Decision in case 48/2015/ANA on the European Food Safety Authority's alleged infringement of the complainant's procedural rights as regards a scientific opinion

Decision
Case 48/2015/ANA - **Opened on** 03/02/2015 - **Decision on** 23/09/2015 - **Institution concerned** European Food Safety Authority (No maladministration found) |

The complainant, Rubinum, a Spanish producer/distributor of animal feed additives, complained to the Ombudsman that EFSA had infringed its procedural rights in the context of the drafting of an EFSA Scientific Opinion which led to the Commission banning Toyocerin, a feed additive used to fatten farm animals.

The Ombudsman inquired into the issue and asked the complainant to clarify its allegations. On the basis of this inquiry, the Ombudsman found that there was no maladministration on the part of EFSA in this case.

The background to the complaint
1. The complainant, a Spanish company called Rubinum, marketed *Toyocerin* , a feed additive for animals based on a strain of bacteria, *Bacillus toyonensis* [1] . *Toyocerin* is used to improve the digestion of nutrients in animal feed. It was first authorised for use in 1994 as a feed additive for pigs. The European Commission's Scientific Committee on Animal Nutrition concluded that Toyocerin was safe in 2001 [2] .

2. Since 2003, the rules governing the authorisation of additives for use in animal nutrition are laid down in Regulation 1831/2003 [3] . On the basis of that Regulation, on 17 December 2010, the complainant submitted applications for the (re)authorisation of *Toyocerin* for fattening cattle, rabbits, chickens and pigs, weaning piglets, breeding pigs and rearing calves.

3. On 31 October 2012, EFSA's Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel), adopted a Scientific Opinion in which it concluded that the strain of *Bacillus cereus* harbours " *resistance determinants* " to two antibiotics (*Bacillus toyonensis* being part of the *Bacillus cereus* group). It also concluded that the *Toyocerin* strain can produce functional toxins. Consequently, it concluded, *Toyocerin* poses a hazard for people who are exposed to it [4] .

4. On the basis of this opinion, on 25 March 2013, the European Commission adopted Implementing Regulation 288/2013 (hereinafter, the 'Commission Implementing Regulation') [5] , which suspended the existing authorisations for *Toyocerin* .

5. In December 2013, the complainant provided the FEEDAP Panel with additional data, including new studies and asked for a re-assessment of the file. From December 2013 to June 2014, the complainant submitted to EFSA five additional expert reports on the safety of *Toyocerin* .

6. On 19 May 2014, aware that the FEEDAP Panel was expected to approve its Scientific Opinion at its plenary meeting of 1-3 July 2014, the complainant requested a meeting with EFSA.

7. On 17 June 2014, the complainant submitted further documents including further expert reports.

8. On 24 June 2014, EFSA acknowledged receipt of the expert reports and noted that this was the third spontaneous submission of information by the complainant. EFSA drew the complainant's attention to the fact that the FEEDAP Panel cannot consider any further documents unless they contain raw experimental data. Moreover, EFSA pointed out that the Panel has the legal obligation to perform its own assessment and draw its own conclusions.

9. On 26 June 2014, a meeting took place between the complainant, which was accompanied by four scientific experts, and the members of the EFSA Working Group on Microorganisms, which was in charge of the *Toyocerin* file [6] . In that meeting, the complainant presented its views and explained its arguments in favour of the safety of *Toyocerin* . EFSA drew the complainant's attention to the fact that the content of the Panel's Scientific Opinion had not yet been finalised and that it could not be disclosed at the meeting.

10. On 30 June 2014, the complainant's lawyer wrote to EFSA summarising the content of the meeting of 26 June 2014. In his letter, he expressed his dissatisfaction with the fact that the members of the Working Group on Microorganisms neither commented on the evidence presented by the complainant's scientific experts present nor posed any questions. The complainant's lawyer expressed his hope that this was because EFSA's experts did not question the evidence presented to EFSA by the complainant and they consider that *Toyocerin* was safe. According to the complainant's lawyer, should there have been any doubts on this issue, failure to raise them at the meeting would entail an infringement of fair procedure and of the complainant's right to be heard.

11. On 1 July 2014, EFSA's FEEDAP Panel issued its Scientific Opinion on *Toyocerin* [7] . In its Scientific Opinion, EFSA confirmed the conclusions drawn in its Scientific Opinion of 2012, that is, that a) *Bacillus toyonensis* poses a risk that genes coding for resistance to antibiotics will be spread and b) *Bacillus toyonensis* has the capacity to elaborate functional toxins. As a result, according to EFSA, *Toyocerin* poses a risk to humans who come into contact with it.

