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Swedish Chemicals Agency

Authorisations and Guidance

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Guidance for applications for mutual recognition in Sweden

Regulation (EC) No. 1107/2009

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Swedish Chemicals Agency

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June 2019	1.0	First Guidance for applications for mutual recognition in Sweden.
March 2020	2.0	Inserted a new section: 2.1 Applicant

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1 Introduction

This guidance is to clarify the requirements to be fulfilled when applying for mutual recognition of authorisations in Sweden. These requirements are according to Regulation (EC) No. 1107/2009[1] article 40-42, hereinafter referred to as the Regulation, as well as Swedish conditions and practice.

This is first and foremost a guidance aimed towards prospective applicants on how to prepare an application for mutual recognition for a plant protection product in Sweden.

More information regarding the legal basis and procedure of mutual recognition can be found in "Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009" (SANCO/13169/2010 rev 9).

Please note that this document contains the Swedish Chemicals Agency's interpretation of the Regulation. Other member states may have a different interpretation. Users of this guidance are reminded that the text of the Regulation is the only authentic legal reference and that the information in this document does not constitute legally binding advice. Questions of interpretation of the Regulation are finally resolved by the Court of Justice of the European Union.

The Swedish Chemicals Agency does subsequently not take on any legal responsibility for the content of this guidance.

1.1 Minor use

The authorisation holder, official or scientific bodies involved in the agricultural activities, professional agricultural organisations or professional users may apply for mutual recognition of an extended authorisation for minor uses, not yet covered by an authorisation in Sweden.

An application can be made through mutual recognition according Article 51.7 in the Regulation, provided that the concerned plant protection product is authorised in Sweden. A prerequisite is that the use is considered to be a minor use in Sweden.

[1] Regulation 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market.

2 Preparation of your application

2.1 Applicant

It is only the holder of an authorisation in the reference Member state that can apply for a mutual recognition of authorisation according Article 40.1 in the Regulation. This means that it is the holder mentioned on the authorisation in the reference Member state.

The applicant shall fill out the electronic form MIP-0012-E on the Swedish Chemicals Agency's website.

2.2 Documents to be attached to the application

The documents to be submitted along with the application for mutual recognition are presented below. The documentation should preferably be submitted in digital form.

2.2.1 Member State Authorisation

A copy of the reference member states' original authorisation certificate should be submitted, together with a translation of the certificate to English or Swedish.

2.2.2 GAP

The reference member state's GAP and the GAP for Sweden should be submitted. An application for mutual recognition can only be granted for the same use as authorised by the reference member state. However, the Swedish Chemical Agency accepts a few changes in the GAP:

Crops: The crops should be the same or limited, referred to the reference member state's GAP. Additional crops can be added to the GAP if the evaluation can be extrapolated from the crops included in the authorisation of the reference member state. Please, see following tables for guidance on extrapolation for efficacy (https://www.eppo.int/ACTIVITIES/plant_protection_products/extrapolation_tables) and residues (https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_app-d.pdf)

Application timing: The application timing can be changed as long as it is within the same application window as the authorisation in the reference member state.

Number of applications and reduced dose: The number of applications and/or dose can be reduced compared to the GAP of the reference member state. Such change may be complemented with new efficacy studies to support the reduced number of applications or dose (see section 3.2 for further guidance).

2.2.3 Label and user instruction

The label and user instruction of the reference member state should be submitted, together with a translation of the label and instruction to English or Swedish.

A proposed Swedish label and user instruction, in Swedish, should be submitted.

2.2.4 Composition and sources

Information on the complete composition of the product and the sources of the active substance(s) accepted by the reference member state should be submitted as well as a formal statement that the plant protection product is identical to that authorised by the reference member state. The Swedish Chemicals Agency may however request the applicant to submit additional documentation on the composition of co-formulants.

2.2.5 Registration report

A complete registration report for the concerned product in accordance to Uniform Principles and in the dRR-format[2], should be submitted, and if applicable translated to English.

2.2.6 Data package

The complete data package used by the reference member state should be submitted. If necessary, documentation that shows access to such data should also be submitted.

