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[Plant Protection](#)
[Harmful Organisms](#)
[Property Rights](#)
[Genetic Resources](#)
[Seeds and Plant Propagating Material](#)
[GM Plants & Seeds](#)

Plant Protection Products - Guidance documents

Guidance document agreed between the Commission services and the competent authorities of Member States for the biocidal products Directive 98/8/EC and for the plant protection products Directive 91/414/EEC on: Borderline between Directive 98/8/EC concerning the placing on the market of Biocidal product and Directive 91/414/EEC concerning the placing on the market of plant protection products

Introduction

The determination of clear borderlines between the Biocidal Products Directive 98/8/EC (BPD) (OJ L 123, 24.4.98. p. 1) and the Plant Protection Products Directive 91/414/EEC (PPPD) (OJ L 230, 18.8.91. p. 1), is identified as a crucial issue for a proper implementation of the Biocidal Products Directive as well as of the Plant Protection Products Directive. Many borderline cases of BPs and PPPs have been identified so far and there is a need to give practical guidance and examples. It is also essential to ensure transparency of the legislation, legal security for industry and other stakeholders and an effective internal market for the products. The present document has been elaborated on the basis of the discussion held in an expert group including experts from Member States' competent authorities for Biocidal Products, the European Commission, as well as industry trade associations. A questionnaire on borderline cases described below has been circulated to contact points for both Directives and the contributions received have been taken into account.

This document should attempt to provide guidance to Member States on borderline cases. It has been conceived as an opinion of the Commission Services involved, however it does not oblige in any way Member States to adopt the same attitude and it is not legally binding since only the Court of Justice can give an authoritative interpretation of existing Community law.

A proposal for amendments to the Biocidal Products Directive (notably to the description of Product types in Annex V) is under discussion and, if appropriate, amendments to the Plant Protection Products Directive could be foreseen to introduce in the legal text the agreed adjustments on scope.

For the relevant definitions and legal requirements reference is made to:

| | |
|-------------------------------------|--|
| Directive 98/8/EC | Directive 91/414/EEC |
| BPD | PPPD |
| Definition | Definition |
| Article 2.1(a) (Biocidal Product) | Article 2.1 (Plant Protection Product) |
| Article 2.1 (f) (Harmful organisms) | Article 2.6 (Plants) |
| - | Article 2.7 (Plants Products) |
| - | Article 2.8 (Harmful organisms) |

General principles

As a general rule a relevant product is regulated either by the BPD or by the PPPD, though there may be some significant exceptions. In these exceptions exactly the same physical product would fall within the scope of both Directive 98/8/EC and 91/414/EEC for the purpose of these Directives. This means that for this product dual authorisation will be needed. The authorisation procedure to be followed prior to placing a given product on the market will be governed in most cases either by the BPD or by the PPPD. Normally the procedures of both directives do not apply cumulatively. For defined features, however, some cross-references could be made within one regime to specific provisions of the other regime (see Article 20.4 (BPD)).

Definition

Some definitions from the Biocidal Product Directive and Plant Protection Product Directive are reproduced here for reference.

Biocidal Product (98/8/EC)

Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. An exhaustive list of 23 product types with an indicative set of descriptions within each type is given in Annex V.

Harmful organism (98/8/EC)

Any organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment.

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WTO
Import Conditions
Pets and Animal
Welfare
Enlargement
Agreements
EU - Russia: SPS issues



Plant Protection Product (91/414/EEC)

Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

- protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;
- influence the life processes of plants, other than as a nutrient, (e.g. growth regulators);
- preserve plant products, in so far as such substances or products are not subject to special Council of Commission provisions on preservatives;
- destroy undesired plants; or
- destroy parts of plants, check or prevent undesired growth of plants;

Plants (91/414/EEC)

Live plants and live parts of plants, including fresh fruit and seeds;

Plant products (91/414/EEC)

Products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves as defined above.

