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Norwegian Food Safety Authority



Establishing the representativeness of available surface water scenarios for pesticide risk assessment in Norway

The Norwegian Food Safety Authority (NFSA) requests an evaluation of the relevance of the surface water scenarios used in environmental risk assessment of plant protection products. The evaluation is needed as part of a review of the current risk assessment methodology.

Background

In a letter from the Ministry of Agriculture and Food dated 28 January 2020, the NFSA was asked to evaluate the current use of FOCUS surface water scenarios in the environmental risk assessment of plant protection products. The NFSA was also asked to examine the feasibility of approving use of certain plant protection products for limited areas only, in those cases where they cannot be approved for the entire country due to risk of contamination of the aquatic environment.

Assessment of risk to the aquatic environment in the EU evaluation of active substances

Prior to approval for use in plant protection products under Regulation (EC) No 1107/2009¹, active substances are required to undergo an environmental risk assessment. A key element of this process is the assessment of risk to the aquatic environment. Potential exposure of surface water in agricultural areas (ponds, ditches and streams) to active substances and their metabolites must be assessed using a modelling approach developed within the European Commission FOCUS framework (FOCUS, 2001).

Several risk evaluation steps are incorporated into the FOCUS scheme. Steps 1 and 2 in FOCUS are screening level steps based on conservative assumptions of surface water exposure potential. Step 3 employs 10 realistic worst-case scenarios representing combinations of crops, pedoclimatic regimes and routes of loss of pesticides to surface water (spray drift, run-off and drainage) across the EU.

Data on the physico-chemical properties of the active substance and environmental fate and behaviour data in soil, sediment and water are used in combination with the scenarios and the

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, incorporated into the EEA Agreement in 2014 and implemented in Norwegian law through FOR-2015-05-06-455.

FOCUS models to estimate loadings of active substances and metabolites to surface water and their distribution and fate in aquatic systems, resulting in predicted environmental concentrations (PECs) that can be compared with appropriate ecotoxicity endpoints in the risk assessment for aquatic organisms.

Aquatic risk assessment in the national registration of plant protection products

Post-approval registration of plant protection products at a national level can include the use of standard FOCUS scenarios and/or national/region specific scenarios.

The project “*National Scenarios – Norway. Introduction of national scenarios for approval of new pesticides in Norway*” (Bolli et al. 2011), financed by the Action Plan for the Sustainable Use of Pesticides, was initiated with the aim of improving the risk assessment of pesticides in Norway by establishing scenarios from experimental fields which could be representative for Norwegian conditions. Four scenarios were developed. None of these scenarios are currently used for the surface water exposure assessment due to the limitations of the model tool in which they are parametrised. The Norwegian Institute of Bioeconomy Research (NIBIO) has received funding over the Action Plan for the Sustainable Use of Pesticides to address this issue.

At present, Norway requires simulation with 9 of the standard FOCUS scenarios for the surface water exposure assessment. The reasoning behind this, is that based on the pedoclimatic characteristics of each FOCUS scenario as described in FOCUS (2001), none of the scenarios have a combination of characteristics that seem to be a realistic worst-case for the Norwegian agricultural landscape as a whole. It was questioned whether the FOCUS scenarios would be protective² enough of the Norwegian agricultural landscape, and it was thought that this uncertainty would decrease with an increasing number of scenarios.

More knowledge on the relevance of available surface water scenarios is needed

Currently, no overview exists of which agricultural areas are represented (or protected) by the national scenarios or FOCUS scenarios. To decide on the appropriate use of the national and/or FOCUS scenarios in future regulatory risk assessment, it is necessary to investigate in more detail the range of relevant environmental characteristics within the Norwegian agricultural landscape and to what extent these characteristics are defined by the existing scenarios.

As regulatory submissions for approval of plant protection products are prepared for specific crop uses, it is important to consider the proportions of a national crop that are directly represented by each scenario. It is also important to evaluate what proportion of the national crop is grown in areas where the pedoclimatic conditions may be considered more challenging (in terms of pesticide loss and degradation) than those represented by the available scenarios that are relevant for Norway. If directly relevant surface water scenarios only encompass negligible areas associated with cultivation of an important crop, other information would need to be considered, for example in the form of an assessment based on indirectly relevant scenarios.

Protection goal set in the legislation

There are no clear, specific protection goals for surface water set in Regulation (EC) 1107/2009, to aid in the selection of appropriately protective surface water scenarios. One must therefore consider the general protection goals set in Article 4 (3e): A PPP shall have no unacceptable effects on the environment, having particularly regard to the following considerations: i) its fate and distribution in the environment, particularly contamination of surface water, including estuarine and coastal water ii) its impact on non-target species and iii) its impact on biodiversity and the ecosystem. Further, it is important to consider that Regulation (EC) 1107/2009 is underpinned by the precautionary principle, as set down in Article 1(4). It is also relevant to consider the Norwegian Water Regulation. The environmental objective given in § 4 is that the state of surface water shall be protected against deterioration, improved and recovered with the aim of achieving good ecological and chemical status of the waterbody³.

² The terms “representativeness” and “protectiveness” need to be clearly distinguished. A scenario is *representative* of agricultural areas that have similar soil and climate conditions as the scenario. A scenario is *protective* of an area when it represents either similar soil and climate conditions or a more vulnerable situation in terms of pesticide loss and degradation.