12. On 3 July 2014, EFSA replied to the complainant's letter of 30 June 2014. In that reply, EFSA confirmed that all the submissions put forward by the complainant, including the presentation at the meeting of 26 June 2014, were brought to the attention of the FEEDAP Panel. In fact, EFSA showed flexibility in order to accept those submissions that were sent

after the relevant deadline. Regarding the meeting of 26 June 2014, EFSA suggested that the meeting served its purpose and took place within the terms agreed. Any additional expectations from the complainant are outside these terms and not supported by EFSA. Regarding the substance of the complainant's submissions, EFSA stressed that its scientific experts present at the meeting had no doubts as to how to interpret the data submitted by the complainant. In any event, EFSA highlighted that the decision would not be taken by the Working Group, but by the FEEDAP Panel on the basis of the principle of collegiality, and that at the time of its meeting with the complainant the FEEDAP Panel had not yet reached a conclusion.

13. On 30 August 2014, acting in accordance with Article 19 of Regulation 1831/2003 [8] , the complainant applied to the Commission for the administrative review of EFSA's Scientific Opinion.

14. On 23 December 2014, the complainant lodged this complaint with the European Ombudsman. At that point, the Commission had not yet replied to the complainant's application for an administrative review

The inquiry

15. The Ombudsman has analysed the complainant's arguments and EFSA's position on them and identified the following allegations and claim made by the complainant.

The complainant alleges that:

1) EFSA infringed the complainant's procedural rights, in particular its right to be heard, in the procedure leading to the adoption by the FEEDAP Panel of a Scientific Opinion on the Safety and Efficacy of *Toyocerin* .

2) EFSA infringed the complainant's right to equal treatment.

3) EFSA infringed the complainant's right to the protection of legitimate expectations.

4) Members of the EFSA Working Group on Microorganisms were not impartial.

The complainant claims that:

5) EFSA should launch a reassessment of the safety of *Toyocerin* by a new Working Group.

16. On 3 February 2015, the Ombudsman wrote to the complainant informing it that, before deciding whether to request EFSA to submit an opinion to the Ombudsman, certain aspects of the complaint needed to be clarified. Specifically, the Ombudsman drew the complainant's attention to the fact that, on the basis of the information on file, EFSA appeared to have given it the opportunity to present its views to EFSA. Further, it examined these views in its Scientific Opinion of 1 July 2014. Moreover, the Ombudsman noted that the complainant had not submitted any evidence to support its assertion that the scientific experts of the Working Group on Microorganisms lacked impartiality in the handling of the complainant's application to approve *Toyocerin* .

17. In its clarifications of 23 February 2015, the complainant stated that the file submitted to EFSA in December 2013 fulfilled all the requirements in the EFSA Guidance Documents relevant to its product [9] . It argued that it had provided EFSA with new evidence for the safety of *Toyocerin* and that 34 scientists of recognised experience in the fields of taxonomy, molecular biology, bio-informatics, bacterial antibiotic resistance and toxicity were involved in the preparation of the data included in the file. This evidence was reviewed by independent professors of recognised experience in the fields of taxonomy, molecular biology, bacterial antibiotic resistance and toxicity who, in a total of 8 expert reports, concluded that the new data provided to EFSA in December 2013 corroborated the safety of *Toyocerin* .

18. Moreover, the complainant argued, the presentation to the FEEDAP Panel which the Working Group on Microorganisms made at the meeting of 1 July 2014 was only a short summary of findings that lacked scientific rigour; hence, according to the complainant, the FEEDAP Panel gave its Scientific Opinion of 1 July 2014 without access to the full set of data the complainant had submitted to EFSA. In addition, the complainant contended, the FEEDAP Panel did not take into account the presentation prepared by its own recognised scientific experts. Moreover, the members of the Working Group on Microorganisms did not raise any concerns about the safety of *Toyocerin* in the meeting of 26 June 2014. Finally, the complainant argued that EFSA did not follow its own rules when it found that *Toyocerin* could produce functional toxins. It argued that the toxicity of *Toyocerin* was far below the safe thresholds and even below the toxicity of microorganisms used in human food.

19. In light of the above arguments, the complainant maintained its allegation that its procedural rights had been infringed.

20. In the subsequent months, the complainant provided the additional information and further clarifications which the Ombudsman has taken into account.

