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EUROPE'S BIOCIDAL PRODUCTS DIRECTIVE: BENEFITS AND COSTS IN URBAN PEST MANAGEMENT

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Abstract The European Commission's Biocidal Products Directive, Council Directive 98/8 EC (BPD), is the largest regulatory exercise ever to affect the urban pest control industry. Its impact is global because any company selling pest control products in the European Union must follow its principles. All active substances come within the Directive's scope of regulatory control, and involve re-registration of existing and new products. Substances, such as the rodenticides and insecticides, are already regulated but others, such as embalming fluids, masonry preservatives, disinfectants, repellents and attractants will be regulated for the first time. One of the purposes of the Directive is to offer enhanced protection for human health and the environment. The potential benefit for suppliers of pest control products is mutual recognition of regulatory product dossiers across 25 Member States of the European Union. This process, requiring harmonisation of all regulatory decision-making processes, should reduce duplicated effort and, potentially, allow manufacturers speedier access to European markets. An understanding of the BPD is essential to those who intend to place urban pest control products on the European market and may be useful to those considering the harmonisation of regulatory processes elsewhere. This paper reviews the operation of the first stages of the BPD for rodenticides, examines the potential benefits and costs of the legislation to the urban pest control industry, and looks forward to the next stages of implementation involving all insecticides used in urban pest management.
Key Words Rodenticides, insecticides, anticoagulants, BPD, 98/8/EC

INTRODUCTION

Directive 98/8/EC of the European Parliament and of the Council (European Community, 1998), which has come to be called the Biocidal Products Directive (the BPD), came into European Law on 14th May 1998. Before that time the regulation of biocidal products in the European Union (EU) was a complex amalgam of several pre-existing EU Directives and much disparate Member State legislation. Countries, such as Belgium, Denmark, Netherlands, Sweden and United Kingdom already had systematic controls over certain types of biocidal products, while in Germany and France authorisation has not been required for many products and their uses. The operation of the BPD has become the largest and most complex single regulatory initiative ever to affect the global market for public health pesticides. It serves as a useful and timely model for the global harmonisation of the regulatory control of all pesticides. The BPD has already had an impact on companies and markets and will continue to do so for many years.

The main purpose of the BPD was to establish common principles of authorisation for the sale and supply of biocidal products in each EU Member State, while the active substances used in those products are assessed at European Commission level by the appointment of a Rapporteur Member State for each substance submitted.

The principles of the BPD are the delivery of high standards of protection for humans, animals and the environment and this is done by the establishment of positive lists, primarily Annexes 1, 1A and 1B of the Directive, of approved active substances which are considered to present no unacceptable risks in use. Subsidiary aims are: to reduce barriers to trade within the EU by the harmonisation of assessment criteria and the introduction of the mutual authorisation of products among Member States; reduction of work duplication among regulatory authorities and biocide producers; minimisation of animal testing by the promotion of data-sharing; prevention of unacceptable effects on target animals such as, in vertebrates, any unnecessary suffering and pain, and the development of resistance or other unacceptable tolerance. These are ideals which are supported and shared by all those concerned with placing biocidal products on the market.

The implementation of the BPD is entirely within the states of the European Union, although some states outside the EU, such as Norway, Iceland and Switzerland, are also involved to a degree in the harmonisation and review process. The scope is growing rapidly as the 15 Member States that comprised the EU at the inception of the BPD in 1998 are now 25; and a further four 'candidate countries' will join in the coming years. The sale and use of public health pest control products in the largest single market in the world is now regulated by the BPD. However, the impact of the legislation is not restricted to the EU. All public health products imported into the EU from countries outside it must be registered according to its standards and regulations and, therefore, the impact of the BPD is truly global. This impact is all the greater because the standards set by the BPD are so high. It used to be the case that the global regulatory benchmark for a public health product registration was US Environmental Protection Agency's Federal Insecticide, Fungicide and Rodenticide Act. Now, the costs of studies for the BPD are higher (see Annexes II-IV in the Directive) and compliance standards are more rigorously implemented (Knight and Cooke, 2002). The BPD has set new regulatory standards for public health products, and the cost of the process is only now being met, in terms of new study requirements and staff resources, by manufacturers and users of these products.

