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REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

Evaluation of the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (submitted in accordance with Article 18(5) of the Directive) and progress report on the work programme referred to in Article 16(2) of the same Directive

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1. INTRODUCTION

Directive 98/8/EC of the European Parliament and the Council, adopted on 16 February 1998, regulates the placing of biocidal products on the EU market. It sets out a Community harmonised system for the authorisation and placing on the market of biocidal products; for the mutual recognition of these authorisations within the Community; and for the establishment at Community level of a positive list of active substances which may be used in biocidal products. It aims to ensure a high level of protection for human and animal health and for the environment.

Among other actions, the Directive established a 10-year work programme for the systematic examination of the active substances used in biocidal products that were present on the market before its entry into force (14 May 2000). During this 10-year period, Member States may continue to apply their structures for the placing of biocidal products on the market.

Before the Directive came into force, many Member States did not have in place full legislative regimes for these products. In the past eight years, the active substances being used have been systematically inventoried, and a programme for the evaluation of these substances has been set up. As a consequence of the implementation of the Directive, active substances that were of marginal use, along with a number that had unfavourable environmental or health profiles have been removed from use. A process of assessment of the active substances has been set up, with a rigorous system of peer review. This extensive body of work has now laid the groundwork for the evaluation of the remaining active substances over the next years, and for the product approval stage over the next decade. The report identifies a number of provisions of the Directive that require attention in the forthcoming revision of the Directive.

2. CONTEXT OF THE REPORT

Article 16(2) of the Directive requires the Commission to forward to the European Parliament and Council a report on the progress achieved with the review programme no later than two years before its scheduled completion. Article 18(5) requires the Commission to draw up a report on the implementation of the Directive, and in particular on the functioning of the simplified procedures, seven years after the entry into force of the Directive. In the interests of efficiency, the Commission has decided to present its conclusions on the implementation of the Directive and on the progress of its review programme in the form of a joint report.

For the preparation of this report, a study on the implementation of the Directive was commissioned. This study was prepared on the basis of an extensive stakeholder consultation. In addition, a separate study had previously been commissioned on the specific issue of articles treated with biocides[1].

The conclusions of the present report also draw on facts and figures from the composite report required under Article 24 of the Directive, based on information supplied by the Member States.

[1] Both studies available at: http://ec.europa.eu/environment/biocides/study.htm

The aim of the present report is to inform the other Community Institutions, the Member States and the public about the implementation of the Directive and the review programme in particular, over the period from 14 May 2000 to 1 March 2008. It has to be noted, however, that the implementation of a significant part of the Directive's provisions has not started. Notably, there have been no authorisations of biocidal products yet.

The report includes the situation in the 10 Member States who joined the EU on 1 January 2004, but does not cover the situation in Bulgaria or Romania.

3. IMPLEMENTATION OF THE DIRECTIVE - THE REVIEW PROGRAMME FOR ACTIVE SUBSTANCES

Following the adoption of the Directive, the Commission and the Member States embarked on a programme of work with the aim of systematically examining the risks associated with active substances that may be authorised for use in biocidal products.

The programme has been set up under a Commission Regulation[2] which laid down the rules for the first phase of the review of active substances. During this phase, the industry had to identify the active ingredients they used in their products, and if they wished to continue using them for biocidal purposes, to notify them for evaluation by providing initially a limited dossier with information on the substances.

At the end of this exercise, another Commission Regulation[3] was adopted on the second phase of the review programme, drawing up an inventory of the identified existing active substances; a timetable for the evaluation of the notified substances; a list of the designated Rapporteur Member States for the first two priority lists; and provisions regarding the procedural aspects of the review programme.

The second Commission Regulation was subsequently amended[4] to designate Rapporteur Member States for the two remaining priority lists, as well as to address certain other issues that arose during the implementation, such as the possibility to grant temporary derogations for active substances that were not scheduled for evaluation, but the use of which is considered essential for one or more Member States.

In parallel to developing the regulatory framework for the review of active substances, the Commission has produced and agreed with the Member States a significant number of publicly available[5] comprehensive guidance documents, to assist the Member States and industry with their tasks.

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2 Commission Regulation (EC) No 1896/2000 of 7 September 2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products (OJ L 228, 8.9.2000, p. 6.)

3 Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market, and amending Regulation (EC) No 1896/2000.