Harmful organism (91/414/EEC)

Pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens

Criteria for borderline setting

On the basis of the above definitions it is easy to decide in the vast majority of cases which Directive applies to a given product. But sometimes difficulties may arise. Therefore in order to decide which regime applies, the following criteria should be thoroughly examined, either together or alone:

Step 1 The intended purpose of the product with special reference to:

- **The target organism.** If it is detrimental to plant or plant products then the product used is considered as a PPP either if applied directly on plants or plants products or applied indirectly on empty structure to control pests of plant or plants products exclusively.

Products like pheromones or any other attractants and repellents that need to be applied before or during the pest attack shall be considered as PPPs if they are used against pests that can damage plant or plant products.

- On the other hand if it is detrimental in other field e.g. detrimental to humans or to products other than plants or plant products then the product used is considered as a BP.

Step 2 **The place where the product is applied to achieve the principal intended action.** As for the case e.g. of wood-preserved and rodenticides considered in more details below, the saw-mill stage (here it is intended that the wood has undergone more than just a simple preparation) and the plant growing areas (agricultural field, greenhouse, forest), in this second case in combination with the purpose to protect plants, are regarded as the most important factors for setting the borderline. Products applied to the soil before sowing or planting of plants and intended to destroy plant pests should be considered as plant protection products (e.g. soil fumigants).

Proposal for general and specific borderline

According to its definition, the main purpose of a Plant Protection Product is to protect plants and plant products against organisms **harmful to plants and plant products**. When these products are **directly** applied on plants and plant products it is clear that the purpose is according to the definition and therefore they are clearly Plant Protection Products. This applies in every place where these products are used, both inside and outside the farm, for example in stores of plant products.

The above applies also when they are applied **indirectly** since Directive 91/414/EEC does not make any distinction between direct or indirect application of products used to protect plants or plant products against harmful organisms. Therefore products for the treatment of empty structures and articles (for example for the disinfection or the disinfestation of empty store rooms or other structures and articles like greenhouses, growing houses, containers, boxes, sacks, barrels etc.) are considered PPPs on condition that the purpose of the use is to destroy exclusively and specifically organisms harmful to plants or plant products and that after the treatment only plants or plants products will be grown or stored in the treated structure.

In the cases where products are used for a general hygiene purpose (normally not directly applied to protect plants or plant products) or when it is not clear which kind of products will be stored after the treatment it is agreed to consider these products as biocidal products.

According to the definition of Plant Protection Products, herbicides are clearly within the scope of Directive 91/414/EEC, whereas for the specific case of algaecides, it is agreed to consider all these products as Biocidal Products with the exclusion of those clearly used to protect plants, as described below.

On the basis of the above consideration the following borderline is agreed:

Plant Protection Products: Products directly applied on plants (including in garden and house) and on plant products inside or outside the farm. Products applied indirectly (for example for the disinfection or the disinfestation of empty store rooms or other structures and articles like greenhouses, growing houses, containers, boxes, sacks, barrels etc.) provided that the purpose of the use is to destroy organisms exclusively and specifically harmful to plants or plant products and that after the treatment only plants or plants products will be grown or stored in the treated structures. These include arthropods

growth regulators, plants growth regulators and products for the inhibition of germination.

All herbicides regardless of whether they are applied to soil or other surfaces for agricultural and non-agricultural purposes are considered Plant Protection Products.

Examples:

1. Products used on soil for agricultural purposes (including soil fumigants)
2. Space disinfectants in growing houses (for mushrooms, used to kill unwanted spores) or greenhouses (for example to kill micro-organisms that can attack plants that will be subsequently grown there)
3. Products to control growth or penetration of plant roots and sprouts (radizides)
4. Products for use against garden snails
5. Products used to protect cultures of ornamental plants, for instance against ants
6. Products that are used in stores on plants or on plant products either against being devoured or against decay. Products for the disinfection or the disinfestation of empty store rooms or other structures and articles like greenhouses, growing houses, containers, boxes, sacks, barrels etc. provided that the purpose of the use is to destroy organisms harmful to plants or plant products and that after the treatment only plants or plant products will be grown or stored there.
7. Products for post-harvest treatment of fruits and vegetables against plant diseases
8. Repellents used to treat seed against birds and on fruit trees or forestry
9. Products to protect trees or other plants from damage by squirrels or wildlife
10. All herbicides regardless of whether they are applied to soil, water (river, stream, waterway etc.) or other surfaces (tennis court, concrete, pavement, car parks, railways, etc)
11. Algaecides applied on soil or water to protect plants (e.g. in paddy field rice, turf, golf course, glasshouse crops, to protect aquatic plants in aquaria, etc.)
12. Plant growth regulators and products for the inhibition of germination.
13. Arthropod growth regulators and other pheromones used to control organisms harmful to plants or plant products.
14. Products for the control of birds when used to protect plant or plant products.

