



Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

The authorisation of plant protection products for non-professional users and for use in home gardening

Summary

Plant protection products for non-professional users must comply with special requirements. This document lists criteria that the Federal Office of Consumer Protection and Food Safety applies regarding the suitability of a plant protection product for application by non-professional users in home gardening. In addition, the documents contains explanations as to the legal framework and information for applicants.

Contact:

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Abteilung Pflanzenschutzmittel

Messeweg 11/12

38104 Braunschweig

Telephone: +49 531 299-3401

Email: 200@bvl.bund.de

www.bvl.bund.de

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1 Legal framework

1.1 Differentiation between professional and non-professional users

Contrary to previous regulations of plant protection law, a differentiation is now made between plant protection products for professional users and non-professional users (since 14 June 2011 according to Art. 31 (4) (d) Regulation (EC) No 1107/2009 [1]).

The new Plant Protection Act [2] also implements the regulations of Directive 2009/128/EC [3]. According to Art. 6 (2) Directive 2009/128/EC, the Member States shall take necessary measures to make sure that sales of plant protection products authorised for professional users are only sold to persons holding a certificate providing evidence of expert knowledge. Furthermore, Art. 13 (2) of the Directive stated above provides for the handling and storage of pesticides and dealing with their packaging and left-over products as follows: "Member States shall take all necessary measures regarding pesticides authorised for non-professional users to avoid dangerous handling operations. These measures may include use of pesticides of low toxicity, ready to use formulations and limits on sizes of containers or packaging."

According to Article 33 (1) no. 1 Plant Protection Act, the Federal Office of Consumer Protection and Food Safety (BVL) is the competent authority in Germany for authorising plant protection products. The BVL decides according to Article 34 (1) no. 1 to 3 Plant Protection Act, in consultation with the Julius Kühn-Institute (JKI), the German Federal Institute for Risk Assessment (BfR) and in agreement with the Federal Environment Agency (UBA) on the authorisation of plant protection products. This includes evaluating the suitability of plant protection products for non-professional users.

1.2 Additional provisions concerning evaluation for the purpose of authorisation

Generally, according to Article 12 (3) p. 2 no. 1 Plant Protection Act, only plant protection products which are authorised for use by non-professional users may be used for home gardening, or plant protection products which are authorised for professional users according to no. 2 and which the BVL has determined suitable for use in home gardening according to Article 36 (1) sentence 2 no. 3 or (2).

As far as authorisation is concerned, in addition to the provisions stipulated in Art. 31 (2) and (3) Regulation (EC) No 1107/2009, the BVL can in particular determine conditions of application according to Article 36 (1) German Plant Protection Act in order to protect human and animal health and for protection against other harmful effects, in particular on the environment, including those

1. concerning required buffer zones and application measures for protecting water when the product is applied correctly and as intended,
2. which stipulate the persons authorised to apply plant protection products, and
3. concerning specific risk mitigation measures for certain areas.

The BVL can also determine

1. the kind of packaging for authorisation,
2. the suitability of the plant protection product for non-professional users, in particular taking into account the properties of the active substances, their suitability for dosing, dosage form and the size of the packaging or

3. the suitability of the plant protection product for use on areas in the context of Article 12 (3) p. 2 no.2 and Article 17 (1).

According to Article 36 (2) German Plant Protection Act, the BVL can, on application, determine that due to its properties, a plant protection product authorised for professional users may also be used by professional users for home gardening (according to Article 12 (3) p. 2 no. 2 German Plant Protection Act) if the plant protection product authorised for professional users only deviates from a plant protection product authorised for non-professional users due to its packaging size or dosage form. In this case, the BVL checks to see whether the professional user can apply the product under the conditions which were determined for use in home gardening. If this evaluation should conclude that the intended conditions of application for professional users are not comparable with the conditions which were determined for non-professional users in home gardening, no authorisation is granted for professional users in home gardening.