4 By Commission Regulations (EC) n° 1048/2005 and 1849/2006. Regulation 2032/2003 was repealed and replaced by Commission Regulation (EC) n° 1451/2007 (mostly for simplification and consolidation purposes).

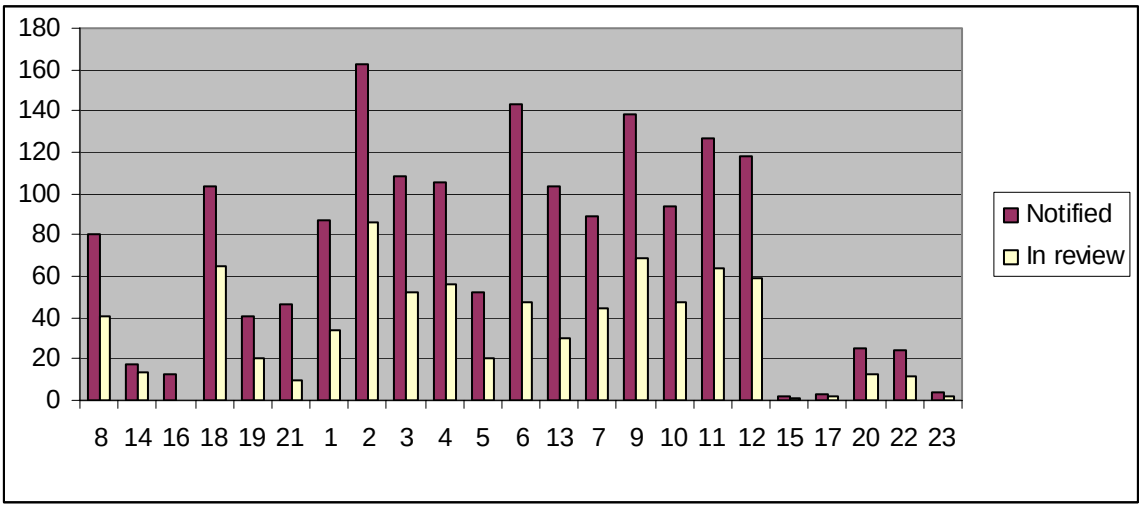
5 Available on: http://ec.europa.eu/environment/biocides/index.htm and http://ecb.jrc.it/biocides/

3.1. Progress made under the review programme to date

At the end of the first phase of the review programme, the industry had identified 964 substances as active ingredients of biocidal products that were present on the market before 14 May 2000. Of these, 416 active substances were notified for evaluation in one or more product-types. 548 (about 60%) of the identified substances were not supported and were subsequently phased-out by 1 September 2006. Based on the results of the study referred to in chapter 2, it is estimated that these active substances were used in only 13%-33% of the biocidal products on the market. Some of these active substances were no longer used in biocides, while others were not supported due to their unfavourable toxicity profile. In some cases, they were addressing a limited market that would not permit to cover the evaluation cost. The preparatory work for this report did not identify any cases where the loss of these active substances left users without a substitute, or led to the proliferation of the target harmful organisms, but those risks can not be fully excluded. On the other hand, the withdrawal of certain substances of known high toxicity is a clear beneficial effect of the review programme.

By 1 March 2008, half of the initially notified active substance/product-type combinations have been withdrawn from the review programme (see Figure 1).

Figure 1: Active substance/PT combinations initially notified and eventually supported by the industry[6]



This may be explained by the fact that some active substances were notified without a serious intent to submit the full dossier for evaluation; others were notified for too many product-types, and for some it became apparent during the course of dossier preparation or evaluation that the cost would be higher than initially expected.

As the finalisation of the evaluation of active substances has only recently begun, Annex I to the Directive currently lists only a small number of active substances. Annex IA contains one approved active substance.

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[6] The order of the PTs in figure 1 follows the order of evaluation. For substances of the 4th priority list (i.e. for product-types 7, 9, 10 to 12, 15, 17, 20, 22 and 23) a drop off of 50% has been assumed on the basis of the experience of submission rated for the previous priority lists.

3.2. Ongoing work under the review programme

The original timetable of the review programme was based on the assumption that two years would suffice from submission of the dossier by the participant to adoption of a decision on the inclusion of an active substance. In practice this proved impossible to achieve, given the timelines set out in the Directive, and those imposed by procedural requirements for implementing measures. No active substance has been evaluated to-date in less than three years and the average period of evaluation seems to be closer to approximately four to five years so far.