21. On 20 May 2015, the Commission took a decision on the complainant's request for an administrative review of EFSA's Scientific Opinion of 1 July 2014 [10] . It noted that, in its request for an administrative review of EFSA's Scientific Opinion, it had alleged that its right to be heard, the right to equal treatment and the right to the protection of legitimate expectations were violated by EFSA. The complainant also questioned the impartiality of the members of the Working Group on Microorganisms.

22. In its detailed decision on the request for an administrative review of EFSA's Scientific Opinion, the Commission concluded that EFSA did not breach the complainant's right to be heard, right to equal treatment or the right to the protection of legitimate expectations. In addition, the administrative review did not give rise to concerns as to the impartiality of EFSA's experts. On this basis, the Commission decided that there was no reason to require that EFSA withdraws its scientific opinion of 1 July 2014.

23. On 21 May 2015, the General Court gave its judgment in the complainant's action for annulment of the Commission Implementing Regulation concerning the 2012 Scientific

Opinion [11] . The General Court dismissed the complainant's application.

24. In June 2015, the complainant sought to convince the Commission to arrange a scientific meeting between the FEEDAP Panel and the complainant's own experts.

25. By e-mail of 19 June 2015, the complainant repeated its request for a scientific meeting prior to the submission of a new application to demonstrate the safety of *Toyocerin* . The complainant enclosed a letter from a trade association, FEFANA [12] , supporting the complainant's request.

26. In its reply of 15 July 2015, the Commission informed the complainant that it was up to the complainant to decide whether to submit a new application for authorisation of *Toyocerin* in accordance with the procedures set out in Regulation 1831/2003. The Commission added that the authorisation of feed additives has to be based on a risk analysis carried out by EFSA, which acts as the independent scientific point of reference at the European level. The Commission informed the complainant that, on the basis of EFSA's Scientific Opinion of 1 July 2014, the Commission was in the process of adopting the Implementing Regulation to replace Regulation 288/2013. Once this process was finalised, the complainant could submit a new application for the authorisation of *Toyocerin* containing all the required data according to Regulation 1831/2003.

27. The Commission also gave an undertaking to explore the possibility of facilitating contacts between the complainant and EFSA, in the context of the preparation of the new application, in order to help the complainant obtain a better understanding of the outstanding issues concerning the evaluation of the product.

29. On 29 July 2015, the trade association FEFANA informed EFSA that there was considerable controversy among scientists in relation to some of the findings in the FEEDAP Panel's Scientific Opinion. It asked EFSA to consult with scientific experts concerning certain areas of controversy, such as the assessment of antibiotic resistance mechanisms.

30. In its reply of 5 August 2015, EFSA welcomed the proposal to improve scientific dialogue. It went on to list the steps it had already taken to keep its scientific knowledge up to date [13] .

The complainant's case against EFSA

Preliminary remarks

31. The complainant informed the Ombudsman of the Commission's decision on the administrative review of the Scientific Opinion of 1 July 2014 and, more broadly, of its exchanges with the Commission concerning the scientific dialogue between applicants and EFSA's experts. The Ombudsman notes that the present inquiry concerns the actions of EFSA and not the Commission. The first preliminary remark is that the actions of the Commission fall outside the scope of this decision.

32. It is clear from the file documents in this case that the complainant disagrees with the

scientific merits of EFSA's position. However, the essence of the complaint to the Ombudsman is not the complainant's substantive disagreement with EFSA's scientific opinion but, on the procedural level, the opportunity given to it to present and defend its position to EFSA. In the interest of clarity and thoroughness, the Ombudsman makes a second preliminary remark that the Ombudsman takes no view on the scientific merits of EFSA's position [14] ; the Ombudsman's assessment focuses only on the complainant's allegations and claim as set out in point 15 above.

The Ombudsman's assessment

33. As regards the complainant's right to be heard, the complainant argues that, as EFSA did not raise any concerns or doubts about the safety of *Toyocerin* prior to its scientific opinion, the complainant was not given the opportunity to present its views and to prove the safety of its product.

34. The right to be heard is a constituent element of the fundamental right to good administration recognised in Article 41 of the Charter of Fundamental Rights of the European Union. That article refers to " *the right of every person to be heard, before any individual measure which would affect him or her adversely is taken* ".

35. As regards the content of the right, the European Court of Justice has ruled that every person should have the opportunity to make known that person's views effectively during an administrative procedure and before the adoption of any decision liable to affect that person's interests adversely [15] . As a corollary, the right to be heard also requires public authorities to pay due attention to the observations thus submitted by the person concerned, examining carefully and impartially all the relevant aspects of the individual case and giving a detailed statement of reasons for their decision [16] .