2.2.7 Reference list

A compiled complete reference list containing all test- and study reports submitted in support of your application is required. The format should be in accordance with SANCO/12580/2012 rev 3.1 - references for plant protection products. The list should be submitted as a word-document. More information regarding data protection can be found on our website (https://www.kemi.se/en/pesticides-and-biocides/plant-protection-products/apply-for-authorisation-for-plant-protection-products/data-protection).

3 Swedish requirements and comparable conditions

According to Article 40.1 in the Regulation, an authorisation holder of a plant protection product may apply for an authorisation for the same plant protection product, for the same use and under comparable agricultural practices in another member state.

[2] http://ec.europa.eu/food/plant/docs/pesticides_ppp_app-proc_guide_doss_reg-report-draft_2015.zip

The applicant may need to submit supplementary information to address Swedish agricultural and environmental conditions in the environmental risk assessment and efficacy evaluation.

3.1 Environmental risk assessment

The environmental risk assessment (e-fate and ecotoxicological risk assessment) need to address Swedish national requirements. The Swedish requirements for soil, groundwater and surface water are specified in the Northern Zone Guidance document[3] (hereafter NZ GD). Note that the requirements for groundwater and surface water differs between the countries within the Northern Zone. Furthermore, an updated ecotoxicological risk assessment based on PEC-values relevant for environmental conditions in Sweden and with the first tier ecotoxicological endpoints accepted by the reference member state should be submitted. If higher tier risk assessment is needed for birds and mammals, this should include relevant focal species for Sweden and follow the NZ GD.

When field studies are included in the risk assessment, a justification of the relevance of the studies based on Swedish environmental (including climatic) and agricultural conditions and the proposed use, should be provided. Results from field studies not considered relevant to Swedish conditions may be disregarded.

3.2 Efficacy

If the reference member state belongs to the Northern zone, additional efficacy studies relevant for Swedish climatic conditions does not have to be submitted. This also applies when the efficacy studies are conducted outside the Maritime zone. If the reference member state do not belong to the Northern zone, new efficacy evaluation and studies may have to be submitted to support efficacy towards relevant pests. If new studies are needed depends on climate and agricultural conditions. The applicant may submit a justification as to why submitted efficacy studies are relevant for Swedish conditions.

When the number of applications and/or dose have been reduced in the Swedish application compare to the reference member state, new efficacy data may have to be submitted to support these changes. New submitted efficacy studies have to be relevant for Sweden and in accordance with the Northern Zone Guidance on efficacy[4].

[3] Guidance Document on work-sharing in the Northern Zone in the authorisation of plant protection products. https://www.kemi.se/en/pesticides-and-biocides/plant-protection-products/apply-for-authorisation-for-plant-protection-products/plant-protection-products/plant-protection-products/application-forms-and-guidance-documents-for-plant-protection-products

[4] https://www.kemi.se/en/pesticides-and-biocides/plant-protection-products/apply-for-authorisation-for-plant-protection-products/plant-protection-products/plant-protection-products/application-forms-and-guidance-documents-for-plant-protection-products

3.3 Residues

A compilation of the residue studies carried out within the Northern residue zone, corresponding to the use applied for, should be submitted unless included in the reference Member States' registration report.

3.4 Assessment of the submitted data

New data, submitted in support the application and to address Swedish agricultural and environmental conditions should be summarised in National addendum. It should also follow the requirements in the latest version of the NZ GD.

4 Assessment of the application

A member state that receives an application for mutual recognition of a plant protection product shall decide on the application within 120 days, according to Article 42.2 in the Regulation.

It is recommended that an application for mutual recognition is notified to the Swedish Chemicals Agency at least 6 months before the application is submitted

4.1 Time to complete the application

A submission of a complete application will facilitate the authority to handle the application within the legal time limit and reduce the need for supplementary information later in the process. If the application is not complete and the need for supplementary information is extensive, the Swedish Chemicals Agency may have to refuse the application.

If supplementary information is requested, a period of maximum 4 weeks, is given to the applicant to complete the application.