Furthermore, it should be noted that the review Regulation gives the possibility to take over the role of participant to support an active substance for which all initial notifiers have withdrawn. In such cases, a new deadline is set for the person taking over, in order to compile and submit a complete dossier. This process gives a second chance to have an active ingredient evaluated and available on the market, but can stretch the time needed for the review to five years or more.

Several factors can be noted as reasons for the slower than scheduled pace of the review programme: technical complexity of the work; insufficient human resources; in certain cases, lack of experience with dossier preparation and dossier evaluation; the need to develop appropriate testing methodologies and exposure scenarios for a wide range of uses; overly optimistic timeframe for the review, considering the significant number of active substance/product type combinations that were subsequently notified.

It is estimated – taking into consideration the progress rate with the review programme so far - that the last decisions on the remaining active substances will be taken only in 2014. Annex 1 sets out the anticipated timing for the remaining work.

Lastly, it has to be noted that Article 16(3) of the Directive does not specify a particular period of time for the preparation of biocidal product dossiers following the inclusion of an active substance into Annex I or IA, the submission of product authorisation applications to the Member States, and for granting, modifying, or cancelling product authorisations on the basis of the evaluation of the submitted dossiers. This stage is however essential for harmonisation and the achievement of the biocides internal market and also prolongs the time requirements in the transitional period.

4. IMPLEMENTATION OF THE DIRECTIVE - SIMPLIFIED PROCEDURES

In addition to Annex I covering 'standard' active substances, the positive list of the Directive comprises two further Annexes, Annex IA and IB. Annex IA is for active substances that have a low toxicity and ecotoxicity profile, and therefore may be used in 'low-risk' biocidal products. Annex IB lists 'basic substances', or 'commodities', that is, substances which are not primarily marketed for biocidal purposes, but that nevertheless have a certain biocidal action.

4.1. Low risk products

The possibility of lower data requirements with regard to the biocidal product dossier, and shorter deadlines for registration and mutual recognition presents a substantial benefit to the companies marketing biocidal products.

However, for the producers of active substances, there is no real benefit in the inclusion of an active substance in Annex IA instead of Annex I. This is due to the fact that, initially the same amount of data has to be submitted for all active substances. In particular, the same studies have to be generated and submitted for the evaluation of active substances that are of recognised concern, as for those that are generally considered to be of low risk. It is only after the evaluation that it is decided whether an active substance can be included in Annex IA or in Annex I.

4.2. Basic substances

So far, there has been no request by the industry or the Member States to include an active substance into Annex IB. There appear to be two main reasons: whilst the amount of data – and therefore, expense - necessary to compile a basic active substance dossier is the same as for a 'regular' substance, ownership of these data is not protected by the Directive. Furthermore, the only advantage of this simplified procedure, which is that no marketing authorisation or registration is needed for products containing basic substances, is counteracted by the prohibition to market them directly for biocidal use.

4.3. Frame formulations

A frame formulation contains specifications for a group of biocidal products, which present minor variations with regard to a reference product. As the first authorisations of biocidal products are not expected to be issued before 2009, no frame formulations have been created yet in practice. It appears, however, that several Member States already apply the principle of this simplified procedure in their existing national systems, by reducing the administrative requirements when an application for authorisation concerns the same product in a range of different colours. The study referred to in section 2 concluded that the concept behind this simplified procedure has the potential to deliver genuine benefits, but that greater clarification on what is covered and how it will operate is needed.

5. IMPLEMENTATION OF THE DIRECTIVE – OTHER ISSUES

5.1. The scope of the Directive

During implementation, a number of issues have arisen in relation to exact scope of application of the Directive. One such issue that needs to be addressed concerns treated articles. Articles that are treated with biocidal products in order to protect them from deterioration, which have no external biocidal effect, nor are they marketed as a biocidal product, are currently outside the scope of the Directive. When the treatment takes place within the EU there is no particular problem, because the supply of the biocide to the operator that treats the articles counts as placing on the market and can be regulated. However, the case is different when the articles are treated in third countries and are then imported into the EU (e.g. treated wood or textiles). They may have been treated with substances found unacceptable for human health or for the environment and banned or severely restricted in the EU. This situation presents risks for human health and the environment, and could be discriminatory to European industry.