The BPD has been in EU law for more than 7 years and two groups of products, Product Type 8 (Wood Preservatives) and Product Type 14 (Rodenticides) (Table 1), have entered their period of evaluation in the implementation of the first list of compounds for review (European Community, 2000). Across the Industry there is now a great deal of experience in the working of the BPD. It is timely to review the operation of the BPD with respect to the rodenticide compounds and to try to assess the potential impact of the Directive on other product types that are entering the review stage, particularly insecticides.

BIOCIDAL PRODUCTS

The term biocide applies to a wide range of active substances. This diversity is one of the most important and difficult challenges facing the Commission and Member States in implementing the BPD. A conventional biocide is one where a single chemical compound is used as the active substance. However, biocidal products may contain mixtures of active substances, and this is often the case particularly with insecticides. Active substances may also be microorganisms or extracts or fermentation products of them, or plant extracts. Biocides are intended to destroy, render harmless, prevent the action of or otherwise exert a controlling effect on any harmful organism. A total of 23 Product Types have been identified (Table 1). The diversity includes wood preservatives, public health rodenticides and insecticides, which have been widely regulated for many years. For these, the BPD represented a challenge that comprised changes to the framework of reporting, summarising and presentation of studies that make up active substance and product dossiers. For some of the other Product Types, such as repellents, attractants, some preservatives, and most disinfectants, the BPD constitutes the first attempt to bring active substances and their products under regulatory control.

Many rodenticides are used to protect growing plants and to protect the health and well-being of humans and animals. There was a possibility that a single active substance might fall within the scope of both the BPD and the Plant Protection Product Directive (91/414/EEC) (European Community, 1991). After Industry representations to the Commission that the majority of rodenticide use was for the protection human and animal health and well-being, it was agreed that all rodenticides be considered 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. The operating characteristics of the BPD are largely similar to those set out for the previously enacted Plant Protection Products Directive, 91/414/EEC.

OPERATION OF THE BIOCIDAL PRODUCTS DIRECTIVE

Existing and New Active substances

Products regulated under the BPD are either existing active substances, i.e. those on the market before the implementation of the Directive on 14th May 1998, or new active substances, i.e. those submitted for registration after that date. The situation with new active substances is a relatively straightforward one. Prospective registrants must submit a dossier for consideration by the European Commission which satisfies all of the required data points as set out in the Directive (Annexes II-IV). The process for review of existing active substances is complex and is described in the First Review Regulation (European Commission, 2000). This review, which is to be completed for all biocidal products within 10 years (May 2010), involves identification, notification, completeness check, submission and evaluation of a full study dossier, and listing on Annex I of the Directive. When these stages are completed the formulated products can begin to be registered for sale in Member States.

The main implementing agency of the BPD on behalf of the Commission is the European Chemicals Bureau (ECB). Also, appropriate organisations, the Competent Authorities, were identified in each Member State to lead agencies on matters relating to the BPD. Guidance documents for those entering the review process and for competent authorities were provided by the ECB.

Identification and Notification

The first stage of review was the submission of limited commercial, technical and regulatory data in order to identify existing active substances to the Commission. The dead-line for the submission of this information was 28 March 2002. The regulation also specified a phase-out time-table for active substances that were not identified by that date and for any products based on them. A list of identified existing active substances, submitted either by manufacturers or by Member States, was published as Annex I to the Second Review Regulation (European Community, 2003). The list contains about 30 active substances that might be useful for rodent control.

Simultaneous with the process of identification, and with the same dead-line of 28 March 2002, chemical producers were required to supply a set of data, including those used in identification, and summaries of end-points of a physico-chemical, toxicological and environmental EU base-set. Notifying companies were required to give an assurance that a complete dossier of compliant studies, fulfilling all data-points set out in the Directive, would be submitted for full review at a later time and were thereby permitted to continue to market the notified active substances until such time as a full review was conducted by the Commission. Compliant studies are those conducted within the principles of Good Laboratory Practice (European Community, 1987) and to approved methods, such as those of the European Union and the Organization for Economic Co-operation and Development (OECD).

