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Norwegian Food Safety Authority



## COMMISSION FOR REASSESSMENT OF MRLS FOR ISOPYRAZAM FOR THE EU

### Background for the case

#### Maximum residue limits for pesticide residues in food

Pesticide residues in food can pose a danger to public health. For this reason, we have a comprehensive legislation that defines rules for the approval and use of pesticides and for pesticide residues in food.

To ensure that the residue level in food is safe and that pesticides are used legally, limits are set for residues (maximum residue level, MRL) in food stuffs. The MRL for pesticides are set out in the EU's regulations<sup>1</sup> and implemented in the Norwegian pesticide residue regulations<sup>2</sup>. The Norwegian Food Safety Authority (NFSA) enforces these regulations. Overview of all MRLs can be found in the EU database; (<http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database>).

#### Assessment of Maximum residue levels (MRLs)

MRLs are derived from extensive documentation of the agronomic properties of the pesticide. The overall aim for setting an MRL is to ensure that residues of pesticides in food do no harm the human health. This is done by carrying out intake calculations, where the MRL is combined for the various foods with consumption data and the intake of the pesticide is compared with safe levels of the health, i.e. acceptable daily intake (ADI) and acute reference dose (ARfD). If the calculation shows unacceptable risks, the MRL will be discarded and the pesticide will not be approved for use. Existing MRLs can be changed if the application is changed, or if new documentation has emerged about the toxicological properties of the substances.

Both first time assessments and reassessments of an active substance and related MRLs are jointly carried out at EU level. An appointed country, either in EU or Norway, will be the reporting member state (RMS) for a pesticide. The RMS makes a draft assessment sent to the European Food Safety Authority (EFSA). EFSA finalises the risk assessment. Based on EFSA's assessment and conclusion, the European Commission proposes whether or not to approve the active substance and which MRLs should apply. Finally, EU member states adopt the proposals of the standing committee on pesticide residues for plants, animals, food and feed (SCoPAFF).

<sup>1</sup> Regulation (EC) no 396/2005 - <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1585293820826&uri=CELEX:32005R0396>

<sup>2</sup> Plantevernmiddelestoffrestforskriften - <https://lovdata.no/dokument/SF/forskrift/2009-08-18-1117?q=plantevernmiddelestoffrestforskriften>

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## Collaboration with EFSA

EFSA's Pesticides Unit collaborates closely with member states on the scientific basis for MRLs. The results of EFSA's MRL assessments are presented as "reasoned opinions."

In the safety assessments of EU MRLs for pesticides, or proposals for MRLs, the chronic and acute dietary consumer exposure to pesticide residues is estimated by using a calculation model developed by EFSA (PRIMo – Pesticide Residue Intake Model). The model is based on national food consumption figures and unit weights provided by Member States and the model applies internationally agreed risk assessment methodologies to assess the short-term (acute) and long-term (chronic) exposure of consumers.

There are many pesticides that have a temporary authorization and are to be reconsidered. In this work, the Commission appoints an RMS that will assess the provided documentation and draft an assessment. There are procedures and guidelines for how this work should be carried out.

## Isopyrazam assessment

The Norwegian Food Safety Authority is responsible for approving products used in Norway<sup>3</sup>. In 2015, Norway implemented the EUs regulation for pesticides<sup>4</sup>. This means that Norway also will take part in the obligations that come with the agreement, such as helping EFSA assess active substances.

- In December 2018, Norway by the National Approvals Department under the NFSA , were commissioned to assess the pesticide isopyrazam.
- December 2019 Norway was asked to be RMS for the reassessment of MRLs for the active substance isopyrazam. This according to the pesticide residue regulation.

Data collection of documentation for the use of isopyrazam according to good agronomic practice (GAP) from applications was finished 17 March.

EFSA's assessment of existing residual amount limits (MRLs) is in place in EU pesticide regulations, Article 12. EFSA is assisted by the member states in this assessment.

Norway have not made any MRL assessments before.

Isopyrazam was approved for use 1 April 2013. It should be reapproved by 1. April 2023.

## Mission

The NFSA asks the Scientific Committee for Food and Environment (VKM) to reassess MRLs for isopyrazam together with EFSA, in accordance with Article 12 of Regulation (EC) 396/2005.

Data collection of documentation for applications (GAP) from member states was set for 17 March 2020.

EFSA will contact VKM and provide further guidelines and guidance on the assignment. EFSA will also be able to provide training in the use of the PRIMo model.

More information about the procedure, please refer to:

SANTE/2015/10595 Rev. 5.4 27 November 2018 Technical guidelines MRL setting procedure in accordance with articles 6 to 11 of regulation (EC) No 396/2005 and article 8 of regulation (EC) No 1107/2009 - [https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_mrl\\_guidelines\\_mrl-setting-proc.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-setting-proc.pdf).

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<sup>3</sup> [Forskrift om plantevernmidler](#)

<sup>4</sup> [https://ec.europa.eu/food/plant/pesticides\\_en](https://ec.europa.eu/food/plant/pesticides_en)

**Time frame**

The time frame is according to deadlines set by the EFSA and the European Commission.

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Yours Sincerely

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