# Decision in case 1769/2017/JAS on the European Chemicals Agency's handling of concerns regarding the herbicide ingredient glyphosate

Decision
**Case** 1769/2017/JAS - **Opened on** 11/01/2018 - **Decision on** 11/01/2018 - **Institution concerned** European Chemicals Agency ( No maladministration found ) |

The case concerned the European Chemicals Agency's (ECHA) correspondence with the complainant, a British national, in response to his concerns on ECHA's hazard assessment of glyphosate, an active ingredient in weed-killers.

The Ombudsman inquired into the issue and found that ECHA had held a public consultation during its assessment. The complainant had not availed himself of the opportunity to contribute to that public consultation. Nevertheless, ECHA replied to the complainant's concerns.

The Ombudsman concluded that ECHA had adequately communicated with the complainant and that there had thus been no maladministration by ECHA.

## Background to the complaint

**1.** The complainant has been corresponding with the European Chemicals Agency (ECHA) on the issue of **glyphosate** , an active substance used in the production of widely-used herbicides. This correspondence took place during the year 2017.

**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] . During this process, a discussion arose concerning the potential carcinogenicity of glyphosate. In January 2014, the European Food Safety Authority (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* " [2] .

**3.** However, the EU Member States could not agree on the renewal of the approval of glyphosate before the expiry of the approval period [3] . A number of Member States considered that it was appropriate to obtain an opinion from ECHA's Committee for Risk Assessment (RAC) before taking a decision on renewal. The Commission thus temporarily extended the approval of

glyphosate until the end of 2017 [4] .

**4.** In the context of its assessment, ECHA held a public consultation from June to July 2016 [5] . The replies it received were subsequently made publicly available [6] . The complainant did not avail himself of the opportunity to contribute to the public consultation.

**5.** In March 2017, RAC concluded by consensus that the available scientific evidence did not support the classification of glyphosate as a carcinogen, as a mutagen or as toxic for reproduction [7] . RAC's opinion was taken on the basis of a report submitted by the German Federal Institute for Occupational Safety and Health ( *Bundesanstalt für Arbeitsschutz und Arbeitsmedizin* ) [8] , which contained a proposal for classification and a scientific evaluation of the available data [9] . RAC maintained the previous EU classification of glyphosate [10] .

**6.** The Commission then decided to re-open the discussions with Member States about the possible renewal of the approval of glyphosate [11] . After a number of discussion rounds, the Standing Committee on Plants, Animals, Food and Feed, comprising representatives of all Member States [12] , could not decide [13] on whether to agree with the Commission's proposal to renew the approval [14] . In such cases, the Commission may then submit the draft decision to an appeal committee [15] .

**7.** On 27 November 2017, the appeal committee voted in favour of the Commission's proposal [16] to renew the approval of glyphosate for a period of 5 years [17] . The Commission is thus obliged to adopt a corresponding decision [18] .

**8.** In the meantime, the complainant, dissatisfied with the replies he had received from ECHA, had submitted a complaint to the Ombudsman.

# The inquiry

**9.** The Ombudsman opened an inquiry into the complainant's position that ECHA had failed to properly address his concerns concerning glyphosate.

**10.** The Ombudsman's decision takes into account the arguments and documents provided by the complainant as well as information available in the public domain.

# Handling of the complainant's concerns regarding glyphosate

## Arguments presented to the Ombudsman

**11.** In his correspondence with ECHA, the complainant set out his concerns regarding potential hazardous features of glyphosate (namely carcinogenicity, germ cell mutagenicity and

reproductive toxicity). The complainant referred to several studies and opinions of researchers that he considered supported his concerns. In his view, RAC should have taken these studies into account in its opinion on glyphosate.

**12.** In reply, ECHA stated that, in arriving at its opinion, **RAC** *"has primarily relied on the material provided in the* [...] *proposal submitted* **by the German Competent Authority** . *RAC has also taken into account the* **information submitted during the 45-day public consultation** *on the proposal* [...] *."* (emphasis added).

**13.** ECHA stated further that studies can be taken into account by RAC only if they have been *"performed in accordance with internationally agreed methodology and quality requirements (OECD or equivalent technical guidelines and good laboratory practice). Standardised methodology is intended, among other things, to maximise the reproducibility of the results from these studies"* . In this regard, ECHA also explained to the complainant which studies it considered not to be in compliance with those standards and why.

**14.** Regarding the procedure, ECHA clarified that it is " *not involved in the approval of the active substances used in plant protection products* ". Rather, in the process applicable to glyphosate, the work of RAC " *is restricted to an assessment of the hazards of chemical substances* ". ECHA stated that it was thus not in in a position to respond to those of the complainant's concerns that related to the assessment of the risks associated with the use of glyphosate.

