

## Guidance for application of authorisation for plant protection products.

This guidance document provides information regarding the application process for the authorisation of plant protection products in order to place plant protection products on the Icelandic market. It includes information concerning the application for mutual recognition of authorisation for a plant protection product and permit for a parallel trade of plant protection product. The procedure for the application is according to [Regulation \(EC\) No. 1107/2009 concerning the placing of plant protection products on the market](#), which was implemented in Iceland on the 5th of June 2015 with national [regulation no. 544/2015 on plant protection products](#). Guidance document on zonal evaluation and mutual recognition<sup>1</sup> and guidance document concerning the parallel trade of plant protection products<sup>2</sup> by the European Commission are also followed during the application procedures.

### 1. Mutual recognition of authorisation for a plant protection product

#### 1.2 Introduction about the mutual recognition of authorisation

The member states (MS) in the European Union has been grouped into three zones, north-, center- and south-zone for the authorisation of plant protection products, based on the conditions in each country. Member States may, in the following cases, grant a mutual recognition of authorisation for a plant protection product, according to article 40 in Regulation (EC) No. 1107/2009:

- Member States may grant a mutual recognition of an authorisation, if the authorisation was granted by a Member State (reference Member State) which belongs to the same zone, for the same plant protection product, the same use and under the comparable agricultural practices.
- Member State may grant a mutual recognition of authorisation for plant protection product, if the authorisation was granted by a Member State (reference Member State) which belongs to a different zone, provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another Member State in the same zone.
- Member States may grant a mutual recognition of authorisation for plant protection product, regardless of the zone to which the reference Member States belongs, if the intended use is in greenhouses, for post-harvest treatment or for treatment of empty rooms or containers used for storing plant or plant products, or for seed treatment.

A plant protection product, which has been granted a mutual recognition of authorisation, shall be placed on the market and used only in accordance with the provisions in the authorisation of the reference Member State.

#### 1.3 Application

Applicants may apply for a mutual recognition of authorisation in Iceland by filling out the application form that can be found on the [website of The Environment Agency of Iceland](#) and send the application accompanied with the necessary documents to the Agency.

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<sup>1</sup> SANCO/13169/2020 rev. 9. Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009.

<sup>2</sup> SANCO/10524/2012 vers.5.2. Guidance document concerning the parallel trade of plant protection products.

The following documents shall be accompanied with an application, according to article 42 in Regulation (EC) No. 1107/2009:

- Copy of the authorisation granted by the reference Member State.
- Translation of the authorisation into Icelandic, English or another Scandinavian language except Finnish, if the authorisation is not already in the abovementioned languages.
- A formal statement that the plant protection product is identical to that authorised by the reference Member State (Statement of identity).
- An assessment report of the reference Member State containing the information on the evaluation and decision on the plant protection product (Registration Report).
- Copy of the product label from the reference Member State.
- Draft of Icelandic label.

Applicants may also apply for mutual recognition of authorisation in Iceland on the same time as an application for authorisation is submitted to a zonal Rapporteur Member State (zRMS). In that case Iceland would need to be appointed as a concerned Member State (cMS) in the submitted application for authorisation or renewal. The zRMS will complete the assessment of the application, and when finished, the zRMS will send core assessment and proposal for authorisation the other concerned Member States.

#### **1.4 Application fee**

The Environment Agency of Iceland charges a fee for the processing of application for authorisations of plant protection product according to its list of [administrative fees](#).

If the work processing an application for a mutual recognition of authorisation takes more time than included in the amount given in the list of fees, an extra fee may be charged. The applicant will be notified of the additional work as soon as possible. An invoice for additional work will be issued when a decision has been made regarding the authorisation of the plant protection product.

If, on the other hand, the work is less than anticipated, the Environment Agency can rebate the applicant for authorisation of the plant protection product. Repayment can never be higher than 80% of the fee.

An invoice will be issued when all necessary data has been delivered in accordance with Regulation 544/2015 on plant protection products. Assessment of the application will begin when the payment has been received.

## **2. Parallel trade permit of plant protection product**

### **2.1 Introduction about the parallel trade permit of plant protection product**

A plant protection product which has been authorised in one Member State (Member State of origin) may be granted a parallel trade permit in order to place the plant protection product on the market and for the use in another Member State (Member State of introduction). That depends on the Member State of introduction if it determines that the plant protection product is identical in composition to a plant protection product already authorised in its territory (reference product). The application should be submitted to the competent authority of the Member State of introduction. It is possible to apply for a parallel trade permit for a plant protection product meant for placing on the market in Iceland as well as for personal use. In order to apply for a parallel trade permit, the plant protection product must be considered as identical to the reference product in the Member State of introduction. According to article 52 (3) in Regulation (EC) No. 1107/2009, plant protection product is considered identical to the reference product if:

- a) they have been manufactured by the same company or by an associated undertaking or under license in accordance with the same manufacturing process,

- b) they are identical in specification and content to the active substances, safeners and synergists, and in the type of formulation,
- c) they are either the same or equivalent in the co-formulants present and packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.

Plant protection product, which has been granted a parallel trade permit, shall be placed on the market and used only in accordance with the provisions of the authorisation of the reference product.

## 2.2 Application

Applicants may apply for a parallel trade permit of plant protection product in Iceland by filling out the application form that may be found on the [website of The Environment Agency of Iceland](#) and send the application accompanied with the necessary documents to the Agency.

The following information and documents shall be accompanied with an application, according to article 52 (4) in Regulation (EC) No. 1107/2009:

- The name and registration number of the plant protection product in the Member State of origin,
- The Member State of origin,
- The name and address of the authorisation holder in the Member State of origin,
- The original label and instructions for use with the plant protection product to be introduced and is distributed in the Member State of origin,
- Translation of the original label into Icelandic, English or another Scandinavian language except Finnish, if the label is not already in the abovementioned languages.
- The name and address of the applicant,
- The name to be given to the plant protection product to be distributed in the Member State of introduction,
- Draft Icelandic label for the product intended to be placed on the market,
- The name and registration number of the reference product.

The following information and documents are excluded from the application if applicant applies for a parallel trade permit of plant protection product for personal use:

- The name to be given to the plant protection product to be distributed in the Member State of introduction,
- Information about the packaging/repackaging.
- Labels, except if translation of the label has been required into Icelandic, English or another Scandinavian language except Finnish.

## 2.3 Application fee

The Environment Agency of Iceland charges a fee for the processing of application for authorisations of plant protection product according to its list of [administrative fees](#).

If the work processing an application for a parallel trade permit takes more time than included in the amount given in the list of fees, an extra fee may be charged. The applicant will be notified of the additional work as soon as possible. An invoice for additional work will be issued when a decision has been made regarding the authorisation of the plant protection product.

If, on the other hand, the work is less than anticipated, the Environment Agency can rebate the applicant for authorisation of the plant protection product. Repayment can never be higher than 80% of the fee.

An invoice will be issued when all necessary data has been delivered in accordance with Regulation 544/2015 on plant protection products. Assessment of the application will begin when the payment has been received.