

## **PROSPECTS FOR URBAN PEST MANAGEMENT IN EUROPE UNDER THE BIOCIDAL PRODUCT DIRECTIVE 98/8/EC**

**ANDY J. ADAMS**

Bayer Environmental Science, 16 rue Jean-Marie Leclair, 69266 Lyon Cedex 09, France.

**Abstract** The Biocidal Products Directive (98/8/EC), or BPD, is a recent piece of pan-European legislation that has been incorporated into the national law of each member state. It will regulate all biocidal products that are not covered by earlier legislation that deals with crop protection products (91/414/EC). The objective of the BPD is to foster free trade, within Europe, of effective biocidal products that do not pose a significant risk to human health, non-target animals or the environment. However, it imposes a heavy cost burden on the manufacturers of a wide range of what are essentially niche market products, due to the standards required in the updated registration dossiers. Implementation of the BPD may result in many active substances, and their associated products, being withdrawn from the market. More than half the chemicals that were covered by the legislation will be withdrawn by the end of August 2006 since the manufacturers will not try to defend them. For the 370 remaining substances, industry is faced with dossier submissions in 4 rounds. List 1 dossiers, comprising rodenticides and wood preservatives, were submitted in early 2004. List 2 dossiers, which include public health insecticides, will be submitted early in 2006. Many of these substances are also covered by 91/414/EC. Full implementation of the BPD will mean that the European biocides market will contain substantially fewer active substances in 2010 than in 2000.

**Key Words** Insecticides, rodenticides, biocidal, registration

### **INTRODUCTION**

A presentation about pesticide legislation to an audience of scientific researchers, students and pest management specialists sounds like a recipe for disaster. However, the fact remains that the prevailing and impending regulatory environment is what determines the availability of end products to the user. This, in turn, helps to direct research and development and can be the driving force behind innovative approaches to reducing pesticide use, improving dose targeting, creating novel formulations etc.

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 has become known as The Biocidal Products Directive, or BPD. It resulted from a recognition that biocidal products are necessary for the control of a wide variety of organisms that affect man, domestic animals, manufactured products etc, while addressing the European Council's concern that there was a lack of harmonised Community provisions to regulate non-agricultural pesticides. Under the Directive, each Member State (MS) identifies the Competent Authority (CA), which assumes responsibility for putting the Directive into practise by participating in the review process on behalf of their country.

A new language is forming and the main abbreviations that will be used throughout this article are: MS, Member State (country in the European Union); RMS, Rapporteur Member State (responsible for dossier review); CA, Competent Authority (organisation in each MS that reviews dossiers); EC, European Commission; PT, Product Type (grouping of biocidal products with similar purpose); TnG, Technical Notes for Guidance, EC documents to assist dossier preparation; ESD, Emission Scenario Document, Guide to environmental fate of product according to specific use patterns; GLP, Good Laboratory Practice (International standard for testing); LOA, Letter of Access (from data owner allowing third party to refer to proprietary data in support of a registration); a.s., Active substance.

The BPD is 22 pages long, with 36 articles and 6 Annexes, which cover the list of active substances (a.s.), the common core data set (actives and products), additional data, data on active organisms (where they are used as control agents), types of biocidal products (23 product types) and principles for dossier evaluation. It is accompanied by Technical Notes for Guidance (TNG) and Emission Scenario Documents (ESD) to help prepare the a.s. and product dossiers. An earlier European Directive 91/414/EC, concerning the placing of

plant protection products on the market, provided the framework for the BPD. However, a number of important lessons were learned from the 91/414 experience, and some of these are addressed in the BPD.

I will address the common issues between the two Directives and their intent. With a look at the current variation in the way biocides are regulated across the European Union (EU), it is clear that a consistent approach is required and that it will be beneficial for all concerned. There is common agreement that any products available on the market should be “safe”, (which for the purposes of brevity in this paper actually means: does not pose an unacceptable risk to humans, non-target animals or the environment) and effective.

### **COMMON THEMES OF 91/414/EC and the BPD**

Harmonization is becoming evident in many ways that affect everyday life in Europe, from the appearance of the Euro as the (almost) common currency, to freedom of movement between (most) Member States, and the supremacy of the European Courts of Justice and Human Rights. In common with this objective, both Directives seek to address certain underlying principles of the EU: free trade, fair competition, protection of man and the environment, through harmonisation of the regulatory environment across the MS. In practise, as in any other situation, it has not been easy to get 15 Member States to agree. Expanding the EU to 25 MS is unlikely to make this any easier, but at least decision-making for the BPD is by qualified majority voting (the number of votes is approximately in proportion to the population of the MS), so no country has the power of veto.

