

25 - Plant protection products and biocides

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Abstract

Today we have two directives and some amendments that regulate use of pesticides in most European countries. Directive 91/414 regulates placing of plant protection products (PPP) on the market whereas Directive 98/8 regulates placing of biocidal products (BP) on the market. Evaluation process for the registration is in most parts similar because it takes into account same parameters (efficacy, toxicity, ecotoxicity). Due to the same active ingredients that are used overlapping arise within the group of insecticides, acaricides, rodenticides and avicides.

Introduction

Storehouses with/for agricultural products are treated with the same a.i. as storehouses with/for stored food or feed. These products are registered according to different directives and in many countries under responsibility of different ministries (agriculture and health).

The application of the different regulations is particularly difficult, because the same pest rodent, insect, mite... cause damage on agricultural products as well as on food or feed (also under responsibility of different ministries in some situations) and "move" among different legal areas like biocidal law, plant protection law and public health regulations.

According to the mentioned it will be important to take an initiative to integrate biocidal, plant protection and public health regulations to strengthen pest control.

Plant protection products and biocides: Plant protection products and biocides are placed on the market according to two directives and amendments in most European countries. Directive (91/414/EEC) concerning plant protection products was published on 19 August 1991 (OJ L 230). It came into force on 26 July 1993.

The main elements of the Directive are as follows:

- (a) To harmonise the overall arrangements for authorisation of plant protection products within the European Community (EC) by harmonising the process for considering the safety of active substances by establishing agreed criteria whereas product authorisation remains the responsibility of each Member State.
- (b) The establishment of a positive list of active substances (Annex I), that have been found without unacceptable risk to people or the environment.
- (c) Member States can only authorise the marketing and use of plant protection products after an active substance is listed in Annex I. Exception are transitional arrangements.

The Directive consists of six Annexes. Set out are common rules and guidance on data requirements, data evaluation, risk assessment; the transition from a national to the EC authorisation system, the protection of commercial information (data protection); and public access to information on pesticides.

- Annex I - the 'positive' list of active substances that are authorised for use in plant protection products within the Community.
- Annex II - a comprehensive list of the tests and studies required for an active substance to support its inclusion in Annex I.
- Annex III - a comprehensive list of the tests and studies required on the plant protection product active substance either to support an application for product authorisation following inclusion of the active substance in Annex I or required for at least one representative product to support the inclusion of an active substance in Annex I.
- Annex IV and Annex V - provide for additional specific phrases for special risks and safety precautions for plant protection products.
- Annex VI - lays out the "Uniform Principles" which are the harmonised criteria for evaluating products at a national level. Application of the Uniform Principles ensures that authorisations issued in all Member States are assessed to the same standards.

The Directive also allows mutual recognition. This allows Member State to authorise the product without the submission of further data if the product was authorised in the original Member State in accordance with Uniform Principles. Comparability in terms of climate, soil, cultural methods, and that the Member State that has already authorised the product has implemented the Annex I decision, must be demonstrated. If the product is different, for

example in use or formulation, then further data on safety and/or efficacy will be required before an authorisation can be granted.

Here are plant protection products discussed only in the scope of stores and plant products: Directive 98/8/EC of the European Parliament and of the Council on the placing on the market of biocidal products was adopted in 1998. The Biocidal Product Directive aims to harmonise the European market for biocidal products and their active substances.

This Directive concerns:

- The authorisation and the placing on the market for use of biocidal products within the Member States;
- The mutual recognition of authorisations within the Community;
- The establishment at Community level of a positive list of active substances which may be used in biocidal products. Active substances have to be assessed and the decision on their inclusion into Annex I of the Directive shall be taken at Community level. Inclusion to Annex I may be denied if there are less harmful, suitable substitutes available for the same purpose. The biocidal products should be authorised in accordance with the rules and procedures set in Annex VI of the Directive.

There are:

- Annex I - List of active substances with requirements agreed at community level for inclusion in biocidal products
- Annex IA - List of active substances with requirements agreed at community level for inclusion in low-risk biocidal products
- Annex IB - List of basic substances with requirements agreed at community level
- Annex II - Common core data set for biocidal products
- Annex III - Additional data set for active substances
- Annex IV - Data set for active substances
- Annex V - Biocidal product-types and their descriptions are presented in an exhaustive list of 23 biocidal product types.
- Annex VI - Common principles for the evaluation of dossiers for biocidal products

The available knowledge and control of biocidal products has been significantly improved across the EU, and particularly in those Member States that did not have any existing systems, or where only a part of all 23 groups of biocides was covered. As a direct result of identifying and starting to evaluate the biocides that were on the EU market, a number of obsolete products have been removed.

Equal but different: Due to similarities and possible overlapping there is a 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. Explanations are presented in "Manual of decisions for implementation of directive 98/8/EC concerning the placing on the market of biocidal products". The Manual is updated from time to time with new information whereas last modification was in July 2008.

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 Directives 98/8/EC and 91/414/EEC for the purpose of these Directives. This means that for this product dual authorisation will be needed. Good example is *i. deltamethrin* registered under both Directives for control of same insect species (e.g. *Tribolium* spp. and *Plodia interpunctella* are pests treated with PPP or BP in different stores on different commodities). 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.

Products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants are treated with PPP. 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 pest 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.

Proposal for general and specific borderline: Products for the treatment of empty structures and articles are considered PPPs on condition that the purpose of the use is to destroy exclusively and specifically organisms harmful to plant products and that after the treatment only plants products will be stored in the treated structure.

