Decision in case 1375/2016/JAS on the European Commission's handling of concerns regarding the renewal of the approval of the herbicide ingredient glyphosate

Decision
Case 1375/2016/JAS - **Opened on** 08/02/2017 - **Decision on** 08/02/2017 - **Institution concerned** European Commission (No maladministration found) |

The case concerned the European Commission's engagement with the complainant, a British national, who had been in contact with it for more than a year regarding the renewal of approval for glyphosate, an active ingredient in weed-killers. Following several exchanges of correspondence, the Commission decided not to reply any longer to the complainant. The complainant said that he had continued to write to the Commission as he believed it had not properly addressed the valid concerns he had raised.

It constitutes good administration for a public body to correspond properly with citizens. This is particularly important for EU institutions, such as the Commission, since there is always a greater inherent risk for such supranational bodies to appear remote to citizens. However, it is also in the public interest that efforts to maintain contacts with citizens be reasonable and proportionate. If correspondence from a citizen becomes repetitive, it may serve no useful purpose to continue with that correspondence.

The Ombudsman inquired into the issue and found that the Commission had on a number of occasions addressed the issues and concerns raised in the complainant's letters. It had explained in detail the process of scientific evaluation put in place to evaluate substances such as glyphosate. Furthermore, no decision has yet been taken on whether to renew the approval of glyphosate; pending that decision, the existing approval has been extended in the short term. The Ombudsman thus concluded that the Commission had adequately communicated with the complainant and that there had been no maladministration by the Commission.

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The background to the complaint

1. The complainant, a British national, wrote to the European Commission on several occasions in 2015 and 2016 about the **renewal** of the approval of **glyphosate** , an active substance used in the production of widely-used **herbicides** .

2. The background is as follows. Since 2012, glyphosate has been under evaluation for a **possible renewal of the EU-wide approval** in accordance with the procedures laid down in EU legislation [1] . In January 2014, the European Food Safety Authority (EFSA) launched its peer review of the German report on glyphosate. Germany is the lead Member State responsible for the renewal assessment. In March 2015, the International Agency for Research on Cancer (IARC), a specialised cancer agency of the World Health Organisation, published a report stating that glyphosate was " *probably carcinogenic to humans* " [2] . The Commission then asked EFSA to examine the IARC findings in reaching its own conclusions.

3. In November 2015, EFSA concluded that glyphosate is " *unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential* " [3] .

4. Subsequently, the EU Member States failed to agree on the renewal of the approval of glyphosate before the expiry of the existing approval period [4] . A number of Member States considered that it was appropriate to have an opinion of the Committee for Risk Assessment of the European Chemicals Agency (ECHA) before taking a decision on renewal.

5. In June 2016, the Commission **temporarily extended the approval** of glyphosate, until the end of 2017 at the latest [5] . It stated that it did so to allow time for ECHA to give its opinion on glyphosate. It stated that ECHA's findings would then be taken into account when the Member States and the Commission decide on the renewal of the approval of glyphosate.

6. At the same time, the Commission made a number of recommendations as to the use of glyphosate-based products [6] . These include reinforced scrutiny of the pre-harvest use of glyphosate and an obligation to minimise its use in specific places, such as in public parks and playgrounds.

7. The complainant wrote to the Commission about the renewal of glyphosate approximately twenty times during 2015 and 2016. The Commission replied several times to the complainant. Eventually, the Commission informed the complainant that it would no longer reply to future correspondence on the subject, as it considered it repetitive.

8. In September 2016, the complainant made a complaint to the Ombudsman. The complainant clarified that his concern was not so much with the refusal of the Commission to reply to his correspondence as with "the failure of EU officials to address the very valid concerns raised in these letters". In particular, the complainant argued that while glyphosate "was reviewed as a herbicide [...] it is also a biocide, of which nothing is said".