Under the BPD, it is the responsibility of a.s. manufacturers, and other interested parties, to formally state that they supply a biocidal compound into the European market and intend to support (or not) its continued use by providing a dossier according to the format required by the Directive. Then, for each a.s., one MS acts as the Rapporteur (the RMS) and, essentially, acts on behalf of the other countries to evaluate the dossier. An a.s. dossier must be submitted with at least one product dossier for full evaluation. The RMS reviews the dossiers to make sure they are complete (all the data requirements that are specified in the Directive have been addressed), conducts their evaluation, addresses questions to the notifier and summarises the dossier for the other MS. Where more than one company notifies an a.s., all the companies are encouraged to co-operate to submit a common dossier for review. This procedure is easier and less time-consuming for the RMS, but may not be in the commercial interests of the companies involved. Nevertheless, all parties (notifiers and Member States) have an obligation to avoid unnecessary animal testing such that notifiers will supply their rapporteur with a list of vertebrate studies that have already been completed, and will not initiate any more tests unless specifically required by the RMS.

Figure 1 summarises the theoretical timescale for dossier review, post-submission, which should be completed in approximately 2 years. The RMS should finish a completeness check within 3 months to ensure that all data requirements have been addressed either by studies or argumentation. There is the option to extend this phase to 6 months if it becomes necessary to seek input from the EC or other MSs (eg. where a similar active is under review by a different RMS). Following evaluation and a period for comments from the MS, there is a vote on whether or not to include the a.s. in Annex I (the list of a.s. with requirements agreed at community level for inclusion in biocidal products), and the results of that vote are then published. Post-Annex I listing is a phase for the re-registration of products containing the listed actives at MS level. At the time of writing, this phase was not clearly defined and timing could vary depending on the MS, but another 2-year phase seems to be a reasonable estimate. The EBPF (European Biocidal Product Forum) has proposed that a partial dossier, including label and letters of access should be submitted to an MS for all registered products within 6 months of the official publication of the Annex I decision. Evaluation and review could take up to 18 months. If the formulator applied for mutual recognition of the registration, then Article 4 of the BPD requires other MS to grant a corresponding product registration within 60 days (120 days for a product authorisation). In the case that an MS considers the product should not be granted a registration, it must justify this position to the EC. If successful, the EC may require the revocation of the original registration, if not, the EC can require the MS to register the product.

There are 23 PTs that are regulated under the BPD, and dossier submission dates for the actives are shown in Figure 1, as determined by their inclusion in one of 4 lists of PTs. For Urban Pest Management, the most relevant product types are PT8 (wood preservatives, list 1, submission deadline March 28 2004), PT14 (rodenticides, list 1), PT15 (avicides, list 4, submission deadline 31 October 2008), PT18 (insecticides, acaricides and products to control other arthropods, list 2, submission deadline 30 April 2006) and PT19 (repellents and attractants, list 2).