In the cases where products are used for a general hygiene purpose 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.

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

- 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.

The following are considered to be examples of biocidal products:

- Products to destroy dust mites from textiles, as opposed to products used against mites that cause harm to plants.
- Fumigants used in storage rooms for food like cheese and meat.
- Products for the control of termites when used as bait or as a soil-drench treatment.
- Products for the control of birds for hygiene purposes.
- 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.
- Rodenticides are considered as biocidal products if used for the control of mice, rats or other rodents in farms, cities, industrial premises etc, and inside plant growing areas not to protect plant or plant products.
- Rodenticides are considered as plant protection products if 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 Directives and it will need dual authorisation for the relevant use.

Explanations on border lines: Question: A company uses a product to treat empty storage areas for plant products such as grain and flour. This product is within the scope of the Plant Protection Products Directive. The same or other products are used against cockroaches in storage areas where flour is stored to be used in bread production.

Answer (agreed in June 2003): According to the Guidance Document on the borderline between biocides and plant protection products, products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants. If the target organism 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 structures to control pests of plant or plants products exclusively. Products used for a general biocidal purpose are biocides. These would include general hygiene disinfectants in empty structures when it is not clear which kind of products will be stored after the treatment. Flour produced at a mill from grain is a plant product having undergone a simple preparation such as milling etc. However, additional steps, such as transport to another food production site, go beyond simple processing. Therefore, products used to treat storage areas in mills or other installations of 'simple processing' are plant protection products, whereas products used to treat storage areas in installations of more advanced food processing are biocides. If such a product is an insecticide it is placed in Product Type 18, if it is a repellent than it is Product Type 19.

Question: A fumigant is used for treatment of mills and pasta factories (both processing and storage areas) which are located directly adjacent to the mills. The factory and the mill will be fumigated at the same time. Is the fumigant to be authorised as PPP or biocide?

Answer (agreed in June 2003): The fumigants used anywhere in the mill would have to be authorised as PPP. This, however, does not seem to hold for the pasta factory. Here the processing step is more advanced and fumigants used in the pasta factory are then biocides. Therefore, strictly speaking, the same fumigant has to be authorised both as a PPP and as a biocide. However, if indeed the pasta factories are situated directly adjacent to the mills and are treated at the same time with the same product, Member States could in a pragmatic approach also decide to authorise the product for both uses as PPP.

Conclusion

There are equivalences as well as differences between regulations regarding plant protection products and biocides. The same pest species, rodent, insect, mite... is detrimental to plant products as well as on food or feed. Due to this narrow border line between these two groups and in unclear situations the need is for clear explanations like in "Guidance manual".

The application of the different regulations is particularly difficult due to responsibility of different ministries in some countries and that pests "move" among different legal areas like biocidal law, plant protection law and public health regulations.

According to the mentioned it will be important to take an initiative to integrate biocidal, plant protection and public health regulations to strengthen pest control and make providing easier.

Literature

Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC)

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market

Manual of decisions for implementation of Directive 98/8/EC concerning the placing on the market of biocidal products - 2008

26 - Latest developments in the registration of SPP chemicals in Germany and Europe

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Abstract

Regulation of the European Parliament and of the Council (EC) No 396/2005 of 23 February 2005 on maximum residue levels of pesticides in and on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. The review process of active substances under Directive 91/414/EEC led to a rapid decline in the number of available existing active substances on EU level. New active substances to protect stored products are missing. Consequently the number of available storage insecticides is reduced even more. The aim of Regulation 396/2005 is to harmonise the maximum residue levels (MRLs) on EU level to eliminate barriers to trade and to increase the transparency of the market. A reduction of MRLs and as a result the reduction of the number of available active substances is possible. Subsequently the number of gaps and resistance problems will increase. In the consequence all persons involved, including farmers, industry, government and administration, research and trade are requested to spare no effort to reach a long-term and effective store protection, which is save to users and consumers as well as the environment. The influence of the new Regulation on placing plant protection products on the market will depend on its arrangements on EU and national level.

Introduction

Referring to actual estimations about 20 to 25 % of the crops are damaged by stored product pests worldwide. The main management techniques in the protection of stored products are:

- hygiene,
- air circulation/ventilation and
- chemical treatment.

Due to different conditions during storage and infestation pressure, precautionary measures are often insufficient to protect the stored products. The infested stored products have to be treated, not only to ensure the necessary quality (nil tolerance) and quantity, but also because of health precautions. In many cases no alternatives to chemical treatment exist. At EU level two legislative regulations have an important impact on the availability of plant protection products:

- Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.
- Regulation of the European Parliament and of the Council (EC) No 396/2005 of 23 February 2005 on maximum residue levels of pesticides in and on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.
- EU evaluation program for active substances under Council Directive 91/414/EEC.

Current situation regarding the evaluation of existing active substances. Table 1 shows the current situation regarding the evaluation of existing active substances.

Tab. 1 Current situation regarding the evaluation of existing active substances				
Stage	No. active substances	Inclusion in Annex I	Non-inclusion or withdrawal	Not yet decided
Stage 1	90	55	35	0
Stage 2	148	32	116	0
Stage 3	387	62	319	6
Stage 4	316	62	252*	2
Total	941	211	722**	8

*It was decided that 25 active substances from the original stage 4 do not fall under the scope of Directive 91/414/EEC. They were withdrawn from Reg. 2229/2004. **64 non-inclusions of active substances due to voluntary withdrawal (3rd stage: 49; 4th stage: 15). Authorised PPP can remain on the market. Possibly re-submission according to Reg. 33/2008.