

Update of the methodology document for health and environmental risk assessments for use in the Panel on Plant Protection Products

Self-initiated mandate

Mandate

The Panel will update and expand the methodology document published in 2012 with new data requirements stemming from current regulations and terminology for plant protection products, as well as guidelines and methods for risk assessments of these products regarding health and environmental risks.

The update will be written in English.

Background

The purpose of the methodology document from 2012 was to describe the methods used by the Norwegian Food Safety Authority, for use as background documentation for the Norwegian Scientific Committee for Food and Environment (VKM). The methodology document also describes the criteria VKM's Panel on Plant Protection Products uses as a basis for risk assessment of plant protection products. The methodology document was intended to be a dynamic document that always reflects current practice, in line with changes in regulations and the supply of new knowledge.

Norway adopted the EU regulations on pesticides in a new regulation for plant protection products in the summer of 2015, since Norway through the EEA agreement uses the European Union's approval scheme for the use of plant protection products.

VKM shall, in accordance with one of its main objectives in its strategy document 2021-2024, ensure an independent, high-quality base of knowledge by:

- Developing methods and contributing to international methodology work
 - Following international standards and guidelines
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This will help ensure VKM's assessments are verifiable and based on updated and relevant knowledge. Updating the methodology document of 2012 is vital to ensuring the quality of future risk assessments in the Panel on Plant Protection Products.

Data / Central Documents

1. VKM 2012. Methodology document for health and environmental risk assessments – Panel on Plant Protection Products.
 2. 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. Accessible from: <https://eur-lex.europa.eu/>
 3. Regulations on plant protection products, 2015. FOR 2015-05-06-455. Accessible from: <https://www.lovdata.no>
 4. Proposed amendment – Approval of plant protection products in Norway, 2022. Proposal from the Norwegian Food Safety Authority for the Ministry of Agriculture and Food. Scheduled to be published autumn 2022 on https://www.mattilsynet.no/planter_og_dyrking/plantevernmidler/bruk_av_plantevernmidler_vann/miljorisikovurderingen_av_plantevernmidler_skal_revideres.40583
 5. VKM 2021. Establishing the representativeness of available surface water scenarios for plant protection products in environmental risk assessment in Norway. VKM Report 2021:11. Accessible from: <https://www.vkm.no>
 6. Available guidance documents on the zone-divided approval of pesticide trade commercial preparations of plant protection products include guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009, SANCO/13169/2010 Rev. 11. Commission staff working document, last updated January 2021. Accessible from: https://food.ec.europa.eu/system/files/202101/pesticides_aas_guidance_mut_rec_en.pdf)
 7. Northern Zone, 2021. Guidance document on work-sharing in the Northern zone in the authorization of plant protection products. Version 10, June 2021. Accessible from: <https://www.kemi.se/download/18.663e01517a129aa97f20/1623826662866/Northern-Zone-Guidance-Document-2021.pdf>
 8. An overview of procedures and resources related to the approval of active substances in plant protection products in the EU/EEA is accessible from: <https://www.efsa.europa.eu/en/applications/pesticides>
 - where regulations and scientific guidance documents are accessible from: <https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance>
 - available tools are accessible from: <https://www.efsa.europa.eu/en/applications/pesticides/tools>
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9. EFSA Scientific Opinions. Accessible from:
<https://www.efsa.europa.eu/en/publications>
 10. ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with technical support from the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018. Guidance on the identification of endocrine disruptors pursuant to Regulation (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311, 135 p. Accessible from: <https://doi.org/10.2903/j.efsa.2018.5311>. ECHA-18-G-01-EN
 11. Commission Communication within the framework of the implementation of Commission Regulation (EU) No 284/2013 of 1 March 2013 laying down pesticide data requirements in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council on the marketing of pesticides.
 12. Commission Regulation (EU) No 283/ 2013 of 1 March 2013 laying down data requirements for active substances in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council on the marketing of plant protection products.
 13. OECD Test Guidelines for Chemicals.
<https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm>
 14. EU biocide regulations: <https://echa.europa.eu/information-on-chemicals/biocidal-products>
 15. Biocide regulations Norway:
<https://www.miljodirektoratet.no/ansvarsomrader/kjemikalier/biocider/>
 16. VKM (2019). Kriterier for forfatterskap og faglig ansvar i VKMs uttalelser.
https://vkm.no/download/18.48566e5316b6a4910fc2dbd6/1561035075341/VKMs%20forfatterskapskriterier_revidert%20versjon%2020.06.2019.pdf
 17. VKM (2018). Rutine for godkjenning av risikovurderinger.
<https://vkm.no/download/18.433c8e05166edbef03bbda5f/1543579222271/Rutine%20for%20godkjenning%20av%20risikovurderinger.pdf>
 18. Regulations for biopesticides

Timeline

The project will submit a draft by June 30th, 2023. The final document shall be submitted by December 15th, 2023.