A total of 17 active substances in Product Type 14 were listed in Annex II of the review regulation, considered by the Commission to have satisfied the identification and notification procedures. These rodenticides entered the review programme in November 2003 (Table 2). Among these compounds, five are first-generation anticoagulants: warfarin and diphacinone, chlorophacinone and coumatetralyl, and five are second-generation anticoagulants: bromadiolone, difenacoum, brodifacoum, flocoumafen, and difethialone. Carbon dioxide and aluminium phosphide are gasses used for rodent control. Bromethalin and trizinc diphosphide (zinc phosphide) are acute rodenticides used in some European countries for rat and mouse control, and chloralose (alphachloralose), is also an acute rodenticide and used mainly indoors for control of house mice. Trimagnesium diphosphide is a fumigant, also used in wood preservation, insect control, and for the control of vertebrates, and powdered corn cob is used in pelleted formulations for control of rats and mice (Buckle, 1994).

Absent from this list were the calciferols. One of these compounds, ergocalciferol, used mainly in Europe for the control of house mice, has been the subject of research into alternatives to anticoagulants for the management of anticoagulant-resistant Norway rats (Quy et al., 1995). Other active substances that also did not enter the review programme comprised a further 12 rodenticide compounds, including strychnine, coumachlor, scillirocide, crimidine, fluoroacetamide and norbormide. Presumably, the manufacturers of these identified compounds had insufficient compliant data to satisfy the requirements for the notification criteria. Member States are required to remove products containing these active substances from the market beyond 1 September 2006.

Review

The Second Review Regulation also set out a time-scale for the review of active substances by publishing what are known as review lists 1 and 2. List 1 required the submission of full study dossiers for Product Types 8 (Wood Preservatives) and 14 (Rodenticides) by 28 March 2004. These two product types were chosen by the Commission to be considered at the start of the review process because they belonged to categories of biocides that were thought already to have extensive data sets available from previous national authorisation schemes. In the case of rodenticides, this proved to be true for a number of the modern compounds, particularly the anticoagulants, but was certainly not the case for the older, mainly acute compounds, the majority of which have fallen out of the review process and will leave the market in the coming years. The second review list further required the submission of full dossiers for Product Types 16, 18, 19 and 21 no later than 30 April 2006. The next years will be as busy as the last for those involved in the registration of public health pesticides, both in industry and in government regulatory agencies, because this list includes the insecticides used as biocides. Full dossiers are required for Product Types 1-6 and 13 by 31 July 2007 and for Product Types 7, 9-12, 15, 17, 20, 22 and 23 by 31 October 2008.

A total of 17 rodenticides entered the review process and, in some cases, several manufacturers, known as participants, submitted dossiers for the same active substance. Rapporteur Member States had three months in which to review the completeness of the submitted dossier from each participant. This was extended to six months where Rapporteur Member States needed to consult with other competent authorities, as was usually the case. Participants are currently listed on the ECB web-site (European Chemicals Bureau, 2005) for only 13 of the 17 rodenticide active substances in the review (Table 3). Therefore we must assume that a further four active substances failed at the completeness check stage. These are the first generation anticoagulant diphacinone, trizinc diphosphide, trimagnesium diphosphide and bromethalin. We must await the outcome of the reviews, to be confirmed in September 2006, to see which of the remaining active substances satisfy the requirements of their Rapporteur Member States and the Commission to achieve listing on Annex I of the Directive. When this has been achieved, manufacturers are able to submit dossiers for registration of formulated products. Only manufacturers who hold an Annex I listing for an active ingredient, or who have obtained a Letter of Access from a company which owns a full dossier that has resulted in an Annex I listing, can apply for authorisation of a formulated product.

Table 1. Products defined as biocides under the BPD (from Knight and Cooke, 2002).

Main Group 1	**Main Group 3**
Disinfectants and general biocides	Pest control
Product types:	Product types:
1. Human hygiene products	14. Rodenticides
2. Private and public health are disinfectants	15. Avicides
3. Veterinary hygiene biocides	16. Molluscicides
4. Food and feed areas disinfectants	17. Piscicides
5. Drinking water disinfectants	18. Insecticides, acaricides and products to control other arthropods
	19. Repellents and attractants
Main Group 2	**Main Group 4**
Preservatives	Other biocides
Product types:	Product types:
6. In-can preservatives	20. Preservatives for food and feedstocks
7. Film preservatives	21. Antifouling products
8. Wood preservatives	22. Embalming and taxidermist fluids
9. Fibre, leather, and polymerised materials preservatives	23. Control of vertebrates
10. Masonry preservatives	
11. Preservatives for liquid cooling systems and processing	
12. Slimicides	
13. Metal-working fluid preservatives	

Table 2. Product Type 14, rodenticide, active substances considered to have entered the BPD review stage (from European Commission, 2003) and the Rapporteur Member States responsible for their review.