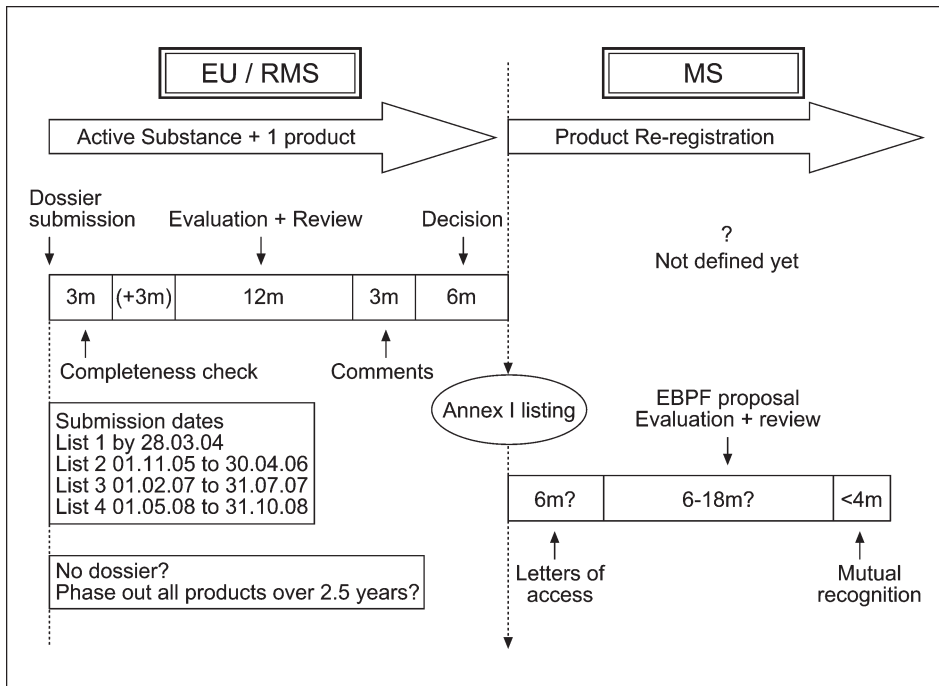


Figure 1. Summary of the theoretical timescale for dossier review, post-submission, which should be completed in approximately 2 years.

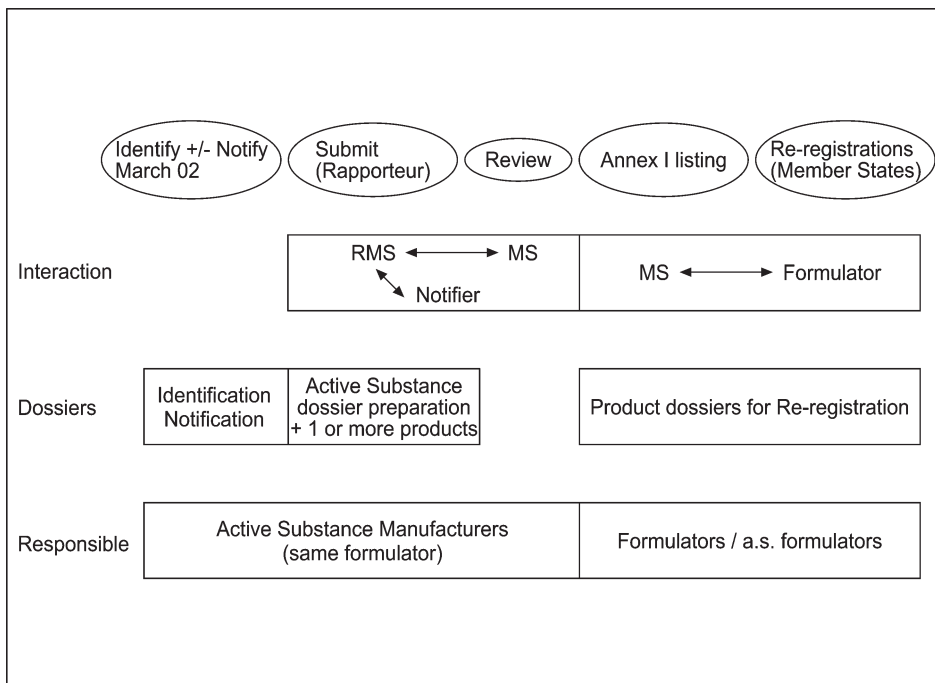


Figure 2. Summary of the steps involved in BPD and who takes responsibility during each phase.

Regarding their basic mechanics, the two Directives have much in common. Under 91/414, agricultural pesticide dossiers were also submitted according to 4 lists, although submission dates were phased over 12 years (1993-2005), versus 6 years for BPD. The review process under 91/414 also starts with the completeness check, then review by the RMS. Comments, appeals, re-reviews, new data, MS-specific concerns, discussion about the use pattern and risks associated with the representative product led to a very protracted procedure. At least one product dossier must accompany the a.s. dossier submission, and at the outset, this was intended to be a product that covered uses of the active in question that addressed the most significant risks. In most cases, it took at least 10 years from submission of list 1 pesticides to an Annex I inclusion decision. This timescale is reduced for later lists, not least because the accompanying product dossier is now intended as a safe use. Re-registration of other products is made at MS level, following Annex I inclusion. The BPD aims to complete the review of one list prior to the submission of dossiers for the next list, and while a safe use product dossier could be submitted, the result may be an Annex I inclusion with some restrictions.

Both Directives allow for new data to be protected by the owner. Under 91/414, new data is protected for 5 years from the time the inclusion in Annex I is published, while for BPD this period is 10 years. Since companies holding product registrations will be required to obtain new letters of access to a.s. data during the re-registration phase, it is clear that a.s. manufacturers who participate in the process have an opportunity to benefit from data protection much more under BPD than under 91/414.