1.3 Labelling

According to Art. 65 (1) Regulation (EC) No 1107/2009 in conjunction with Art. 1 and Annex I (1) (u) Regulation (EU) No 547/2011 [4], the plant protection product label must state the user category. In addition, the fields and conditions of application determined by the competent authority according to Article 31 (2) p. 2 Plant Protection Act must be clearly visibly separate from the other details on the packaging.

According to Article 74 (12) Plant Protection Act, plant protection products which were labelled before 14 February 2012 for use in home gardening are authorised for non-professional users and may be placed on the market with this labelling up to 14 June 2015.

1.4 Home gardening

A plant protection product which is authorised for non-professional users may be used by non-professional users for home gardening according to Article 12 (3) sentence 2 no. 2 Plant Protection Act. In particular the properties of the active substances, their suitability for dosing, dosage form and the size of the packaging must be taken into consideration for the suitability of a plant protection product for non-professional users according to Article 36 (1) sentence 2 no. 2. Plant Protection Act. Furthermore, a product which is authorised only for professional users may only be used for home gardening by professional users according to Article 12 (3) p. 2 no. 2 Plant Protection Act if this has been decided by the BVL according to Article 36 (2) on application due to the properties of the plant protection product. The prerequisite is that the plant protection product authorised for professional users may only deviate from the plant protection product authorised for non-professional users due to its packaging size or dosage form.

A specific assessment of the use of plant protection products in home gardening, which can deviate from the assessment for professional users, is especially necessary for the following reasons:

- According to Article 9 (5) no. 1 Plant Protection Act, as a rule non-professional users do not have expert knowledge of plant protection nor of handling plant protection products. To assure the protection of humans, animals and the environment, the requirements for non-professional users differ from those for professional users, who are required to have a certificate of expert knowledge according to Article 9 Plant Protection Act.

- The fact that correct and intended applications by non-professional users cannot be monitored by the competent authorities to the extent professional users are monitored must be taken into consideration for the evaluation for authorisation. Therefore, care should be taken that only plant protection products are authorised for non-professional users, and conditions of application are granted, where it can be assumed that the conditions of application can be complied with under preexisting conditions in home gardening and that products can also be used according to good professional practice.
- Non-professional users can only be expected to wear limited protective equipment (gloves, long-sleeved shirt, long trousers, headgear, sturdy footwear such as rubber boots).
- Home gardening areas are mostly used intensively, and in particular by sensitive groups of persons (e.g. children, the elderly and the ill).
- Often, areas to be treated verge directly on neighbouring pieces of land / gardens or public paths and areas, so that as a rule, it is not possible to maintain larger buffer zones to these areas.

The plant protection products used in home gardening must therefore satisfy these requirements and conditions. The BVL combines authorisation with collateral provisions, in particular restrictions of use, which are tailored especially to the specific conditions of home gardening. For example, the definition of uses for spray applications specifies the use of handheld, portable equipment.

2 Requirements concerning the suitability of plant protection products for use by non-professional and professional users in home gardening

2.1 General Requirements

In view of the special conditions stated above, high demands must be made on the protection of human and animal health and the environment when using plant protection products in home gardening. Since it cannot be assumed that non-professional users have the necessary expert knowledge, the use of plant protection products which are particularly critical for health and the environment must especially be excluded to avoid hazardous handling with subsequently grave consequences for health and/or the environment. For the estimation of exposure, the specific conditions in home gardening must be observed and/or available data on this area of use taken into consideration (e.g. special basic drift values, smaller treated areas). Risk mitigation measures which deviate from those for professional use must therefore be taken into consideration, which non-professional users are able to comply with. Generally, plant protection products with a low risk for use in home gardening should preferably be used.

Plant protection products should therefore be authorised for non-professional users for use in home gardening

1. which carry a low risk in the context of Article 47 Regulation (EC) No 1107/2009, and
2. which furthermore fulfil the special demands specified for the areas of health, the environment, suitability for dosing, packaging size and dosage form or which fulfil these by determining suitable risk mitigation measures or
3. which show low toxicity (according to Art. 13 Directive 2009/128/EC).