Name	EC Number	CAS Number	Rapporteur Member State
warfarin	201-377-6	81-81-2	Ireland
diphacinone	201-434-3	82-66-6	Belgium
warfarin sodium	204-929-4	129-06-6	Ireland
carbon dioxide	204-696-9	124-38-9	Portugal
trizinc diphosphide	215-244-5	1314-84-7	Austria
chlorophacinone	223-003-0	3691-35-8	Spain
coumatetralyl	227-424-0	5836-29-3	Denmark
trimagnesium diphosphide	235-023-7	12057-74-8	Germany
choralose	240-016-7	15879-93-3	Portugal
aluminium phosphide	244-088-0	20859-73-8	Germany
bromadiolone	249-205-9	28772-56-7	Sweden
difenacoum	259-978-4	56073-07-5	Finland
brodifacoum	259-980-5	56073-10-0	Italy
powdered corn cob	310-127-6	999999-99-4	Greece
flocoumafen	421-960-0	90035-08-8	Netherlands
bromethalin	Plant Protection Product	63333-35-7	Austria
difethialone	Plant Protection Product	104653-34-1	Norway

Registration of Formulated Products

Authorisation of formulated products, or preparations, containing biocidal active substances is to be carried out at the Member State level. When an active substance has an Annex I listing, an applicant for authorisation may choose a Member State to whom to submit a dossier on the formulated product. This Lead Member State must then evaluate the dossier and make a decision about authorisation within a reasonable time. Having successfully authorised a product in one Member State a manufacturer may then submit the dossier to other Member States and may anticipate authorisation within 120 days, under the process of mutual recognition. A Member State may only reject authorisation by mutual recognition if: (1) the target pest does not exist in the country, (2) where unacceptable levels of resistance exist to the active substance, or (3) if other circumstances, e.g. climate, are substantially different to the Lead country. A process for the resolution of disputes is available.

Table 3. Rodenticides with Complete Dossiers currently undergoing review (adapted from Rudd, 2005)

Name	Rapporteur Member State	Number of Participants*†	Number of Participants with Complete Dossiers
warfarin	Ireland	3	1
warfarin sodium	Ireland	4	1
carbon dioxide	Portugal	2	2
chlorophacinone	Spain	1	1
coumatetralyl	Denmark	1	1
choralose	Portugal	2	1
aluminium phosphide	Germany	2	2
bromadiolone	Sweden	2	2
difenacoum	Finland	2	1
brodifacoum	Italy	1	1
powdered corn cob	Greece	1	1
flocoumafen	Netherlands	1	1
difethialone	Norway	1	1

* from European Chemicals Bureau (2005).
† Several participants may form a Task Force which results in only one complete dossier.

AFFECTS ON THE PUBLIC HEALTH PEST CONTROL INDUSTRY

The BPD will continue to exert affects on public health pest control, both in Europe and world-wide. One of the most obvious impacts is the cost to the industry. Knight and Cooke (2002) summarised an exercise conducted by the UK Health and Safety Executive (UK Competent Authority) which examined the cost to the Industry of achieving product registrations under the BPD. It was estimated that, on average, each active substance reviewed under the BPD will require expenditure (combined cost of studies and resources of regulatory affairs personnel) of EUR 2.74 million. This calculation made allowance for a number of active substances having the majority of studies that were already available and considered compliant. The total cost of implementation of the BPD regarding active substances was estimated to be EUR 534 million. An estimated 800 formulated products, and this appears to be a conservative estimate, will be registered containing these active substances at an average cost of EUR 113,000 per product, resulting in an additional expenditure of EUR 90 million. These are not the only costs of the review programme. The Directive sets out the requirement that the costs of the review in Member State competent authorities should be fully recovered from those seeking to place biocidal products on the market. These costs are recovered via fees paid by each applicant and are expected to be in the range of EUR 5-30,000. There is an additional mechanism whereby each Member State who is mandated to peer review the decisions of the Rapporteur Member State charge the applicant for that review.

The biocides industry involves the use of a large number of active substances, but the value of the sales of many of these is small in terms relative to say an active substance used in the agrochemical industry. It remains to be seen whether commercial imperatives permit public health business managers to commit large sums of money, and the resources of their regulatory affairs departments, to products of low commercial value.