Many of the most widely used compounds in urban pest management are also used in crop protection and if an active has been submitted for 91/414, then the same Rapporteur is assigned for the BPD review. The dossier formats differ, even if the actual content of the core data package is broadly similar. For example, BPD dossiers will not require all the crop residue data, and will probably not require as much ecotoxicological data where use is restricted to indoors, but they may include some new studies that have been completed since the 91/414 dossier was submitted. In addition, the operator risk assessments will be specific to non-crop uses.

So far, I have considered the broad outline of the process. Figure 2 depicts a summary of the steps involved and who takes responsibility during each phase. An active substance manufacturer informs the European authorities that it intends to support the use of substance X and then submits a.s. and product dossiers to the RMS which acts on behalf of all the MS. Dossier preparation may occur over a couple of years prior to submission, and it could take another 2 years from submission to a decision to include the active substance in Annex I. During the evaluation period, the RMS will interact with the CAs of other countries, and with the notifier, to address questions or additional data requirements that arise during review. Assuming the dossier is complete, and the active plus product are considered safe and effective, the RMS recommends Annex I inclusion to the European Commission, and the other MS vote. Assuming there is a qualified majority in favour, then the inclusion decision is published, the post-Annex I phase begins and further product dossiers containing that a.s. are submitted by individual formulators to be re-registered at MS level. So the balance of effort moves from the interaction between active substance manufacturer and RMS, to formulator and MS.

According to the principle of mutual recognition, each MS respects the ability of all the others to review a product dossier and ensure it meets the common standards, and will then grant registration without further review or delay. Ideally, a dossier is reviewed once by one MS, and that review applies for registration by all the others. Harmonious and efficient. It also ensures a synchronous re-registration cycle for each product at European level instead of the present situation where, for example, product A is due for re-registration in the UK in 2010, then in Germany in 2012 and in the interim, new data becomes necessary thanks to legislation passed in 2011. Under those circumstances, there may be dose rate or use pattern restrictions applied in one MS several years before they are applied in others.

## WHAT IS THE PROBLEM?

A utopian, harmonious Europe is not quite reality, and there is a gulf to bridge between the principle and the practise. The main areas of concern are cost, resource, consistency, data protection and (fair) competition.

### Cost

Estimates vary, but if no data is available it is likely to cost 5-10 mio € to generate the data required for an a.s. dossier. For crop protection actives where a significant amount of information is already available, it may still cost 0.5-1.0 mio € to meet modern dossier requirements (Good Laboratory Practise). Simply compiling the information and respecting the formatting requirements of the BPD could add the equivalent of 50k € either via a consultant, or people-time, with a further 100K € per product dossier (study plus dossier compilation costs). Photocopying costs to provide copies to 25 MS (plus Norway and Switzerland) are not insignificant.

Upon submission, there are fees to pay to the RMS. Logically, one might anticipate that for an equivalent review (the RMS represents the other MS) there would be some similarity in the review fees. In fact, while some countries charge about 100K € for the review, others may charge 3 times as much as an initial fee, with the promise to return money left over after the review is completed.

The process will be more economical for compounds where there is already a modern dossier and a large market. For many older products, the financial benefits of staying in the market will not be sufficient to justify the investment in new studies. There may be an argument that some of these products do not meet modern standards and should, therefore, be withdrawn anyway. Unfortunately, it may be equally true that they have been in effective use for decades with no evidence of any ill effects but the market value is simply too low to justify the extra costs. It also means that the entry cost for a new a.s. is very high, and this will impact upon commercial decisions whether or not to develop products for niche markets.

### **Resource**

In nearly all MS (Sweden is a notable exception), there has been no increase in personnel to cope with the review of the BPD dossiers. Therefore it seems logical to conclude that the reviews will occur through re-allocating personnel. Consequently, ongoing re-registrations and new product registrations will be negatively impacted. Some MS are taking a pragmatic view that existing product registrations will be extended provided the a.s. is notified for support through the BPD. In that case, re-registration would occur post-Annex I listing.

Where there are multiple notifiers for an a.s. in a single PT, those companies are encouraged to work together to submit a single dossier. This economises on submission fees per company, and facilitates the dossier review. Each company can still retain ownership of proprietary studies, such that co-submitters still require a letter of access to specific elements of the dossier, or gain access via sharing the cost of the studies concerned (data compensation). In the event that the common notifiers do not submit a joint dossier, the RMS is obliged to conduct separate reviews, constituting a drain on resources, especially when the end result will be the Annex I inclusion of the a.s., independent of the notifier.

