chemicals do not pose a significant risk to human health. This tool allows regulators to assess the risk posed by substances based on their chemical structure, the estimated exposure to them and a comparison with known chemicals.
- 3.** According to its proponents, the use of the TTC (a) eliminates the need for extensive toxicity testing when the human intake of a chemical is below the threshold, (b) focuses resources on those substances posing a greater potential risk to human health, and (c) helps reduce animal testing.
- 4.** In 2012, EFSA issued a Scientific Opinion on '*Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC)*' [1]. EFSA's Scientific Committee concluded in that opinion that the TTC approach could be recommended as a useful **screening tool**, either for priority setting or for deciding whether further data are needed in a given case.
- 5.** In December 2014, EFSA and the World Health Organisation (WHO) hosted an expert workshop to review the science underlying the TTC concept (hereinafter 'the workshop'). The experts taking part in the workshop were selected following a call for experts **organised by the WHO**. Following the workshop, EFSA carried out a public consultation on the conclusions and recommendations reached.
- 6.** In March 2016, EFSA and the WHO published the '*Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree*' (the 'report'). The report concluded that the TTC is a valid screening tool that is fit for purpose and based on scientific risk assessment principles. It made recommendations to improve upon and expand the use of the TTC concept.
- 7.** On 25 March 2016, the complainant wrote to EFSA complaining about EFSA's use of the TTC. In that context, it questioned the independence of the experts who took part in the workshop. It also stated that its contribution to the public consultation had been disregarded. The complainant asked that the 2016 report be retracted and that an independent review of the TTC be carried out.
- 8.** In its reply of 27 April 2016, EFSA noted that the report simply summarised the discussions that took place at the TTC workshop. As such, EFSA could not "retract" its content. Regarding the independence of the experts, EFSA noted that the screening of their declarations of interests (Dols) was performed by the WHO according to that organisation's rules. As for the complainant's responses to the public consultation, EFSA said that they were outside its scope. Finally, EFSA explained its use of the TTC in reply to the complainant's criticism of the TTC.



9. Dissatisfied with EFSA's reply, the complainant turned to the Ombudsman.

The inquiry

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

1) EFSA should no longer use the TTC approach.

2) EFSA failed to guarantee the independence of the experts reviewing the TTC.

11. The Ombudsman received the reply of EFSA on the complaint and, subsequently, the complainant's comments on EFSA's reply. The Ombudsman's inquiry team also met with the EFSA team responsible for the case. After that meeting, the Ombudsman received a further reply from EFSA and the complainant's comments.

EFSA's use of the TTC approach

Arguments presented to the Ombudsman

12. The complainant contended that EFSA's use of the TTC approach disregards current scientific knowledge and violates EFSA's founding principle to contribute to a high level of protection of human life and health.

13. The complainant also contended that setting a threshold of toxicity is a risk management decision that should not be taken by a risk assessment body, such as EFSA, but by the European Commission's Standing Committee. Thus, by using the TTC tool EFSA is acting outside its remit.

14. In its reply, EFSA noted that the TTC is a risk assessment tool that has been used for decades by a range of scientific risk assessment bodies, including the Commission's former Scientific Committee on Food and the European Medicines Agency.

15. EFSA noted that setting threshold values or determining safety factors [2] is not specific to the TTC approach, but inherent to the field of toxicological risk assessment. The choice and application of safety factors is not a risk management decision, but a scientific matter. Hence, in determining safety factors, EFSA is not going beyond its remit.

16. EFSA noted that it currently employs the TTC approach either as a screening tool or for substances on which toxicological data is missing and it is legally bound to use this method or comparable ones.

17. EFSA stated that it has an institutional and scientific obligation to keep its use of the TTC method up to date and compatible with recent scientific findings. For this, it would review the opinion produced by EFSA's Scientific Committee, and update it if necessary.

18. In its reply, the complainant reiterated its previous arguments and added that EFSA's statements and practice differ. While EFSA claims that the TTC is a screening tool used to set priorities, EFSA uses it, for example, to determine the risk of certain substances [3] in



groundwater. For the complainant, using the TTC for these substances is a risk management decision.

The Ombudsman's assessment

19. The Office of the European Ombudsman is not a scientific body and does not have the expertise to evaluate the merits of the scientific opinions taken by specialised committees. [4]

20. EFSA's use of the TTC approach follows the recommendation of its Scientific Committee of 2012, which concluded that the TTC could be useful to EFSA as a "*screening tool either for priority setting or for deciding whether exposure to a substance is so low that the probability of adverse health effects is low and that no further data are necessary*".

