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Regulatory requirements for biocides on the market in the European Union according to Directive 98/8/EC [1]

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Abstract

In early 1998, the European Commission and Parliament adopted a new Directive concerning the placing on the market of biocidal products. The Directive is to be implemented in the member states by May 2000. The member states are currently concerned with the national implementation into legislation whereas the Commission is setting up the proposal for a review programme for the existing active substances and the products in which they are used. This paper describes the effort currently undertaken (up to the end of December 1998) to define the procedures to be used and characterise the substances covered.

Keywords: Biocides; Active substances; European legislation; Risk assessment

1. Introduction

The European Commission has long recognised that regulation of potentially dangerous chemicals in use in the EU is needed. A number of directives have been implemented that address these chemicals to assure that the properties of the chemicals

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are known and disseminated to industry and the public, and that potential harmful effects are identified and addressed as early as possible. These directives cover the external environment, the work place and the indoor environment, as well as risks associated with production [1] and partly with transport [2]. The research and development of the scientific and technical aspects of these directives are delegated to the Commissions research centre, the Joint Research Centre (JRC), to use the unique bridge between legislation and research.

A recent directive, linked to biocides, will be described in this paper, together with an overview of previous legislation in the area of health and consumer protection related to chemical substances.

Biocides (previously named 'non-agricultural pesticides') are chemicals with an active, and in general toxic, effect on living organisms. They are used in order to disinfect, to eliminate undesired organisms, preserve and conserve various products. Common examples are: sodium hypochlorite used in swimming pools to eliminate bacteria and viruses; warfarin used as rat poison; and propoxur used as ant poison.

It has long been recognised that the beneficial biocidal effect may extend beyond the target organism(s) with resulting undesired adverse effects to man and the environment, e.g. bacteria have built up resistance against disinfectants used in hospitals.

A key concept in Directive 98/8/EC [3] is the term 'active substance'. The directive is on two levels: the first level is the active substance, which needs to be evaluated and approved at EU level, and the second level is the individual products containing this substance. The products need to be approved in one of the member states and that approval is then by default recognised in the other member states. The exemptions foreseen are, e.g. that a member state may refuse to authorise/recognise an insecticide controlling an insect that is not found in that particular member state.

2. Previous EU legislation

The most important earlier directives and regulations on evaluation of chemical substances are listed below, see Fig. 1. They address different groups of chemicals (general chemicals, cosmetics, and those for medical products), setting minimum requirements for information that must be supplied in order to (continue to) market the substances. The information supplied is sufficient to evaluate possible hazardous properties of the substances with regard to human health; and for two directives (67/548/EEC and 91/414/EEC) the effects on the environment can be evaluated and the data is enough to permit a risk assessment.

Discussions about new legislation addressing the biocides were started at the end of 1980s. The aim was to set up an authorisation procedure before placing products containing the active substance on the market. The authorisation should be based on a risk assessment and if the risk assessment indicated that the risk was unacceptable the active substance (and the products) should be prohibited from the market.

Following the usual procedures for negotiating new directives these ideas were implemented in Directive no. 98/8/EC, agreed by the European Council and Parlia-

- The placing of Plant Protection Products on the market (Directive 91/414/EEC) and amendments Ref. [4]
- Directive 67/548/EEC on the classification and labelling of dangerous substances and its amendments, the most important being. Ref. [5]

  Existing substances (Council Regulation 93/793/EC) Ref. [6]

  New Substances (Directive 92/32/EEC Ref. [7]; 96/56/EC Ref. [8])
- Cosmetic products (Directive 76/768/EEC) Ref. [9]
- Medical devices (Directive 93/42/EEC) Ref. [10]
- Medical products (Directive 65/65/EEC) Ref. [11] and Directive 92/73/EEC Ref. [12])

Fig. 1. Directives concerning chemicals (see Refs. [4–12]).

ment in February 1998 and entered into force May 1998. The member states of the European Union have 24 months to implement the Directive, i.e. the Directive should be implemented by May 2000.

The active substances used in biocidal products were covered, to a certain extent, by a number of other directives, however without addressing their specific biocidal property. Only the directive on Plant Protection Products, PPP, (91/414/EEC) covers active substances, the other directives concerning chemicals address the hazards/risks but not the active action of the substances. Thus, the biocides directive closes a gap in the current legislation concerning chemicals.