### **Consistency**

It is not hard to imagine the difficulties associated with translating the Directive into the language of each Member State, and then incorporating it into law. Anybody who has watched a film with an understanding of the original language as well as the subtitles will know that some phrases simply do not translate easily into a second language. Member States were required to implement the BPD in national law by 13 May 2000, and notify the European Commission to that effect. In some cases, the notification was very late but, in all cases, the Commission has been verifying the conformity of the transposed text with the Directive. However, Member States recognise that there will be differences in interpretation that may only be decided in a court case (Iakovidou, 2003).

In some countries, biocidal products have been regulated separately to crop protection products for some time. In the UK, non-agricultural registrations are managed by the Health and Safety Executive, HSE, while agricultural registrations are managed by the Pesticides Safety Directorate, PSD. In Sweden, there has been a specific biocidal products unit within the National Chemicals Inspectorate (KEMI) for almost 20 years. In France and Germany, there has been little or no review of biocidal product dossiers and such products have, in the past, received an authorisation to be placed on the market, which has often been little more than a formality. Even in the UK and Sweden, only 8 and 12 of the 23 PTs, respectively, have been covered by National schemes, and no single European country had addressed all 23. Therefore it could be argued that the BPD is long overdue. It also means that in many cases the reviewing staff in the CAs are facing a very steep learning curve.

### **Data Protection**

The BPD should have been implemented into National laws by 13 May 2000. Any data that has been submitted for review by a MS since then is considered new and companies can claim data protection which will last for 10 years commencing at the time the a.s. is included in Annex I or IA. Since the regulatory requirements evolve over time, it is almost inevitable that active substance and product dossiers submitted in 2006 will contain some studies conducted since 2000. Inevitably, the RMS will become aware of differences between two or more dossiers submitted by different notifiers for the same active substance. Naturally, the RMS will prefer to examine a single environmental risk assessment, or classification proposal, for any individual compound so it makes sense to make use of the “best” data to support the Annex I decision (eg. the most modern, GLP, toxicology study; or a risk assessment based upon actual data versus one based on assumptions



or recognised defaults). Under these circumstances, the RMS may recommend that company A contacts company B to negotiate access to the relevant information. For vertebrate studies, there are moral and ethical reasons to reach agreement (generally the requestor would pay towards the cost of the study plus a risk premium). But in a market where there are fewer and fewer new compounds being registered, it is understandable that companies will want to extract as much leverage, protection and value as possible from proprietary information.

During the re-registration phase, post-Annex I inclusion, one of the first requirements will be for product registrants to demonstrate that they have an LOA to the all the a.s. data that was used to support Annex I listing. The data protection provisions of the Directive will provide the a.s. manufacturers with the opportunity to select who will be given access to the protected elements of the dossier, and under which conditions.

### **Fair Competition**

Assuming rodenticides and wood preservatives achieve Annex I inclusion during the first half of 2006, and insecticides, repellents and others during 2008, then corresponding product re-registrations will occur at MS level over the following 2-3 years. In order to re-register, formulators will require a Letter of Access (LOA) to the data that supported Annex I listing, plus a product dossier.

Once a product registration has been granted, it remains valid for 10 years, with no further requirement to have the LOA to the active substance data set and the formulator is able to change supplier of active, provided the alternative source meets the same specification or is chemically equivalent. Since very few of the active substances that were present on the market in 2000 (the cut-off date for inclusion in the BPD as an existing active) will still have patent protection by 2008, this provides an opportunity for generic suppliers to capitalise on the investment made by other manufacturers that resulted in Annex I listing.

Consider two men who are equally good drivers, with driving licenses and permits to drive a taxi: one of them buys a car that he can use as a taxi and thereby operate a business, but both of them can use it. The only way for the owner to protect his investment is by keeping the keys away from his competitor. Is that fair? Alternatively, company A invests in a required study that takes a year to complete, while company B does not. Company A submits the study with its dossier. The RMS informs company B that the study is required to complete their dossier and directs them to company A for access. Company B can secure immediate access for a price, which is less than the full cost. Is that fair?

Clearly, those who invest in the BPD dossiers will expect a return on their investment and there is considerable concern that free-riders will simply wait for Annex I listing of an off-patent active substance, then approach formulators with low prices. For the regulatory authorities, the priority is on ensuring that only safe and effective products are available for sale. Commercial considerations are a separate issue for manufacturers to deal with. At this point, the elements of data protection (see above) and respect among MS for the implementation of that component of the Directive, become paramount. The Directive encourages notifiers of the same a.s. to work together to produce a common dossier for review, and it makes sense that an equitable means of cost-sharing or data compensation would be agreed prior to commencing the co-operation. This would ensure that the parties worked together towards shared costs and shared benefits. We will see.