Risk mitigation measures can, for example, include suitability for dosing, dosage form or packaging size.

A plant protection product carrying a low risk shall fulfil the following demands in the context of Art. 47 Regulation (EC) No 1107/2009:

- a. the low-risk active substances, safeners and synergists it contains were approved according to Chapter II Regulation (EC) No 1107/2009. An active substance with a low risk according to Article 22 Regulation (EC) No 1107/2009 in conjunction with point 5 of Annex II is not classified as carcinogenic¹, mutagenic², reproduction-toxic³, sensitizing⁴ (chemical substances), very toxic⁵ or toxic⁶, explosive⁷ or corrosive⁸. It is not hazardous to the endocrine system, has no immuno-toxic or neurotoxic impact; it is not persistent (half-life in soil < 60 days), nor is there any bioconcentration tendency (BCF <100).
- b. it does not contain any critical substances in the context of point 4 of Article 3 Regulation (EC) No 1107/2009. Regulation (EC) No 1107/2009 is to be applied correspondingly for judging whether a substance is critical. A substance means any substance in the formulation which is not declared as an active substance, safener and/or synergist. Substances which are not critical are those which
 - fulfil the same criteria as an active substance, safener and synergist must fulfil in order to be recognised as having a low risk or
 - do not fulfil the criteria for being of low risk but are contained in the plant protection product at a concentration which is below the cut-off value according to Art. 11 (3) Regulation (EC) No 1272/2008 [5]
- c. it is sufficiently effective;
- d. it causes no unnecessary suffering or pain to the controlled vertebrates;
- e. it corresponds to Article 29 (1) (b), (c) and (f) to (i) Regulation (EC) No 1107/2009.

Moreover, plant protection products which carry a low risk are products which do not require any special risk mitigation measures following a risk assessment.

Unnecessary plant protection product applications are to be avoided according to the general principles of integrated plant protection. Therefore, in view of the special conditions for home gardening (e.g. no expert knowledge), plant protection products which need to be applied without there being any visible pest infestation or weeds, are generally not authorised for non-professional users (e.g. herbicides which are intended for pre-emergence application on weeds). Unnecessary applications can also be avoided by generally not authorising combination products (e.g. insecticidal and fungicidal active substances as combined formulations).

Handling must also be safe for non-professional users. Therefore, plant protection products which do not permit the intended handling and dosage cannot be authorised. As a rule, ready-to-use plant protection products should generally be favoured.

¹ Carc. 1A or 1B, H350, H350i; Carc. 2, H351

² Muta. 1A or 1B, H340; Muta. 2, H341

³ Repr. 1A or 1B, H360F, H360D, H360FD, H360Fd, H360Df; Repr. 2, H361f, H361d, H361fd; Lact., H362

⁴ Resp. Sens. 1 or 1A or 1B, H334; Skin Sens. 1 or 1A or 1B, H317

⁵ Acute Tox. 1 or 2, H300; Asp. Tox. 1, H304; Acute Tox. 1 or 2, H310; Acute Tox. 1 or 2, H330

⁶ Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331

⁷ Unst. Expl., H200; Expl. 1.1 to 1.5, H201-H205

⁸ Skin Corr. 1A or 1B, H314

2.2 Special requirements concerning the properties of active substances and plant protection products in the field of “health”

For health reasons the following requirements apply for use in home gardening:

- a. Plant protection products which fulfil the criteria as being products which carry a low risk and are at present labelled with Xi (irritant) or Xn (harmful to health) according to Directive 67/548/EEC/EWG [6] or Directive 1999/45/EC [7], but which according to Regulation (EC) No 1272/2008 would normally be labelled in the future with the signal word “danger“, will only be authorised up to 31.05.2015 as products carrying a low risk.
- b. Plant protection products for which special measures can be stipulated (e.g. protective glasses are recommended for handling products which are irritating to eyes (Xi; R36)) can generally be authorised - if more than sturdy footwear, rubber boots, gloves, a long-sleeved shirt and long trousers, headgear or protective glasses are required, the product cannot be authorised.
- c. Plant protection products which are labelled as very toxic, toxic, corrosive or sensitizing (chemical active substances) can generally not be authorised - in individual cases, a plant protection product which is classified as sensitizing and therefore is not a plant protection product with a low risk can be authorised if, for example, contact with the undiluted product is negligible due to corresponding dosage forms, packaging and/or dosing systems when applied for the intended use, or the ready-to-use plant spray is diluted so that it is no longer considered sensitizing (content of the product or components relevant for classification in the plant spray < 1% w/w).
- d. If a plant protection product is to be used indoors, it must be assured that any contamination of the air indoors does not have a lasting effect.

2.3 Special requirements in the field of “environment”

Considerable disadvantageous effects on non-target organisms are considered as critical for applications in home gardening, even if these only occur for a limited period. Generally plant protection products which carry a low risk should be authorised for home gardening for the purpose of also protecting the environment. Since criteria have not been established in detail yet, the following specific requirements apply to the area of the environment for authorisations for use in home gardening:

- a. Plant protection products which are classified as hazardous to bees because they belong to categories B1 and B2 are generally not allowed to be authorised for use outdoors.
- b. Systemic products with insecticidal properties (including granules for spreading, products for watering and wiping applications, sticks etc) which are intended for use outdoors on flowering plants are not allowed to be used as long as harmful effects cannot be excluded when the flowers are visited by non-target organisms.
- c. Due to the danger of plant protection product entry into water, the use of plant protection products on paths and public places cannot be authorised.
- d. In general, uses which require additional risk mitigation restrictions to protect terrestrial organisms (including birds and mammals) cannot be authorised due to the strict requirements concerning the correct implementation of restrictions.

- e. Plant protection products with active substances for which the risk assessment shows that, haven taken into consideration the specific conditions of application for home gardening, there is a strong run-off tendency which would require mitigation measures, cannot be authorised for home gardening.
- f. Uses which require buffer zones to water greater than 10 m according to the risk assessment for the protection of aquatic organisms cannot be authorised for home gardening.

2.4 Special requirements concerning suitability for dosing

- a. For ready-to-use plant protection products which are easy to dose (e.g. granules for spreading) it must be assured that the required application rate can be calculated up to an accuracy of $\pm 10\%$ (e.g. using a measuring device, measuring spoon) and that the product is also applied correctly.
- b. For ready-to-use plant protection products for spraying and air-assisted spraying on crops which are not relevant as far as residues are concerned, the necessary application rate can be described as 'spray until visibly wetted' instead of being stated in metric units (e.g. in ml/m²). However, it is essential, in addition, to provide information on the quantitative application rate (e.g. ml/m² for plants up to 50 cm) which is to be taken into consideration for the assessment of efficacy and risk at the time of submitting the application.
- c. The application of ready-to-use plant protection products by spraying or air-assisted spraying (e.g. trigger spray bottles, aerosol cans) must be described comprehensibly in the instructions for use, ensuring that the application rate can be measured correctly and the product is used correctly.
- d. For plant protection products which are not ready to use (e.g. formulations as concentrates) a dosing accuracy of $\pm 10\%$ must be ensured when the particular spray, wiping or watering liquids are prepared for treatment. The dosing system must be designed so as not to endanger operators and other users and the environment when the product is prepared.

2.5 Special requirements concerning packaging size

- a. In order to be suitable for use in home gardening, the plant protection product must not exceed a maximum packaging size. The basis for calculating the maximum packaging size is:
 - the single treatment of an area of 500 m² in size and
 - the lowest application rate intended for a field of use.
- b. At least one packaging size for treating small areas must be available (≤ 100 m² for applications outdoors or ≤ 10 m² for applications in greenhouses or indoors). The maximum packaging size must generally not exceed the amount required for the single treatment of an area of 500 m².
- c. Additionally, the packaging size can be calculated individually if, for example, a calculation is not possible or appropriate for the area (e.g. aerosol can, plant protection sticks).