21. In its Scientific Opinion on the matter, EFSA's Scientific Committee says that it examined the published literature on the TTC approach and analyzed the databases underpinning the TTC [5]. From this analysis, the Scientific Committee concluded that TTC values were adequately supported by scientific data [6].

22. In its reply to this complaint, EFSA stressed that it had a legal obligation to keep its use of the TTC method up to date and, thus to review the Opinion of the Scientific Committee and adapt its use if needed.

23. As stated above, the Ombudsman does not have the expertise to assess whether EFSA's scientific analysis of the evidence dating from 2012 was correct and whether its ongoing monitoring of the latest scientific developments regarding the TTC is adequate.

24. The Ombudsman notes that EFSA took its decision to use the TTC approach in 2012, based on extensive and up to date scientific knowledge. EFSA intends to review that decision whenever new scientific evidence and findings require it to do so.

25. In the light of this, and without taking any view on the merits of EFSA's scientific assessments, the Ombudsman finds that the complainant's argument that the use of the TTC does not take into account current scientific knowledge is not correct.

26. The complainant also considers that the TTC approach constitutes a risk management and not a risk assessment activity. The Ombudsman notes that EFSA's founding Regulation [7] defines risk assessment as consisting of four steps, namely "*hazard identification, hazard characterisation, exposure assessment and risk characterisation*" [8]. According to that Regulation, risk management is "*the process, distinct from risk assessment, of weighing alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options*" [9]. In other words, risk assessors provide advice based on a scientific analysis and risk managers use this advice as a basis for making decisions.



27. EFSA has described the TTC as a screening and prioritisation tool for the safety assessment of chemicals when hazard data are incomplete or missing. EFSA has also said that it uses the TTC to reach conclusions on toxicological safety for substances on which concrete data is missing and where the legislature specifically asked the Authority to use this method or comparable ones. The Ombudsman's view is that these uses of the TTC fall under the definition of risk assessment.

28. The complainant contends that EFSA goes beyond its mandate by using the TTC not just as a screening tool, but also for determining the risk of relevant substances in ground water.

29. The Ombudsman notes that the use of the TTC approach for these substances is recommended in a European Commission guidance paper [10] . Thus, in setting a threshold for pesticide metabolites in ground water, EFSA applies [11] the Commission's guidance paper and acts as risk assessor and not risk manager. Therefore, the Ombudsman has not found that EFSA goes beyond its mandate when using the TTC for these substances.

30. In light of the above, the Ombudsman finds no maladministration in relation to EFSA's use of the TTC approach.

The independence of the experts reviewing the TTC

Arguments presented to the Ombudsman

31. The complainant contends that EFSA failed to ensure the independence of the experts who took part in the workshop reviewing the TTC. In particular, by not itself screening the experts for conflicts of interests, EFSA did not respect its own rules on declarations of interests. In the complainant's view, a majority of the experts who took part in that workshop were conflicted, as they had in the past deemed the TTC approach to be a scientifically sound approach or had links to industry.

32. The complainant also noted that, although EFSA claimed that this event would not necessarily lead to the revision of the 2012 decision of its Scientific Committee, EFSA stated in a press release that it intended to integrate the recommendations contained in the event's report in its risk assessment.

33. In reply, EFSA stated that its rules on DoIs do not apply to public conferences and meetings, but to meetings of its institutional scientific groups [12] only. The reason is that the scientific opinions of these latter bodies **are part of EFSA's decision-making process** . Screening the DoIs of the scientific experts who attended this workshop would have gone beyond what is required in its internal legal rules and what is "*compatible with societal expectations*" concerning the independence of **EFSA's regulatory processes** .

34. EFSA stressed that the report, drafted to reflect the discussions at the event, did not constitute **the views of EFSA** (or of the WHO) on the matter, but rather the views of the experts present at the meeting. EFSA added that should it review its 2012 scientific opinion on the TTC, it would fully apply its independence policy and rules on DoIs to all the experts participating in that revision.



35. Regarding the experts chosen for the workshop, EFSA noted that they were required to submit a DoI, which was examined by the WHO in accordance with its rules. This process was publicised on the WHO's website in advance of the workshop.

36. Concerning the complainant's response to the public consultation, EFSA noted that it was outside the scope of the consultation.

The Ombudsman's assessment

37. The workshop, organised jointly by EFSA and the WHO, gathered a group of thirty-three scientific experts. The call for experts and the screening of their DoIs were carried out by the WHO. EFSA did not carry out its own assessment, considering that it was not legally required to do so.