## **THE STORY SO FAR**

Any biocidal substance that was not identified to the EC by the deadline of 28 March 2002 was required to be withdrawn from the market by 31 December 2003. A total of 955 substances were identified, and 370 of these were additionally notified (intent to defend through the BPD), sometimes by several companies and sometimes for more than one of the 23 PTs. A further 25 substances were notified in a late notification period ending 1 January 2003. The 560 identified, but not notified substances are required to be withdrawn from sale in Member States by 31 August 2006. So, already the impact of the BPD is felt with almost 60% of the identified biocides due to be withdrawn. Of the 98 a.s. dossiers due for submission by the list 1 deadline of 28 March 2004, only 51 were actually received (Berend, 2004). If a similar attrition rate is seen for lists 2-4, then the European market of the future will comprise approximately 200 biocides (Figure 3).

	Notification			List 1 Submission	List 2 Submission			
	March 2002	January 2003	31 December 2003	March 2004	November 2005 - April 2006	31 August 2006		
Identified	955							
	370	395		98 51				
			7		7	560	48	
			955		7	395	347	2007

**Figure 3.** Summary of the biocides in the European market in the future.

An alarming feature of the list 1 submissions was that almost 50 dossiers that were expected for review were never submitted. For the RMSs, this meant that resources that had been set aside for the reviews were no longer needed and, understandably, there is some hesitation to dedicate resource to list 2 without more certainty that the dossiers will arrive. The EC considers that notification should be taken in good faith to mean that a company really intends to support the a.s. However, it must be accepted that the economic equations have become less and less attractive as the real costs of dossier preparation have become apparent. There is no incentive to de-notify (forewarn the RMS that the a.s. will not be supported) when non-submission will allow a much longer sell-out time, giving more opportunity to extract the existing registrations without investing in the affected products or actives. At the time of writing, the Third Review Regulation was in the late stages of preparation and one element might be specific provisions at EU level in case of non-submission (i.e. a maximum sell-out period).

After submission of the 51 dossiers for list 1, 2 were considered incomplete, one was withdrawn, 2 received an extension to complete their dossiers, 4 were deemed complete within 3 months and 42 were deemed complete using the additional 3 months consultation procedure. So far the timescale has been respected, and if this continues through the review and decision phases it will be a commendable achievement after all the difficulties encountered during the implementation of 91/414.

## CONSEQUENCES FOR URBAN PEST MANAGEMENT IN EUROPE

It is not in the commercial interests of companies to invest in excess of 0.5 mio € in dossier preparation and submission fees, only to find that generic suppliers wait for Annex I inclusion and then compete for business. Logically, Letters of Access will become linked to supply agreements and/or other contractual arrangements.

The attrition rate (Figure 3) suggests that by 2010 the Biocides market may contain approximately 20-25% of the compounds present in 2005. The effects upon urban pest management in Europe will become apparent at the time list 2 insecticides achieve Annex I listing, which is likely during 2008 when it will be imperative that formulators have strong links with a.s. manufacturers which have access to the full data set of actives that are included in Annex I. Given the cost of product dossier studies plus compilation and submission fees, there will be a strong incentive to use mutual recognition to obtain Pan-European products, so the total number of products available will become reduced in much the same way as for actives. Free trade and common product registrations should further encourage the Europeanisation of formulators and lead to alliances or mergers/takeovers and harmonised pricing levels. While it is true that some “safe” products will be lost for economic reasons, it is also true that the products remaining will meet high standards for safety to operators, the general public and the environment.

## REFERENCES CITED

- Berend, K. 2004.** Biocidal Products Directive 98/8/EC: Another year on. In: IBC 11<sup>th</sup> Annual Conf. The Biocidal Products Directive, Brussels.
- Directive of the European Parliament and Council of 16-2-98** concerning the placing of biocidal products on the market (98/8/EC). Off.J. Eur. Communities, L123, 24-04-98
- EC Council Directive of 15-7-91** concerning the placing of plant protection products on the market (91/414/EEC). Off. J. EUR. Communities, L230, 19-08-91, (as amended).
- Iakovidou, M. 2003.** Implementation of the BPD in Sweden. In: IBC 10<sup>th</sup> Annual Conf. The Biocidal Products Directive, Brussels IL 1089.