

Guidance on the application of mutual recognition in Norway

Under regulation (EC) No. 1107/2009

Norwegian Food Safety Authority
Region Office, Greater Oslo Region

Official in charge: Tor Erik Jørgensen
Phone: +47 22 40 00 00
Location: Moerveien 12, Ås
E-mail: postmottak@mattilsynet.no

Postal address: Region Office, Greater Oslo Region
P.O. Box 383
N - 2381 Brumunddal
NORWAY

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1 Introduction

This guidance is to describe the procedure of an application for mutual recognition in Norway. Additionally, it will clarify the requirements to be fulfilled according to Norwegian conditions and practice, as well as Regulation (EC) no. 1107/2009¹, hereinafter referred to as the Regulation.

This guidance on mutual recognition will enter into force on the 1st June 2015. Applicants may however apply the guidance prior to this date.

Please note that this document contains the Norwegian Food Safety Authority'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 Norwegian Food Safety Authority does subsequently not take on any legal responsibility for the content of this guidance-

2 Reading directions

The guidance is first and foremost aimed towards prospective applicants for mutual recognition of an authorisation or renewal of an authorisation for a plant protection product in Norway.

The guidance should be regarded as complementary to the "[Guidance document on zonal evaluation and mutual recognition under Regulation \(EC\) No 1107/2009](#)" (SANCO/13169/2010). It addresses the specific requirements that apply to use under Norwegian conditions and is also complementary to the latest "[Guidance document on work-sharing in the Northern zone in the authorisation of plant protection products](#)" (hereinafter referred to as the Northern Zone Guidance).

There is a continuous harmonisation of the authorisation procedure taking place within the European Union, as well as within the zones. Some requirements and prerequisites may therefore have changed since the publication of this guidance. It will be updated whilst on-going harmonisation takes place. Therefore, the Norwegian Food Safety Authority recommends any prospective applicant to visit our website (www.mattilsynet.no) in order to stay updated with the authorisation procedure and the requirements to be fulfilled.

3 Current provisions on product authorisations through mutual recognition

A plant protection product may not be placed on the market or used unless it has been authorised within the concerned Member State. In the event that a plant protection product is to be introduced to the market, an authorisation must be granted prior to the placing on the market. The competent authority entitled to issue such an authorisation in Norway is the Norwegian Food Safety Authority.

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.

The provisions on authorisations through mutual recognition can be found in Articles 40 – 42 in the Regulation.

A plant protection product can only be mutually recognised in Norway if it has been granted an authorisation in the reference Member State which fulfils the requirements of article 29 in the Regulation as well as the Uniform Principles², taking into account the endpoints of the Review Report. An authorisation granted in accordance to article 4 in directive 91/414 can therefore also be mutually recognised. It is the Norwegian Food Safety Authority that decides whether an application fulfils such requirements or not.

The procedure of mutual recognition means that the 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, according to Article 40.1.

According to the Norwegian Food Safety's interpretation:

- The same plant protection product means that the composition is identical, the active substance derives from the same source and that it is the same preparation type. Please note that an equivalent product is not considered to qualify as being the same plant protection product.
- The same use means that it is not possible to extend the use to additional crops other than those authorised by the reference Member State. It is however possible to limit the use to certain crops.
- "Comparable agricultural practices" means that an authorisation through mutual recognition can only be granted on the basis of the prerequisites and conditions adopted by the reference Member State. This means that the dose, application technique, time of application and number of applications cannot be changed.

It is also possible for official or scientific bodies involved in agricultural activities or professional agricultural organisations to apply for an authorisation through mutual recognition, according to Article 40.2. A prerequisite is that the authorisation holder has not yet applied for an authorisation in Norway.

In order for the above mentioned actors to apply for an authorisation through mutual recognition, it must be demonstrated that:

- The applicant has been given consent from the authorisation holder to apply for mutual recognition of the plant protection product, and
- That the use of the plant protection product is of general interest in Norway.

The Norwegian Food Safety Authority may grant an application without consent from the authorisation holder if a product is of public interest, according to Article 40.2.

Examples of situations of public interest are if there is no product authorised in Norway for the use applied for, when a product is considered to result in substantially lower risks than comparable products or in case of a problem with resistance management.

3.1 Comparable conditions

According to Article 29 in the Regulation, certain prerequisites must be fulfilled in order to grant an authorisation for mutual recognition. Some of these requirements relates to specific environmental conditions that may vary between Member States. Therefore,

² Annex VI to Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC), implemented by Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

comparable conditions between the reference Member State and Norway may have to be demonstrated.

When a plant protection product has been assessed by a Member State within the Northern zone, according to Directive 91/414/EEC, or when the reference Member State is located outside of the Northern zone, authorisations may only be mutually recognised if the applicant can demonstrate that there are comparable environmental and agricultural conditions between the reference Member State and Norway (see section 4.3).

Comparable conditions must be demonstrated as environmental conditions in Norway have not been considered when assessing the plant protection product.

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.

According to the document SANCO/13169/2010, an application for mutual recognition should be notified to the concerned Member State 6 months before the application is submitted and registered in the SANCO applications database, when made available.

4.1 Time limit of 120 days

The Norwegian Food Safety Authority shall decide on the application for mutual recognition within 120 days from the day the application was received, according to article 42.2 in the Regulation. The Norwegian Food Safety Authority will therefore refuse applications where the applicant does not provide a complete application.