³ Please see the Water Regulation (FOR-2006-12-15-1446) for further details.

Terms of reference

Objectives and deliverables

Based on currently available data sets and literature, the NFSA asks the Norwegian Scientific Committee for Food and Environment to investigate the following objectives:

1. To identify agricultural areas in Norway that are «represented» by soil and climate conditions in the ten FOCUS surface water standard scenarios or the four national scenarios, and quantify the size and spatial distribution of these areas.
2. To determine how worst-case the areas identified in objective 1 are in terms of surface water exposure potential compared to agricultural land across Norway, and if they could be considered protective of additional areas, even if they are not directly representative. Please see section 3.2 and 3.5 in FOCUS (2001) for an example «worst case assessment».
3. To identify the characteristics and spatial distribution of all agricultural land in Norway that is not represented by any of the ten FOCUS surface water scenarios or the four national scenarios.
4. To assess the relative importance of surface run-off (both dissolved and particulate phases), drainflow and spray drift as routes of aquatic exposure to pesticides in Norway based on pedoclimatic characteristics.

The NFSA would also like the Scientific Committee to give their opinion these questions:

- a) Considering the protection goals for human health and the environment set down in relevant legislation, as well as the findings of this study, which FOCUS scenarios and/or national scenarios should companies use when calculating predicted environmental concentrations (PECs) for Norwegian risk assessments?
- b) How confident is the Scientific Committee that the scenarios recommended in question a) provide a sufficiently high level of protection for Norwegian agricultural areas as a whole?
- c) For areas that are not sufficiently protected, or if risk assessments are uncertain, what supplementary information could be requested from companies to support PEC calculations?
- d) In the context of approval of plant protection products for certain areas only, in those cases where they cannot be approved based on the regular risk assessment: Based on VKM's findings in this assessment, are there any clearly defined areas (either based on administrative units such as municipalities, or areas with a certain soil and climate) that are very well covered (with a high level of protection for health and environment) by one scenario or a combination of scenarios?

Expected outputs include:

- A report containing the information described in objectives 1 to 4 and evaluations of questions a) to d), based on sources including national soil, land use and climate data sets. The basis of evaluations or recommendations should be described in detail.
- Tables showing percentage area of individual crops grown in Norway that is covered by risk assessments using directly relevant FOCUS scenarios or national scenarios. See ADAS (2005) for example tables.
- Simplified maps illustrating objectives 1, 3 and 4. See Alterra et al. (2013) for example figures.

Data sources and other useful publications

National soil, land use and climate data sets, taking into account climatic factors such as precipitation, recharge and temperature, including soil freezing, land use data like land cover and cropping, as well as soil-related factors such as slope, depth, texture, structure, organic matter and drainage status.

ADAS UK Ltd. (2005). Establishing the representativeness of focus surface water scenarios for pesticide risk assessment in the UK landscape part 2. Defra report: PS2220. Accessible from <http://randd.defra.gov.uk/>

Alterra Wageninen UR, NEIKER, ITP, JTI (2013). Recommendations for establishing Action Programmes under Directive 91/676/EEC concerning the protection of waters against

pollution caused by nitrates from agricultural sources. Part A. Appendix 2, Maps of pedo-climatic zones in Europe. Accessible from <https://op.europa.eu/en/>

Bolli, R.I., Haraldsen, T., Haugen, L.E., Holten, R., Eklo, O.M. (2011). National Scenarios – Norway. Introduction of national scenarios for approval of new pesticides in Norway. Bioforsk Report Vol. 6 Nr. 34 2011. Accessible from <https://nibio.brage.unit.no/>

Eklo, et al. (2015) Degradation and mobility of pesticides in Norwegian soils. Opinion of the Panel on Plant Protection Products of the Norwegian Scientific Committee for Food Safety. VKM Report 2015:34. Accessible from <https://nmbu.brage.unit.no/>

FOCUS (2001). “FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC”. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp. Accessible from <https://esdac.jrc.ec.europa.eu/projects/surface-water>

Forskrift om plantevernmidler (2015). Forskrift om plantevernmidler (FOR-2015-05-06-455). Accessible from <https://lovdata.no/dokument/SF/forskrift/2015-05-06-455>

Northern Zone (2019). Guidance document on work-sharing in the Northern zone in the authorisation of plant protection products. Version 8, July 2019. Accessible from <https://www.mattilsynet.no/>

Price, O., Hollis, J., Mackay, N. (2008). Establishing the representativeness of FOCUS surface water scenarios for pesticide risk assessment in the UK landscape. Defra report: PS2229. Accessible from <http://randd.defra.gov.uk/>

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/>

Activities and timeframe

- A start-up meeting with participants from the Scientific Committee for Food and Environment and the NFSA, to take place within the first half of 2020.
- Follow-up meetings as mutually deemed necessary.
- A report should be finalised by 30 November 2020.

Language

The report should be written in English, with a Norwegian summary.

Yours Sincerely

Abdelkarim Abdellaue
Head of National Registrations Department

*This document has been electronically approved, and sent without signature.
Documents that require a signature will also be sent as a paper copy*