Mattilsynet

Request to VKM for Assessment of an MRL Application for Oxathiapiprolin in Potatoes and Preparation of an Assessment Report

Mandate

The Norwegian Food Safety Authority (NFSA) requests the Norwegian Scientific Committee for Food and Environment (VKM) to assess an application for a maximum residue level (MRL) for oxathiapiprolin in potatoes. Norway has previously been designated as the Rapporteur Member State (RMS) for the active substance oxathiapiprolin.

The RMS for an MRL application is responsible for conducting a scientific evaluation of the application and preparing an assessment report that the European Food Safety Authority (EFSA) will use as the basis for its risk assessment and final recommendation regarding the MRL. VKM may maintain ongoing communication with EFSA, which will provide guidelines and further instructions for the assignment.

After receiving the MRL application, it is urgent to assess whether all necessary documentation has been submitted ("completeness check") and whether confidentiality requirements are met ("confidentiality check") in collaboration with EFSA, before the evaluation of the application begins. NFSA requests that VKM perform this as part of reviewing the documents in the IUCLID database. Any assessment of the need to request additional documentation ("clock-stop", meaning a pause in deadlines) will be handled by EFSA if required. EFSA is responsible for the final confidentiality assessment when it publishes its "reasoned opinion."

The RMS prepares a draft assessment report for EFSA, which then finalizes the risk assessment.

Background

Pesticide residues in food may pose a risk to public health. The EU and Norway share a common regulatory framework for both the approval and use of plant protection products, as well as for pesticide residues in food and feed. Evaluation and approval of active substances and the establishment of MRLs are carried out jointly at the EU level.

In connection with the evaluation of active substances, EU Member States or Norway may be appointed as RMS. In 2015, Norway implemented the EU's regulation on the approval and marketing of plant protection products (Regulation (EC) No 1107/2009). This also means that Norway assumes the responsibilities that follow, including assisting EFSA in evaluating active substances as RMS. It is common for MRL applications for substances to be submitted to the country designated as RMS for that active substance. The RMS must evaluate the submitted documentation and prepare a draft assessment. Specific

procedures and guidance documents describe how this work should be performed, along with regulatory requirements for the documentation.

On 18 December 2025, NFSA received an email from the applicant confirming that an MRL application had been submitted, as previously notified, under Regulation (EC) No 396/2005 to Norway (RMS) in the IUCLID database. The application concerns the establishment of an import tolerance MRL for oxathiapiprolin in potatoes based on approved use in the United States.

Requirements for MRL applications and their evaluation are laid out in the EU regulation on pesticide residues, Regulation (EC) No 396/2005 (Chapter II, Articles 6–11).

These MRLs must ensure that residue levels in food are safe for consumers and that plant protection products are used legally. The MRLs are established in Regulation (EC) No 396/2005, implemented in Norway through the Regulation on Pesticide Residues. Current MRLs are found in the EU Pesticide Database. Assessment of MRLs also requires documentation of the agronomic properties of the pesticide.

A key condition for establishing an MRL is that residue levels in food must not pose a health risk to consumers. Intake calculations are therefore performed, combining the MRL with consumption data for different foods, and comparing the estimated intake with safe health limits—acceptable daily intake (ADI) and acute reference dose (ARfD). If the assessment shows an unacceptable risk, an MRL will not be recommended.

EU Member States adopt MRL proposals in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF). EFSA's Pesticides Unit works closely with Member States to ensure solid scientific foundations for MRLs.

The results of EFSA's evaluations are published as "reasoned opinions." Chronic (long-term) and acute (short-term) dietary exposure assessments are conducted using EFSA's PRIMo model, based on national consumption data and recognized risk assessment methods.

Timeline: In accordance with deadlines set by EFSA and the European Commission.

It is important that the completeness check is carried out as soon as possible, particularly in relation to any potential "clock-stop," where the deadlines are temporarily paused.

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Relevant Regulations and Guidance

* Regulation (EC) No 396/2005 on pesticide residues
* Regulation (EU) No 283/2013 on data requirements for active substances
* Regulation (EU) 2019/1381 (Transparency Regulation)
* Guidance document: SANTE/2015/10595 Rev. 6.1 (2021) – Technical Guidelines for MRL Setting
* EU guidance on pesticides and pesticide residues
* Administrative guidance on submission of dossiers for peer review and MRL applications
* Application form for MRL setting under Regulation (EC) No 396/2005
* IUCLID 6.9 MRL Application Manual