

**Guidelines**  
**for emergency situations in plant**  
**protection**

Placing on the market of plant protection products in  
accordance with Article 53 of Regulation (EC) No  
1107/2009

## General information

### Background

- According to Article 53 of Regulation (EC) No 1107/2009 the placing on the market of plant protection products may be authorised in special circumstances for a period not exceeding 120 days if such a measure appears necessary because of a danger which cannot be contained by other means.
- In Austria on average about 30 Emergency Use Authorisations are granted per year with up to one third of the products being destined for the use in organic farming (calculated on the basis of indications this share amounts up to two thirds).
- The Emergency Use Authorisation constitutes an important instrument, in particular also in organic farming in order to enable efficient plant protection and to meet extraordinary situations in a targeted way.

### Presence of an emergency situation

- No indications of authorised plant protection products or not to a sufficient extent with special consideration of resistance management
- Unforeseeable occurrence and/or uncontrollable propagation of a harmful organisms.
- No acceptable alternative control strategies

### Course of the authorisation procedure

- The applicant submits the required data and documents at the Federal Office for Food Safety (Bundesamt für Ernährungssicherheit - BAES)
- The specific emergency situation must be sufficiently justified and documented by the applicant and/or legal representations of interest or the Federal States (Bundesländer).
- In certain cases the individual Federal States (Bundesländer) confirm the need of the use of plant protection products in their Federal State.<sup>1</sup>
- The Federal Office for Food Safety (Bundesamt für Ernährungssicherheit - BAES) examines whether the requirements for authorisation in particular in view of the protection of human and animal health and the environment are met.
- Authorisations are issued by the Federal Office for Food Safety (Bundesamt für Ernährungssicherheit - BAES) by means of an official decision
- Every Emergency Use Authorisation is immediately notified to the EU Commission and to the EU Member States.

### Fundamental restrictions

- Every Emergency Use Authorisation is, in any case, to be restricted in terms of quantity and area and/or taking into consideration the submitted information.
- The authorisation is granted for a period not exceeding 120 days subject to restrictive requirements.
- In certain cases the individual Federal States (Bundesländer) confirm the need of the use of plant protection products in their Federal State (Bundesland). If there is no confirmation the authorisation is to be restricted accordingly by the authorising authority.

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<sup>1</sup> see details at specific requirements

## Submission by the applicant

### General requirements (for all applications)

- All documents according to the provisions of Regulation (EC) No 1107/2009, which are necessary for the evaluation, and which have not yet been submitted within the framework of a licensing procedure or can be derived by means of extrapolation, etc.
  - Detailed composition as well as current safety data sheets of the formulation and of the active substances and co-formulants
  - Intended directions of use and potential risk-reducing measures
  - Information and documents to evaluate the toxicological properties and the environmental behaviour according to the provisions of EU Regulation (No) 1107/2009 which are necessary for the evaluation of the application and which have not yet been submitted
  - Data on the residue behaviour with residue-relevant crops and/or information whether the applicable maximum residue contents can be complied with
- Information/documents on the necessity to apply plant protection products for the use/s applied for
- Information about the efficacy and phytotoxicity, if available
- Comprehensible and plausible data and documents about the importance of pest control with the respective crop (economic importance, frequency of occurrence, problems with the control, economic dimension of damage)
- Information/documents about the availability of alternative methods of control
- Under certain circumstances (e.g. with streptomycin) the regulatory authority can stipulate additional requirements

### Specific requirements (according to status of the active substance) – in addition to the requirements mentioned under “general requirements”

**Category 1:** The application is submitted within the framework of an extension of the scope of application (extension of use to an existing Austrian authorisation)

- If applications are submitted for several consecutive years from the second application onwards a status quo report on the preparations for an application for a regular extension of use has to be provided (except for minor uses according to the decree of the Federal Ministry of Agriculture, Forestry, Environment and Water Management ad reference number BMLFUW-LE.2.1.15/0009-III9a/2012).