4.2 Documents to be attached to the application

The documents to be submitted along with the application for mutual recognition are presented below.

An applicant shall fill out the electronic form on the Norwegian Food Safety Authority's website. Three full sets of documentation should be submitted, preferably in digital form. The first page of the application and any letters of access should be submitted in originals.

4.2.1 Registration report

A complete registration report for the concerned product in accordance to Uniform Principles, Annex VI to directive (EEC) no. 91/414 or the implementing Regulation (EU) no. 546/2011, or newer requirements according to Regulation (EC) 1107/2009 shall be submitted, translated to English or Norwegian. The report must be clear and include:

- The product's chemical and physical properties
- Methods of analysis concerning the product and the active substance(s)
- Toxicological risk assessment
- Risk assessment of residues and compliance with established MRLs
- Risk assessment of the products' degradation, dissipation and distribution in the environment (E-fate)
- Ecotoxicological risk assessment
- Assessment of the product's efficacy

This also applies if an authorisation subject to an application for mutual recognition is based upon the assessment of another product.

4.2.2 Data package

The complete data package used by the reference Member State, for both the active substance(s) and the product should be submitted. If necessary, documentation that shows access to such data should also be submitted.

4.2.3 Member State Authorisation

A certified original copy of the reference Member States' authorisation certificate of the product should be submitted, together with a certified translation of the certificate to English or Norwegian.

4.2.4 GAP

The reference Member State's GAP and the GAP for Norway should be submitted. Please note that an application for mutual recognition only can be granted for the same use (see section 3.)

4.2.5 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 Norwegian.

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

4.2.6 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. Safety data sheets (SDS) for co-formulants and product, including complete composition of co-formulants which are mixtures (more than one compound), shall be submitted in either Norwegian or English, and must not be older than two years.

4.2.7 Reference list

According to article 33.4, a reference list containing information on test and study reports attached to the application should be submitted. The reference list should

include information about test and study reports for which data protection claims has been made

- For each test or study report the applicant has claimed data protection for, information listed in articles 8.1 f and 33.3 d must be submitted.
- A statement confirming that the test or study report has not previously been covered by data protection, or that the test or study report is out of data protection, should also be submitted.
- A confirmation whether the test or study report is compliant with the principles of good laboratory practice (GLP) or of good experimental practice (GEP) should be submitted.
- For each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals should be made, articles 8.1 d and 33.3 c.

4.3 Supplementary documentation to demonstrate comparable conditions

Documents that should be submitted with the application for mutual recognition in order to demonstrate comparable conditions are presented below. These requirements apply when a plant protection product has been assessed by a Member State within the Northern zone according to Directive 91/414/EEC or when the reference Member State is located outside the Northern zone.

These requirements do not apply to applications listed in article 33.2b in the Regulation.

4.3.1 Justification

A justification as to why the evaluation carried out by the reference Member State is relevant to environmental conditions in Norway should be submitted. The justification should include the specific national requirements for soil, groundwater, surface water and focal species that are specified in the current Northern Zone Guidance.

4.3.2 Risk assessment

An updated ecotoxicological risk assessment based on PEC-values relevant for environmental conditions in Norway and with the first tier ecotoxicological endpoints accepted by the reference Member State should be submitted. If a refined risk assessment based on field studies was necessary, it should include the specific national requirements for soil, groundwater, surface water and focal species that are specified in the current Northern Zone Guidance.

4.3.3 Residues

A calculation of the risk for established MRLs to be exceeded when the product is used as suggested should be submitted. The calculation shall only be based on results from residue trials performed within the Northern residue zone.

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. The compilation shall include information on the application rate that has been used in the studies, the number of treatments and growth stage at application and at what pre-harvest intervals possible residues were measured.

4.3.4 Health hazard

The health hazard for the operator, bystanders and workers in fields in Norway should be comparable to that of the reference Member State.

- In case the equipment in the reference Member State differs from that commonly used in Norway, this has to be justified.
- If field studies are used in the risk assessment, these must have been carried out under conditions relevant to Norway. This has to be justified.

4.3.5 In case of environmental differences

A compilation of data according to the table in appendix I together with a justification as to why environmental differences, if any, would not affect the use of the plant protection product concerned should be submitted.

5 Exemptions for products used in glasshouses

At the moment, there is no detailed EU-guidance available on how to estimate contamination from glasshouses. An environmental risk assessment of Norwegian conditions will therefore not be required with regards to uses in glasshouses, until such guidance is available.

6 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 Norway.

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 Norway. A prerequisite is that the use is considered to be a minor use in Norway.

7 Appendix I

Table based on EPPO standard PP 1/278(1) Principles of zonal data production and evaluation, appendix 1 to be filled out in order to demonstrate comparable conditions.

	Reference member state	Norway	Justification
Climate			
Length of growth season			
Rainfall during application period (frequency and intensity).			
Intensity and duration of light during growth season			
Duration of snow cover			
Pest related			
Pest pressure.			
Number of pest generations.			
Pest sensitivity/susceptibility to the plant protection product.			
Product and active substance related			
Susceptibility to high or low temperature with respect to efficacy			
Rate of degradation in soil and plant residues and effect on following crops			
Crop			
Varietal diversity and sensitivity to adverse effects.			
Agronomy			
Cropping practice.			
Crop structures.			
Rotational crops.			
Irrigation.			