2.6 Special requirements concerning dosage form

Plant protection products can only be authorised for use in home gardening if the evaluation of the plant protection product shows that, according to current scientific and technical knowledge, it will cause no harmful effects when used correctly and for its intended purpose, or as a consequence of such, on human and animal health or groundwater nor any unacceptable effects on the environment.

Dosage forms / techniques which do not cause any or negligible exposure of users, third persons and non-target areas are particularly suitable for use by non-professional users in home gardening (e.g. ready-to-use products in trigger spray bottles, plant sticks, ready-to-use products for wiping or spreading).

3 Information to be provided when submitting an application

3.1 Requirements concerning plant protection products

The applicant must apply for the authorisation of a plant protection product for non-professional users and, if appropriate, for professional users as well, and provide special packaging sizes for non-professional users. (This information is generally requested and is a part of the authorisation certificate since it is necessary, particularly for parallel trade).

According to Article 36 (1) p. 2 no. 2 Plant Protection Act, the BVL determines the suitability of plant protection products for non-professional users.

According to Article 36 (2) Plant Protection Act, the BVL can decide, on application, that the use of a plant protection product which is authorised for professional users may also be applied by these users for home gardening if the plant protection product only differs from a product intended for non-professional use due to its packaging size or dosage form. This rule means that large packs are available for professional users which can also be used for home gardening.

Applications both for packaging for professional and for non-professional use can be included in the same application. Information must be provided for each packaging on whether it is intended for professional or for non-professional use.

3.2 Requirements concerning the plant protection product's uses

All applications for uses in home gardening, whether for non-professional or professional users, must be applied for explicitly. According to Article 36 (2) Plant Protection Act, the BVL can decide, on application, that a plant protection product which is authorised for professional users may also be used for home gardening; there are no special stipulations regarding packaging size.

As far as applications for zonal authorisations are concerned, the rules described here are binding as from the time they are published.

4 Data included in the authorisation certificate

4.1 Plant protection products

The authorisation certificate states all the admissible kinds of packaging.

If a plant protection product has been found to be suitable, according to Article 36 (1) p. 2 no. 2 Plant Protection Act, for non-professional users for home gardening, the following must be stated on the packaging which has been applied for non-professional users and which has been found to be suitable: *"Use authorised for non-professional users"*.

If a plant protection product has been found to be suitable, according to Article 36 (2) Plant Protection Act, the following standard sentence must appear in the authorisation certificate for all other packaging sizes for professional users in home gardening: "*Use authorised only for professional users*".

4.2 Use of the plant protection product

The uses for home gardening are referred to explicitly in enclosure 1 or 2 of the certificate.

5 Information on authorised plant protection products

According to Article 33 (4) Plant Protection Act, the BVL publishes a descriptive list of authorised plant protection products. The BVL offers an online database on its website with authorised plant protection products in which authorised plant protection products for non-professional users can be researched specifically.

<http://www.bvl.bund.de/psmdb>

6 Sources

[1] Regulation (EC) No 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing on the market of plant protection products and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309 of 24.11.2009, p. 1)

[2] Act on the reorganisation of plant protection legislation of 6 February 2012 (BGBl. I p. 148)

[3] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309 of 24.11.2009, p. 71)

[4] Commission Regulation (EC) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products (OJ L 155 of 11.06.2011, p. 176)

[5] Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 concerning the classification, labelling and packaging of substances and mixtures for amending and repealing Directive 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006 (OJ L 353 of 31.12.2008, p.1)

[6] Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances of 27 June 1967 (OJ L 196 p. 1) last amended by Directive 2009/2/EC (31st amending directive for the purpose of adaptation) (L 11/6)

[7] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 (OJ L 200 p. 1) concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, last amended by Regulation (EC) No 1272/2008 (OJ L 353/1)