Where decisions are made to progress active substances through this costly review process there will most likely be a requirement to recoup some of this expenditure through increased costs of products to users. It is certain that these commercial decisions will lead to the loss from the market of many active substances. About 30 compounds, capable of use as rodenticides, were listed as existing active substances in Annex I of the First Review Regulation (European Community, 2000). These were reduced to only 17 compounds after the process of identification and notification because insufficient compliant data was available to support them. Although their manufacturers thereby made a commitment to submit full dossiers, only 13 of these 17 substances now remain in the review process and it is not yet certain that all of these will achieve Annex I listing. It is noteworthy that all five second-generation anticoagulants are among the compounds remaining in the review. This is probably because their dossiers are the most modern, requiring the least expenditure to bring up to fully compliant status, and the companies supporting them have considerable experience of contemporary regulatory processes. Nine of the remaining 13 compounds are anticoagulants. The only non-anticoagulants remaining for use in rodenticide bait products are chloralose, mostly used in mouse control, and powdered corn cob. Neither of these products is widely used in the current practice of rat control in Europe. The lack of established alternatives to anticoagulants may pose a future threat to effective rodent control if anticoagulant resistance becomes more extensive.

Benefits of the BPD are not yet apparent. It is not possible to say if any of the active substances that have been removed from the review posed any significant risk, either to human health or the environment, because risk assessments on them were not carried out. It seems likely that any use of these compounds will be replaced by the use of other active substances. What can be said is that any product that remains on the market would have been tested to a rigorous standard and their risks assessed. The main potential benefit to the Industry is the application of harmonised testing and assessment standards. Mutual recognition, if implemented by Member States as intended by the Commission, will mean that registrations can be obtained quickly and efficiently in many European countries. It remains to be seen if Member States are prepared to relinquish their particular requirements.

Experience with the operation of the BPD in respect of rodenticides indicates the likely effects of the similar forthcoming reviews of insecticides used in public health. It goes without saying that substantial resources will be required from all companies who wish to obtain an Annex I listing for an active substance. Many of the compounds in the review are old, with dossiers containing many missing or non-compliant studies. Undoubtedly, many of these compounds will eventually be removed from the market and the impact of this on the effective control of insect pests of importance in public health will depend on the ability of the newer compounds adequately to replace those that are lost. The situation with insecticides is different to that of the rodenticides, however, because no one mode of action is completely dominant in the marketplace as is the case with the anticoagulant rodenticides. Experience with the operation of the BPD also provides a useful and timely model for the OECD-led global harmonisation of the regulatory control of all pesticides.

REFERENCES CITED

Buckle, A.P., 1994. Control Methods: Chemical. In, Buckle A. P. and R.H. Smith (eds.). Rodent Pests and their Control.1st ed. Wallingford, Oxon, UK: CAB International

European Community, 1987. Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of the laws, regulations, and administrative provisions relating to the principles of GLP and the verification of their application for tests on chemical substances. Official Journal of the European Communities L 15.

European Chemicals Bureau, 2005. Biocides - List of Participants. Accessed 10 March 2005.

European Community, 1991. Council Directive of 15 July 1991 concerning the placing of plant protection products on the market 91/414/EEC. Official Journal of the European Communities L 230

European Community, 1998. Directive 98/8/EC of the European Parliament and of the Commission of 16 February 1998 concerning the placing of biocidal products on the market. Official Journal of the European Communities L 123/1

European Community, 2000. Commission Regulation (EC) No. 189/2000 of 7 September 2000. The First Review Regulation. Official Journal of the European Communities L 228/6

European Community, 2003. Commission Regulation (EC) No. 2032/2003 of 4 November 2003. The Second Review Regulation. Official Journal of the European Communities L 301/7

Knight, D.J. and Cooke, M., 2002. Regulatory control of biocides in Europe. In: Knight D. J., Cooke M., editors. The Biocides Business: Regulation, Safety and Applications. Weinheim: Wiley-VCH Verlag GmbH. p 45-74.

Quy, R.J., Cowan, D.P., Prescott, C.V., Gill, E.J., Kerins, G.M., Dunsford, G., Jones, A. and MacNicoll, A.D. 1995. Control of a population of Norway rats resistant to anticoagulant rodenticides. Pesticide Science 45:247-256.

Rudd, S. 2005. Industry New - The Biocidal Products Directive finally begins to affect the industry. Pest Control News (February, 2005): 6-7.