36. The legal framework governing the authorisation of the use of *Toyocerin* was Regulation 1831/2003 (cited above) and the detailed rules for its implementation (Regulation 429/2008, in particular, Annex II thereto [17]). That legal framework has been deemed, by the General Court, to provide sufficient guarantees so as to ensure that the right to be heard is respected. Thus, when an applicant makes an application for authorisation of a feed additive, it has every opportunity to present its views on the safety of the additive [18] .

37. EFSA has, the Ombudsman notes, in fact gone beyond the minimum requirements prescribed by this legal framework. It has, in fact, given the complainant the opportunity to make additional submissions. It has even organised a meeting for the complainant with the members of the Working Group on Microorganisms. The complainant has thus had ample opportunity to express its views to EFSA.

38. Moreover, even though the complainant submitted further supplementary information and scientific experts' reports outside the formal deadline, the Scientific Opinion of the FEEDAP Panel expressly states that " *all the information provided has been considered and forms the subject of this opinion* " [19] .

39. As regards the complainant's argument that, if the FEEDAP Panel had any doubts as to the safety of *Toyocerin* , it should have asked for additional information, the Ombudsman notes that Article 8(2) of Regulation 1831/2003 gives the FEEDAP Panel a wide margin of discretion to request additional information [20] . In its letter of 3 July 2014, EFSA explained to the complainant that there was no doubt about the interpretation of the additional data submitted by the complainant. As such, the Ombudsman agrees that the FEEDAP Panel acted within its broad margin of discretion when it did not ask for further information from the complainant.

40. Regarding the right to equal treatment, the European Court of Justice has ruled that the principle of equal treatment implies that similar situations should not be treated differently unless such treatment is objectively justified [21] .

41. As regards equal treatment in the procedures followed by EFSA, the complainant did not argue that its application for re-assessment of the safety of *Toyocerin* has been treated less favourably than any other similar application. On the contrary, as mentioned above, the complainant has been given the opportunity to make additional submissions beyond the formal deadlines and the opportunity to make a presentation to the members of the Working Group on Microorganisms.

42. The complainant has, as regards the substantive position taken by EFSA relating to the risks posed by *Toyocerin* , argued that other bacteria, such as *Lactobacillus reuteri* or *Bacillus thuringensis* , which show a higher degree of toxicity, are nevertheless authorised for use in, respectively, food for humans or organic pesticides. The Ombudsman takes no view on the factual assertions made by the complainant relating to *Lactobacillus reuteri* or *Bacillus thuringensis* . The Ombudsman notes, however, that the complainant is effectively arguing that EFSA should have concluded that *Toyocerin* was safe simply because other, different products were declared safe. This argument is not convincing because these are different bacteria and the use for which they were approved concern food and pesticides respectively, as opposed to *Toyocerin* , which concerns animal feed. Therefore, the complainant's arguments about the different treatment accorded to other products by EFSA do not give rise to a conclusion that there could be an infringement of the principle of equal treatment.

43. Regarding the allegation that the EFSA infringed the right to the protection of legitimate expectations, it is settled case-law of the European Court of Justice that the right to rely on that principle extends to any person in a situation in which an administrative authority has caused that person to entertain expectations which are justified by precise assurances provided to him [22] . While it is clear from the information provided by the complainant that it was frustrated by the fact that EFSA did not indicate that it had reservations about the safety of its product, it is established that no assurances were provided to the complainant that its product would be deemed safe by EFSA. On the contrary, EFSA explained that the Working Group on Microorganisms was not entitled to carry out the assessment of the safety of *Toyocerin* , this being the task, in accordance with the rules, of the FEEDAP Panel.

44. As regards the allegation as to the impartiality of the members of the Working Group on

Microorganisms, the complainant did not submit any evidence to support its assertion that the scientific experts of the Working Group on Microorganisms lacked impartiality in the handling of the *Toyocerin* file.

45. It follows that the Ombudsman has not found any maladministration on the part of EFSA in this case. Therefore, she closes the case.

Conclusion

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

There is no maladministration on the part of EFSA in this case.

The complainant will be informed of this decision.

EFSA should also be informed of this decision. It should moreover be asked to keep the Ombudsman up-to-date with any developments in improving scientific dialogue within the context of its policy initiative of transformation to an Open EFSA.

The Catalan Ombudsman, who asked to be informed about this case, will also be informed.

Emily O'Reilly

Strasbourg, 23/09/2015

[1] Originally classified as *Bacillus cereus* .