Other scope questions concerned the exact delineation of products that could also be covered by other Community Directives (i.e. Veterinary Medicinal Products, Cosmetic Products) or whether certain substances generated in-situ are covered or not, and there was general

agreement that active substances that are also food or feed (e.g. pepper used as a repellent, sugar or juices used as attractants in traps) should be exempted from the Directive.

5.2. Data protection and data sharing

While Article 13 of the Directive, and several other of its provisions, clearly encourage applicants to co-operate in compiling the necessary information for the evaluation of active substances or biocidal products, it does not provide explicitly for mandatory sharing of information that is required for the purposes of the Directive. Instead, the owner of the data may decide – but is not obliged – to give a subsequent applicant the right to refer to information they have submitted to a competent authority by providing them with a 'letter of access'. Whenever an agreement cannot be reached between the owner of the data package and the other applicant, the latter may be either obliged to duplicate the studies (particularly undesirable where animal studies are concerned), or to abandon the market until such time that all relevant data protection periods have expired.

At the current stage of the review programme, it is estimated that on a total of 472 dossiers submitted in support of the inclusion of an active substance/product-type combination, approximately 25% of these dossiers were submitted either by a consortium or task force of enterprises or at least two enterprises that joined efforts. In 10% of the cases more than one dossier was submitted for the same active substance/product-type combination, which means that the interested parties did not manage to come to an agreement to share data and submit a collective dossier.

Another issue that was raised repeatedly by the industry is on companies that continue to market products containing active substances which are being evaluated under the review programme, without having themselves notified or in contributed to the cost of the evaluation (the so-called 'free-riders').

5.3. Fees applied by the Member States

Article 25 of the Directive provides that the Member States are responsible for establishing fees to be paid by the persons placing, or seeking to place biocidal products on the market, in order to recover the administrative cost related to the procedures of the Directive. As a result, the systems and fees established are widely disparate throughout the EU. As an example, the fee for evaluating an active substance dossier with regard to one product-type (i.e. type of use) may range from € 50,000 to € 350,000; the payment mode may also differ significantly from one Member state to another. This creates an inequitable situation for the biocides industry, in particular for the participants in the review programme, who have no choice of the Member State that will examine their active substance dossier.

5.4. Data requirements

The substantial requirements of the Directive in terms of toxicity and ecotoxicity studies guarantee a high level of protection for human and animal health and for the environment. However, since the Directive does not distinguish between active substances when it comes to data requirements, these have been perceived as excessive for certain substances that are generally considered to be of low risk. Although the possibility to waive data requirements is provided for under the Directive, the application of this principle seems to be applied unevenly by the Member States. This has led to different approaches and hence a risk of inequality of treatment.

5.5. Product authorisation and mutual recognition

Product authorisation in the Member States, following inclusion of an active substance in Annex I or IA, and mutual recognition have not yet begun in any significant way. However, a Mutual Recognition Facilitation Group has been set up with Member States and stakeholders, in order to smooth the working of the product authorisation stage, and anticipate issues with the mutual recognition of authorisations and registrations in particular.

6. IMPACT OF THE DIRECTIVE ON THE MARKET AND IN PARTICULAR ON SMES

While it is premature to assess the full impact of the Directive on the biocidal products market, some trends have been observed which allow some initial conclusions to be drawn.

Based on the results of the identification and notification exercise, presented as Annexes to Commission Regulation (EC) n° 2032/2003, it appears that 60% of the active substances used in biocidal products before 2000 were not supported for evaluation and had to be taken off the market by 1 September 2006. The percentage of active substances that will disappear from the market by the end of the review programme will probably be even higher, given that for almost 50% of the initially notified active substance/product type combinations no dossier was submitted. However, a part of these substances that were not supported by the industry (from the start, or later), were apparently no longer in use or had few chances of being included in the Directive's positive list, in view of their unfavourable toxicity profile.

Still, for a number of substances the criterion for not supporting their inclusion was evidently financial: the expected profits would never cover the cost of a dossier. In this context, bigger companies fared better than SMEs.

So far eight dossiers in support of the inclusion of new active substances have been submitted to the Member States for evaluation. Of these, five were accepted as complete. It has been argued that the high cost and resource implications of substance evaluation under the Biocides Directive may discourage investments in biocidal products with new active substances and potentially better human health or environmental profiles, especially in 'niche markets'. The Directive currently provides for an additional five years of data protection and the possibility of a provisional product authorisation as the only incentives for the development of new active substances.