The inquiry

9. The Ombudsman opened an inquiry into the complaint and decided to examine any link between the Commission's decision to stop engaging with the complainant and the question of whether it had actually responded to the issues being raised by him. Accordingly, this inquiry deals with the Commission's decision to cease to correspond with the complainant and also with the issue of whether it addressed his concerns regarding approval of the herbicide ingredient glyphosate.

10. The Ombudsman then carried out a thorough analysis of the correspondence between the Commission and the complainant and asked the complainant for additional information. She also carried out her own background research.

Allegation that the Commission had wrongly ceased to correspond with the complainant and had failed to address his concerns

Arguments made by the complainant and the institution

11. The complainant raised several concerns with the Commission about the impact of glyphosate on human health. He claimed that the Commission's approach lacked rigour and failed to deal with some important matters. The complainant also questioned EFSA's scientific assessment and that of Germany, the Member State responsible for the renewal assessment report.

12. The Commission explained to the complainant the process for renewing the approval of glyphosate, which was still underway at the time. The process entailed, the Commission noted, a peer review by EFSA, as well as by all other EU Member States, of the assessment already conducted by the German authorities. The Commission also stated that it took seriously the information and concerns put forward by the complainant. The Commission stated that the

publications mentioned by the complainant had been considered during the scientific evaluation. It added that a public consultation had been carried out, which had given citizens and other stakeholders a platform for voicing their concerns. It stated that EFSA's conclusion, as well as the background documents (including the report by Germany), had been made publicly available [7] .

13. Finally, the Commission stated that it understood the concerns and fears of citizens about glyphosate and their exposure to it from food and other sources. It was therefore important, it stated, to ensure that sound science underpinned the decision-making. With regard to carcinogenicity, the Commission said that EFSA's conclusion that glyphosate " *is unlikely to pose a carcinogenic hazard to humans* " was supported by the risk assessment on glyphosate made by the Joint UN Food and Agriculture Organisation/World Health Organisation Meeting on Pesticide Residues (JMPR) in May 2016. The Joint Meeting had concluded that glyphosate " *is unlikely to pose a carcinogenic risk to humans from exposure through the diet* " [8] . The Commission stated that the " *EU regulatory system for pesticides is extremely robust and ensures that substances undergo a rigorous scientific assessment before any decision is taken on whether they can be approved or not. Substances are only approved when it has been demonstrated that under realistic conditions of use there are no unacceptable effects on human or animal health, or the environment* ". The Commission said that it will continue to remove substances from the market where it cannot be demonstrated that the strict approval criteria are satisfied.

14. The Commission sent approximately seven letters to the complainant before it decided to stop replying.

The Ombudsman's assessment

15. It is good administration for a public body to correspond directly with citizens who put forward concerns regarding public policy. This is particularly important for EU institutions, such as the Commission, since there is a greater inherent risk that they, as supranational bodies, will appear remote to citizens. However, it is also in the public interest that the volume of such correspondence be reasonable and proportionate. If specific correspondence from a citizen becomes repetitive or excessive, it may become disproportionate to continue with that specific correspondence.

16. In this case, the Ombudsman finds that the Commission did, on several occasions, address the issues and concerns raised in the complainant's letters. It explained **in detail** the process of scientific evaluation put in place to evaluate substances such as glyphosate. The Commission also explained how it had addressed the diverging conclusions concerning carcinogenicity. Specifically, the Commission told the complainant that the publication cited by him, in support of the argument regarding the biocidal nature of glyphosate, had been taken into account in the overall assessment [9] . The Ombudsman thus concludes that the Commission adequately communicated with the complainant. She also concludes that the complainant's continued correspondence on the matter had indeed become repetitive and that it was therefore not a good use of public resources to continue that specific correspondence. At the same time, the

Ombudsman recognises that the complainant's continuation of the correspondence, from his position, reflected his genuine concern regarding glyphosate and was not intended to be vexatious. However, in all the circumstances, the Ombudsman finds that the decision of the Commission to discontinue this specific correspondence did not constitute maladministration.