## The Ombudsman's assessment

**15.** The Office of the European Ombudsman is not a scientific body. The Ombudsman deals with complaints about *administrative* activities and it is not within the Ombudsman's mandate to examine the merits of scientific evaluations carried out by specialised scientific agencies.

**16.** However, the Ombudsman may seek to assess whether scientific bodies such as ECHA have the necessary procedural safeguards in place to ensure that the scientific advice they obtain to carry out their evaluations is as complete as possible and independent, and whether these safeguards have been properly applied in any given procedure [19] . The Ombudsman can also check whether such bodies have **provided adequate information to citizens about their work** [20] .

**17.** In this context, it is good administration for a public body to correspond directly with citizens who put forward concerns regarding public policy [21] .

**18.** However, where an EU institution or body has given citizens the possibility to contribute to EU decision-making in an organised way, through a **public consultation** , and this procedure has been conducted properly, **it must be accepted that there are limits to the extent to which institutions or bodies must take into account concerns raised after such a consultation procedure has been finalised** .

**19.** The comments that ECHA received during the public consultation, as well as the German authority's and RAC's responses thereon, have been made publicly available [22] . The complainant acknowledges that he did not raise his concerns during the public consultation.

**20.** Moreover, ECHA has explained to the complainant why certain studies were not taken into account and why certain tests were not performed. It has thus complied with its duty to provide adequate information to citizens.

**21.** The Ombudsman concludes that there was no maladministration by ECHA.

## Conclusion

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

**There was no maladministration by the European Chemicals Agency in its handling of the complainant's concerns regarding its opinion on the herbicide ingredient glyphosate.**

The complainant and ECHA will be informed of this decision **.**

Emily O'Reilly

European Ombudsman

Strasbourg, 11/01/2018

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

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

[4] 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]

[5] More information at: https://echa.europa.eu/harmonised-classification-and-labelling-previous-consultations/-/substance-rev/13838/term

[Link]

[6] https://echa.europa.eu/documents/10162/37f4444b-003e-48c7-9181-59d7bd99d126 [Link]

[7] The opinion of RAC and other supporting documents are available at: https://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-a [Link]

[8] https://www.baua.de/EN/Home/Home_node.html [Link]

[9] Available at: https://echa.europa.eu/documents/10162/9fb5d873-2034-42d9-9e53-e09e479e2612 [Link]

[10] Following the previous examination of glyphosate in the context of the harmonised classification and labelling procedure, it was classified in the EU as a substance causing serious eye damage and eye irritation, and being toxic to aquatic life with long-lasting effects.

[11] For more information, see https://ec.europa.eu/food/plant/pesticides/glyphosate_en [Link]

[12] More information available at: https://ec.europa.eu/food/committees/paff_en [Link]

[13] See Article 5 of Regulation 182/2011 (Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ 2011 L 55, p. 13, available at: http://data.europa.eu/eli/reg/2011/182/oj [Link]). The committee delivers its opinions by so-called 'qualified majority' of at least 55 % of the Member States, comprising at least fifteen of them and representing Member States comprising at least 65 % of the population of the Union. A blocking minority must include at least four Member States (Article 16(4) of the Treaty on European Union, available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1508835020492&uri=CELEX:12016M016 [Link]).

[14] 14 Member States voted in favour (representing 36.95 % of the EU population), 9 Member States voted against (representing 32.26 % of the EU population) and 5 Member States abstained (representing 30.79 % of the EU population) ( https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20171109_pppl_summary.pdf [Link]).

[15] Article 5(4), third subparagraph, of Regulation 182/2011. The appeal committee is also made up of representatives of all Member States and chaired by a Commission representative.

[16] Available at: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyphosate_commission_proposal_revision4.pdf [Link]

[17] 18 Member States voted in favour (representing 65.71% of the EU population), 9 Member States voted against (representing 32.26 % of the EU population) and 1 Member State abstained (representing 2.02 % of the EU population) ( https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20171127_pppl_summary.pdf [Link]).

[18] Article 6(3) of Regulation 182/2011.

[19] Decision in case 1475/2016/JAS on the European Medicines Agency's handling of the referral procedure relating to human papillomavirus (HPV) vaccines, paragraphs 21f, available at: https://www.ombudsman.europa.eu/en/cases/decision.faces/en/84736/html.bookmark [Link]

[20] 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, paragraph 18, available at: https://www.ombudsman.europa.eu/en/cases/decision.faces/en/75832/html.bookmark [Link]

[21] Decision in case 1375/2016/JAS, paragraph 15.

[22] https://echa.europa.eu/documents/10162/41b791ff-7476-bd1e-a2fd-8d5a9feebb9a [Link]