7. IMPACT OF THE DIRECTIVE ON THE ENVIRONMENT AND PUBLIC HEALTH

The Directive has laid down for the first time a framework allowing for a comprehensive assessment of all active substances and 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 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, thereby improving the level of knowledge about the chemicals that are being used. In addition to this, some active substances with highly hazardous profiles (strychnine, arsenic compounds, tributyltin compounds, or certain ozone depleting substances, for example), have been taken off the EU biocides market, which represents a clear environmental and health benefit.

8. CONCLUSIONS AND PROPOSALS FOR THE REVISION OF THE DIRECTIVE

The Directive has set the foundations for improving the level of environmental and public health protection offered to EU citizens in relation to biocidal products. During a five year effort before the effective start of the active substance review in 2004, the Commission, in co-operation with the Member States and industry have inventoried the European biocides market and put into place a structured procedure for the assessment and evaluation of the existing active substances. Although it has not been possible to meet the time lines originally envisaged for the review of the existing active substances, progress has been similar to if not faster than other comparable regulatory systems, such as for plant protection products (Directive 91/414/EEC) or existing chemical substances (Regulation (EC) n° 793/93).

8.1. The future of the review programme up to and beyond 2010

As set out in section 2.2, it has become clear that the review programme will not be finalised by the date originally set, that is, 14 May 2010, which also happens to be the date by which the national rules for the placing on the market of biocidal products will cease to apply. Allowing the transitional period to elapse without completing the review programme for active substances would mean that the harmonised rules of the Directive about product authorisation could not apply for all the biocidal products already on the market. If neither set of rules – harmonised or national – could apply, there would be a legal void with regard to the placing on the market of biocidal products. This could have negative effects on public health (important biocidal products withdrawn from the market), and would have severe adverse economic effects on all companies operating in the biocides sector.

Therefore, this Communication is accompanied by a proposal for the revision of the Directive that would extend the review programme, the transitional period, and certain provisions on data protection that accompany this period for an additional three years.

This will allow time for the substantive revision of the Directive to come into force and to set out an approach to the remaining elements of the review programme that will ensure the timely and effective conclusion of this work.

8.2. The substantive revision of the Directive

A proposal for the substantive revision of the Directive will follow later in 2008. It will address the issues raised in sections 4 to 6 of this report.

The Commission is currently considering a range of measures to address the issues identified, such as:

– the simplification and adaptation of the scope of the Directive;

– a tiered approach to data requirements that will take proportionality into consideration;

– a simplification of the data protection rules, including some mandatory data-sharing;

– greater harmonisation or co-ordination of fee structures;

– improvement of the simplified procedures,

– measures to facilitate complying with the Directive for SMEs, and measures to encourage innovation;

– measures to improve the internal market in biocidal products, including the reinforcement of mutual recognition.

Annex 1

Product-type	Notified	Still in	Dossier to be submitted by	First decision expected by	Last decision expected by	Annex I									
						2006	2007	2008	2009	2010	2011	2012	2013	2014	
Wood preservatives	80	40	28/03/2004	12/01/2007	29/08/2009	1	2	30	7						40
Rodenticides	17	14					2	10	2						14
Molluscicides	13	0	30/04/2006	13/02/2009	1/10/2011										0
Insecticides	104	61						5	30	20	6				61
Repellents & attractants	41	19						3	6	5	5				19
Antifouling products	46	10						2	5	3					10
Disinfectants	87	35	31/07/2007	16/05/2010	31/12/2012					5	25	5			35
	163	82								5	25	25	27		82
	108	50								5	25	20			50
	105	55								5	25	25			55
	52	21								5	15	1			21
Preservatives (in-can & metalworking-fluids)	143	47								5	25	17			47
	104	30								5	25				30

Preservatives (for films, fibres, masonry, liquid cooling & processing systems)	89	45	31/10/2008	17/08/2011	3/04/2014						4	25	16		45
	138	69									4	25	25	15	69
	94	47									4	25	18		47
	127	64									4	25	25	10	64
	118	59									4	25	25	5	59
Avicides	2	1										1			1
Piscicides	3	2										1			1
Food/feed preservatives	25	13										4	9		13
Embalming fluids	24	12										4	8		12
Control of other vertebrates	4	2										2			2
Total	1687	777				1	4	50	50	63	196	230	153	30	777