17. The complainant also **questioned the scientific evaluation** made by EFSA and the Commission's decision based on EFSA's conclusions. Despite the Commission's efforts to give the complainant explanations, the complainant considered that the Commission had failed to take into account the concerns raised by him on the harm that he considered would be caused by renewing the approval of glyphosate.

18. First, the Ombudsman notes that she does not have the expertise to evaluate the scientific assessment of the specialised scientific bodies involved. However, she can check whether such bodies have provided adequate information to citizens about their work. Concerning the present inquiry, this appears to have been the case.

19. The Ombudsman also notes that the Commission has not renewed the approval of glyphosate. It has **temporarily extended** (until the end of 2017 at the latest) its previous approval in order to have ECHA's opinion available when deciding on a possible renewal of the approval. The opinion of ECHA's Committee for Risk Assessment is due by the end of November 2017 [10] . Once the opinion is available, Member States, together with the Commission, will decide on whether or not to renew the approval of glyphosate. The Ombudsman also notes that both EFSA [11] and ECHA [12] have held **public consultations** regarding glyphosate in the context of their respective scientific evaluations.

20. As outlined above, a number of scientific bodies—the IARC (" *probably carcinogenic to humans* "), the JMPR (" *unlikely to pose a carcinogenic risk to humans from exposure through the diet* ") and EFSA (" *unlikely to pose a carcinogenic hazard to humans*)—appear to have come to somewhat different conclusions concerning the carcinogenic potential of glyphosate. Some of these variations might stem from the different assessment methods applied by these scientific bodies. In particular, the IARC conclusion is based on a "hazard" assessment whereas the JMPR assessment is a "risk" assessment; the former does not take account of the level of exposure or ingestion at which glyphosate is likely to be hazardous whereas the latter is concerned with risk at normal or expected levels of exposure or ingestion [13] . Taking this into account, the Commission's decision to await ECHA's scientific opinion appears to be a reasonable approach.

21. Having regard to all of the above, the Ombudsman concludes that there was no maladministration by the Commission.

Conclusion

On the basis of the inquiry into this complaint, the Ombudsman closes it with the following conclusion [14] :

There was no maladministration by the Commission.

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

Strasbourg, 08/02/2017,

Emily O'Reilly

European Ombudsman

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ 2009 L 309, p. 1.

[2] http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf [Link]

[3] https://www.efsa.europa.eu/en/efsajournal/pub/4302 [Link]

[4] http://europa.eu/rapid/press-release_MEX-16-2357_de.htm [Link]

[5] Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate, OJ 2016 L 173, p. 52, available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R1056 [Link]

[6] Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate, OJ 2016 L 208, p. 1, available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.208.01.0001.01.ENG [Link]

[7] Available at: https://www.efsa.europa.eu/en/press/news/151119a [Link]

[8] http://www.who.int/foodsafety/jmprsummary2016.pdf?ua=1 [Link]

[9] Specifically, the Commission said that the publication by Samsel and Seneff, "Glyphosate's Suppression of Cytochrome P450 Enzyme and amino acid biosynthesis by the gut microbiome: Pathways to modern diseases" Entropy 2013, 15, 1416-1463, had been evaluated by the Rapporteur Member State and considered in the peer review for glyphosate. The complainant

relied in particular on this publication in the context of his contention that glyphosate required to be assessed as a biocide.

[10] https://echa.europa.eu/chemicals-in-our-life/hot-topics/glyphosate [Link]

[11] See, in this context, the Decision in case 952/2014/OV on the European Food Safety Authority's (EFSA) public consultation procedure for the renewal of the approval of the herbicide glyphosate, available at: https://www.ombudsman.europa.eu/cases/decision.faces/en/61376/html.bookmark [Link]

[12] https://echa.europa.eu/view-article/-/journal_content/title/public-consultation-on-the-harmonised-classification-and-la [Link]

[13] For a fuller explanation, see http://www.who.int/foodsafety/faq/en/ [Link]

[14] Information on the Ombudsman's review procedure can be found on the website [Link]: http://www.ombudsman.europa.eu/en/atyourservice/complainantsrights.faces [Link]