38. The Ombudsman notes that EFSA's Policy on Independence [13] and Rules on Declarations of Interest [14], in force when the workshop took place, required EFSA to screen the DoIs of experts **in its scientific groups only**, as they participate in EFSA's decision-making process. Thus, under its internal rules, EFSA was not obliged to conduct this exercise for conferences and meetings such as the one at issue.

39. The Ombudsman notes, however, that the WHO screens experts when it organises such conferences or meetings. It is therefore arguably good practice to screen experts for conflicts of interests when a meeting or conference is organised by EFSA with a view to informing its decision-making process. Similarly, if the meeting or conference can reasonably be perceived as having been organized for that purpose, the screening should take place.

40. In this case, the experts who took part did in fact go through a screening process carried out by the WHO following its own rules on DoIs. The WHO identified five experts who had conflicts of interests. These experts were excluded from the meeting on the last day of the workshop, when the workshop agreed its conclusions and recommendations.

41. There is nothing in the file to suggest that EFSA should have questioned the quality or integrity of the WHO's screening of experts. As to the conflict of interests referred to by the complainant, the fact that, before the workshop, the experts had expressed scientific opinions on the issues discussed, is not sufficient to call into question their independence or to presume that they had a vested interest in the TTC approach.

42. The complainant did not provide any concrete evidence to substantiate the alleged links of those experts with industry.

43. The Ombudsman therefore concludes that there was no maladministration by EFSA.

44. The Ombudsman notes that EFSA, in the course of this inquiry and following discussions with her inquiry team, reviewed its policy on independence, and published new rules on



conflicts of interests [15] . These rules do not address the issues put forward in this complaint, namely, they do not require the screening of experts who take part in conferences or meetings organised by EFSA itself or jointly with other entities to inform its decision-making process. [16]

45. The Ombudsman considers that EFSA should further strengthen its procedures. Specifically, EFSA should, to the extent possible, see to it that the Dols of experts taking part in conferences or meetings, organised with a view to informing EFSA's decision-making process, are screened. The Ombudsman will make a suggestion for improvement below.
Conclusion

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

There was no maladministration by the European Food Safety Authority.

Suggestion for improvement

The Ombudsman suggests that the European Food Safety Authority see to it that experts who participate in conferences or meetings have no conflicts of interests, where the conference or meeting — like the one at issue — is organised to inform EFSA's decision-making process, or could be perceived as doing so .

The complainant and EFSA will be informed of this decision.

Emily O'Reilly

European Ombudsman

Strasbourg, 17/12/2018

[1] EFSA Scientific Committee; Scientific Opinion on Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC). EFSA Journal 2012;10(7). Available at: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2750>

[2] A safety factor is a ratio obtained from toxicology studies and used to predict the safe human exposure level or dose.

[3] EFSA uses the TTC for pesticide metabolites in groundwater. Pesticide metabolites are the product of chemical reactions when a pesticide comes into contact with air, water, soil or living organisms.

[4] See Decision in case 1475/2016/JAS on the European Medicines Agency's handling of the



referral procedure relating to human papillomavirus (HPV) vaccines, paragraph 22, available at:

https://www.ombudsman.europa.eu/en/decision/en/84736#_ftnref32

[5] See pp. 26-27 of the Scientific Committee's Opinion.

[6] See pp. 46 of the Scientific Committee's Opinion.

[7] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety OJ L 31, 1.2.2002, p. 1–24.

[8] Article 3(11) of Regulation 178/2002.

[9] Article 3(12) of Regulation 178/2002.

[10] Guidance document SANCO/221/2000 rev 10 of 25 February 2003 (EC, 2003), page 10, available at:

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_fate_metabolites-g, page 10.

[11] EFSA Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on Evaluation of the Toxicological Relevance of Pesticide Metabolites for Dietary Risk Assessment. EFSA Journal 2012;10(07): 2799. [187 pp.] doi:10.2903/j.efsa.2012.2799. Available online: www.efsa.europa.eu/efsajournal

[12] Scientific Committee, Scientific Panel and Working Group.

[13] EFSA Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority of 2011. Available at: http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/independencepolicy.pdf

[14] Decision of the Executive Director on Declarations of Interest of 2014 (in force between 30 Sep 2014 until 30 June 2018, except for Article 19 and 20 thereof, which remain in force until further notice). Available at: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independencerules2014.pdf

[15] EFSA (European Food Safety Authority), 2018. EFSA rules on competing interest management.

[16] See, Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management of 26 October 2017. Available at: <https://www.efsa.europa.eu/en/corporate/pub/independencepolicy17>

