Kemikalieinspektionen
Swedish Chemicals Agency
Authorisations and Guidance

Guidance Document
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Guidance for applications for mutual recognition in Sweden

Regulation (EC) No. 1107/2009

Swedish Chemicals Agency

Mailing address	Visit & delivery	Invoicing address	Phone & mail	Web site	VAT no
Box 2 SE-172 13 Sundbyberg	Vasagatan 12 D 172 67 Sundbyberg	PEPPOL-ID: 0007:2021003880	+46 8 519 41 100 kemi@kemi.se	www.kemi.se	202100-3880

Editing log – Guidance for applications for mutual recognition in Sweden.

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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**
May 2023	**3.0**	**Section regarding products containing CfS, section regarding minor uses and other minor changes.**

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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 to reflect the Swedish conditions and practice in use and be in accordance with article 40-42 in Regulation (EC) No. 1107/2009[1], hereinafter referred to as the Regulation.

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, latest version).

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 Products containing Candidates for Substitution

Swedish Chemicals Agency has decided not to grant authorisations for products containing an active substance that is a Candidate for Substitution via mutual recognition. This applies to applications submitted to the Swedish Chemicals Agency after 30th of September 2023.

This decision is based on that article 41.2 in regulation (EG) no 1107/2009 gives a member state the possibility to derogate from the common principal that mutual recognition is one of the means of ensuring the free movement of

[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.

goods within the Community, if the product contains a Candidate for Substitution.

1.2 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 to 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.

According to article 40.2, it is also possible for an official or scientific body involved in the agricultural activities or professional agricultural organisation to apply for an authorisation via mutual recognition if they have consent from the holder of the registration. In these cases, it has to be shown that the plant protection product is of a general interest.

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 to Article 40.1 in the Regulation. This means the holder stated on the registration certificate in the reference Member state. There is one exception from this general rule of holder. This is if article 30.2 apply. Please see section 1.2 above.

The applicant shall fill out the electronic form MIP-0033-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.

If the authorisation in the reference member state has been amended, also the decision regarding the amendment needs to be submitted or an official consolidated decision containing the amendment.

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 authorised in the reference member state.

Number of applications and reduced dose: The number of applications and/or the 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 fromthe 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, including the full composition of the containing co-formulants, and the sources of the active substance(s) accepted by the reference member state should be submitted. Furthermore a formal statement that the plant protection product is identical to that authorised by the reference member state, should be submitted.

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.

If the product has been amended in the reference member stat, also that evaluation has to be submitted.

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 complete reference list containing all test- and study reports submitted in support of your application is required. The format should be compiled and presented in accordance with "Format of a draft registration report version 2016".[2] The list should be submitted as Appendix 4 to Part A. 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.

[2] Format of a draft Registration Report 2016
https://food.ec.europa.eu/plants/pesticides/approval-active-substances/guidelines-active-substances-and-plant-protection-products_en

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.

Supplementary information may be submit 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) needs 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] 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

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 does 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 compared 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].

3.3 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.

[4] Guidance on requirements for efficacy data for zonal evaluation of a plant protection product in the Northern Zone. 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

It is recommended to notify an application for mutual recognition to the Swedish Chemicals Agency. The notification shall be submitted at least 6 months before the application.

4.1 Time to complete the application

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.