**Category 2:** The plant protection product is authorized with the intended use/s applied for in another EU Member State.

- Submission of the current evaluation report and the official decision of authorisation from the other EU Member State
- Information/documents on the availability of other chemical-synthetical or other plant protection products for the control of the pest (with comparable success of control)
- If applications are submitted for several consecutive years from the second application onwards a status quo report on the preparations for the application for a regular authorisation has to be

provided (except for minor uses according to the decree of the Federal Ministry of Agriculture, Forestry, Environment and Water Management ad reference number BMLFUW-LE.2.1.15/0009-III9a/2012).

**Category 3:** Listed substances according to Annex II of the EU Organic Regulation No 889/2008 if they do not fall within category 1 or 2 as well

- Confirmation of the respective Federal States (Bundesländer) concerning the need to use the plant protection product
- Information/documents on the availability of (other) organic plant protection products for the control of the harmful agent (with comparable success of control)
- Information/documents on the availability and feasibility of other alternative pest control methods (crop rotation, mechanical measures, etc. with comparable success of control)
- If applications are submitted for several consecutive years from the second application onwards a status quo report on the preparations for the application for a regular authorisation has to be provided (except for minor uses according to the decree of the Federal Ministry of Agriculture, Forestry, Environment and Water Management ad reference number BMLFUW-LE.2.1.15/0009-III9a/2012).

**Category 4:** The plant protection product is authorised in another EU Member State, but not with the uses applied for

- Confirmation of the respective Federal States (Bundesländer) concerning the need to use the plant protection product
- Submission of the current evaluation report and the official decision of authorisation in the English and German languages
- Information/documents on the availability of other chemical-synthetical plant protection products for the control of the pest (with comparable success of control)
- If applications are submitted for several consecutive years from the second application onwards a status quo report on the preparations for the regular authorisation has to be provided (except for minor uses according to the decree of the Federal Ministry of Agriculture, Forestry, Environment and Water Management ad reference number BMLFUW-LE.2.1.15/0009-III9a/2012).

**Category 5:** A regular authorisation of the plant protection product has been applied for in Austria, the decision on the authorisation is still pending (the use is not authorised in another EU Member State either)

- Confirmation of the respective Federal States (Bundesländer) concerning the need to use the plant protection product
- Information/documents on the availability of other chemical-synthetical plant protection products for the control of the pest (with comparable success of control)
- Information on the substitution candidates contained
- Information/documents on the availability and feasibility of other alternative pest control methods (crop rotation, mechanical measures, etc.) with comparable success of control

**Category 6:** The plant protection product contains one or several active substances which is/are not approved according to Regulation (EC) No 1107/2009

- Confirmation of the respective Federal Provinces concerning the need to use the plant protection product
- Information about the absolutely necessary quantity of the plant protection product (identified at individual farm level)
- Information/documents concerning the area which is absolutely to be dealt with (identified at individual farm level)
- Comprehensive information concerning efficiency and phytotoxicity
- Comprehensive information regarding the effects on the environment and on animal and human health of the active substance as well as of the plant protection product
- Detailed information about the residue behaviour
- Information/documents concerning the special advantages and/or benefits of the availability of the plant protection product applied for
- Information/documents on the availability of other organic plant protection products for the control of the pest (with comparable success of control)
- Information/documents on the availability of (other) chemical-synthetical plant protection products for the control of the pest (with comparable success of control)
- Information/documents on the availability and feasibility of other alternative pest control methods (crop rotation, mechanical measures, etc.) with comparable success of control
- Information/documents concerning the resistance management for the indication applied for
- Proposal of risk-reducing measures regarding human and animal health and the environment
- Proposal of a plausible exit scenario
  - Status quo of the approval of the active substance
  - Verifiable elaboration of/development of/research into alternative control measures (other chemical-synthetical plant protection products, organic plant protection products, mechanical and other alternative measures ) and their financing
  - Submission of a traceable, plausible schedule