Biocidal Products: All products used for a general biocidal purpose. These would include general hygiene disinfectants in empty structures when it is not clear which kind of products will be stored after the treatment. This excludes:

- Products used specifically and exclusively for the protection of plants or plant products either by direct application or by pretreatment of empty store rooms intended for plants/plant products ¹;
- Products used only to control unwanted plants and algaecides used to protect plants.

Applying the distinctions described above, the following are considered to be examples of biocidal products:

1. Products for hygiene purposes to be used in greenhouses (including on structures and articles like windows, equipment, table, knives etc.) but that are not intended for direct application to plants (PT2).
2. Products used in hydroponic systems, not on the plants, but on the system itself to control harmful organisms that for example can clog pipes (either PT2 or PT 11).
3. Products intended for the control of harmful organisms (other than unwanted plants) including algae, on surfaces like tennis courts, car parks, (PT2) and tombstones, concrete, pavements and walls (PT10)
4. Products used against snails to prevent humans and animals disease transmission, products used against snails that clog water pipes, as opposed to products used against snails that cause harm to plants. (PT16)
5. Products to destroy dust mites from textiles, as opposed to products used against mites that cause harm to plants. (PT18)
6. Fumigants used in storage rooms for food like cheese and meat (not for plant products) (PT20)
7. Repellents against cats, dogs and snakes, as opposed to repellents used against animals that cause harm to plants. (PT19)
- ~~8. Products added to water to wash fruits (for example chlorine wash) for public hygiene, not to protect the fruits against plant pathogens (PT1)~~
9. Products for the control of termites when used as a bait or as a soil-drench treatment, not used to protect plants or plant products. (PT 18)
10. Products for the control of birds for hygiene purposes (PT 15)

Product Type 8 (Wood preservatives). It is agreed that the description of this product type as it is in Annex V of Directive 98/8/EC stating "Products for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms" does not need any additional clarification.

Case of Product type 14 (Rodenticides)

The main purpose for the use of these products on plant products is considered to be for human hygiene rather than for the protection of plant products. In-fact rats and mice can contaminate with their excrements much greater quantity of plant products (with the consequent danger of transmission of diseases) compared with the quantity directly devoured. It is therefore agreed to consider all rodenticides as Biocidal Products with the exclusion of products used in plant growing

areas (agricultural field, greenhouse, forest) to protect plants, or to protect plant products temporarily stored in the plant growing areas. Considering that there could be a need to control the population of rodents in plant growing area not because they devour crops but because they multiply and can subsequently spread to human settlements, it is agreed that products used for this specific purpose are biocidal products.

Therefore the following borderline is agreed:

Biocidal Product 14 (Rodenticides): Products used for the control of mice, rats or other rodents outside plant growing areas (agricultural field, greenhouse, forest), for example in farms, cities, industrial premises etc, and inside plant growing areas not to protect plant or plant products ². Products for the control of squirrels (*Sciurus spp.*), when within the scope of Directive 98/8/EC, are excluded from this product type since they are included in PT 23 (Control of other vertebrate).

Plant Protection Products: Rodenticides applied in plant growing areas (agricultural field, greenhouse, forest) to protect plants or plant products temporarily stored in the plant growing areas in the open without using storage facilities.

If a product is used in both situations, than it falls within the scope of both Directive 98/8/EC and Directive 91/414/EEC for the purpose of these Directive and it will need dual authorisation for the relevant use.

¹ The case of rodenticides is an exception, and it is specifically addressed under the heading "Biocidal Product 14 (Rodenticides)" of this document.

² E. g. to control rats that can spread to human settlements or rodents that can dig holes in dams.