[2] See http://ec.europa.eu/food/fs/sc/scan/out72_en.pdf

[3] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, OJ 2003 L 268, p. 29.

[4] Scientific Opinion on *Toyocerin* ® (*Bacillus cereus*) as a feed additive for sows, piglets, pigs for fattening, cattle for fattening, calves for rearing, chickens for fattening and rabbits for fattening, available at http://www.efsa.europa.eu/en/efsajournal/pub/2924

[5] Commission Implementing Regulation (EU) No 288/2013 of 25 March 2013 concerning the suspension of the authorisations of the preparation of *Bacillus cereus var. toyoi* (NCIMB 40112/CNCM I-1012) as provided for by Regulations (EC) No 256/2002, (EC) No 1453/2004, (EC) No 255/2005, (EC) No 1200/2005, (EC) No 166/2008 and (EC) No 378/2009, OJ 2013 L 86, p. 15.

[6] The mandate of the Working Group on Microorganisms is to deal with questions related

to the safety and efficacy of microbial feed additives and, in this case, to make a scientific contribution on the complainant's application for authorisation for consideration by the FEEDAP Panel. For more information, see http://www.efsa.europa.eu/sites/default/files/assets/feedwgimmicroorganisms.pdf

[7] Scientific Opinion on *Toyocerin* ® for chickens for fattening, weaned piglets, pigs for fattening, sows for reproduction, cattle for fattening and calves for rearing and for rabbits for fattening, EFSA Journal 2014;12(7):3766. Available at http://www.efsa.europa.eu/en/efsajournal/pub/3766.htm

[8] " *Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned* ."

[9] EFSA FEEDAP's Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance, EFSA Journal 2012;10(6);2740; EFSA FEEDAP's Guidance on the assessment of the toxigenic potential of *Bacillus* species used in animal production, EFSA Journal 2014;12(5);3665

[10] Commission Decision of 20.5.2015 on the administrative review of the scientific opinion on *Toyocerin ® (Bacillus toyonensis)* as a feed additive, adopted by the European Food Safety Authority on 1 July 2014, C(2015) 3409 final.

[11] Case T-201/13 *Rubinum v Commission* , judgment of 21 May 2015, ECLI:EU:T:2015:311.

[12] FEFANA is the EU Association of Specialty Feed Ingredients and their Mixtures. For more information, visit www.fefana.org

[13] See, Preliminary Implementation Plan - Transformation to an 'Open EFSA' available at http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/openefsapreliminaryimpleme

[14] Decision of the European Ombudsman closing the inquiry into complaint 346/2013/SID against the

European Food Safety Authority (EFSA), at paragraph 26.

[15] Case C-277/11 *M.* ECLI:EU:C:2012:744,, paragraph 87 and the case-law cited there.

[16] *M.* , cited above, paragraph 88, Case C-269/90 *Technische Universität München* [1991] ECR I-5469, paragraph 14.

[17] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (Text with EEA relevance) OJ L 133, 22.5.2008, p. 1.

[18] In *Rubinum* , cited above, paragraph 104, the General Court stated:

" *Deuxièmement, d'une part, il importe de relever, à l'instar de la Commission, que, la demande d'autorisation a été déposée par la requérante. Cette dernière a donc eu l'opportunité de se prononcer sur l'innocuité de l'additif. D'autre part, l'EFSA a donné l'opportunité à la requérante de fournir ses observations sur les facteurs ayant conduit, d'abord, celle-ci à adopter un avis scientifique négatif et, ensuite, la Commission à adopter le règlement attaqué. En effet, l'EFSA a invité la requérante, par lettre du 7 juillet 2011, à répondre à des questions précises, dont elle reconnaît elle-même dans ses écritures qu'elles visaient à déterminer si la préparation de Bacillus cereus var. toyoi était susceptible de produire des toxines et si la résistance de ladite préparation au chloramphénicol et à la tétracycline pouvait être transmise à d'autres organismes. Or, c'est sur la base de ces informations complémentaires, fournies par la requérante, qui, selon l'EFSA et la Commission, ne permettaient pas d'écarter le risque identifié pour la santé, que la Commission a adopté le règlement attaqué.* "

[19] Scientific Opinion of 1 July 2014, cited above, p. 7.

[20] See, *Rubinum* , cited above, paragraph 105.

[21] Case C-413/08 P *Lafarge v Commission* , ECLI:EU:C:2010:346, paragraph 40.

[22] Case C-585/13 P *Europäisch-Iranische Handelsbank v Council* , EU:C:2015:145, paragraph 95.