In the Directive all active substances used in all products must be evaluated in a 10-year period following the deadline for implementation in the member states. Active substances which are approved are entered in one of the annexes I, IA or IB of the directive for a maximum period of 10 years with the possibility of further extensions. Active substances, which are not entered in one of these annexes, must be withdrawn from the market for biocidal use, as well as the products in which they are used.

3. Comparison with other programmes on chemicals

The Biocides Directive has been adopted after the adoption of other directives on chemicals. It contains elements common to these other directives and includes sub-

stances which were and still may be covered by these. The boundaries and interfaces are in the process of being defined by the Commission and the member states.

It is necessary to create links between the many risk assessment programmes laid down in these directives, so that information supplied under one directive is fed, as far as possible, into the other programmes for assessment of chemicals. However, some programmes have more comprehensive data requirements than others, meaning that the data already supplied under one programme may not be sufficient for another programme.

One of the first tasks after the approval of the Biocides directive is to define in detail its scope. A working group has been set up to discuss coverage especially where overlap with other directives may be possible. The Commission takes part in these discussions and ensures that the Commission services responsible for the other directives are consulted.

Some of the more difficult questions posed in this context are: should an active substance that is used as a preservative in a cosmetic product be covered by the Biocides Directive? Are PPP also covered by the Biocides Directive when they are not used as PPP (but, e.g. as household insecticides)? A working group has been set up to define the delimitations between the different directives. The consensus emerging is that it depends on marketing and use, and the ways in which the products are used. Also, depending on the use of the product, the active substance may be covered by more than one directive.

For new substances currently covered by the new substances Directive (92/32/EEC) that are also active biocidal substances, a regulation transferring the biocidal use from new substances to Biocides' area of responsibility is planned. If they are solely used as biocides the full responsibility for the substance is transferred. Until the creation of this regulation, the substances are covered by both directives.

For existing substances (Directive 79/831/EEC [13]) a similar rule is applied: the biocidal use of the substance is covered by the biocides directive (leading to an authorisation or not for this particular use) and other uses are covered by the risk assessment programme for existing substances.

4. Active substances

Active substances in biocides have a desired effect, typically a chemical activity, e.g., disinfection of drinking water by killing bacteria and viruses in the water. Such desired effects are very important for the general public health and without it significant public health problems may occur.

For specific applications there may be a range of active substances to choose from and an important step is then to select the one causing the minimum adverse effect. In addition, it is an advantage to have a range of active substances on the market to allow changing between substances to avoid biocidal resistance.

The current list of active substances contains chemical substances only; there is one entry for a bacteria. However, under the plant protection products directive some bacteria have been registered as active substances, and thus for the Biocides Directive the same trend is expected, and the directive addresses this issue.

Approved active substances are entered into one of three parts of annex I: annex I which contain active substances in general; annex IA which contain low-risk active substances; and annex IB which contain basic substances. The annexes I, IA and IB are currently empty, as no substance has been evaluated and approved. Whether a substance can enter annex I or IA depends on the properties of the active substance combined with the proposed use. A priori the directive contains a provision that substances which are carcinogenic, mutagenic, toxic for reproduction, sensitising or bioaccumulative and do not readily degrade cannot enter annex IA. The directive contains the following potential examples for annex IB: carbon dioxide, nitrogen, ethanol, 2-propanol, acetic acid, and kieselguhr.

5. List of substances

The list of existing active substances is now being compiled with a major input from CEFIC (Conseil Europeen de l'Industrie Chimique) which has submitted a list containing 915 entries. The Commission has added EC numbers (EINECS [14] or ELINCS [15] numbers) to the entries and checked for double entries. Then the list has been circulated to the 15 member states of the European Union for comments and additions. In this intermediate stage about 200 substances have been added and 'tributyltin co-polymers' has been expanded into 98 single entries. Member states have also been asked to indicate, where possible, in which product type(s) the substances are used.

This list has then been checked with listed information on substances from the following sources: IUCLID [16] list of High Production Volume Substances (HPVC), and the list of actives in PPP. About 200 actives are registered in IUCLID as HPVC chemicals and about 10% of these have been risk assessed or are undergoing risk assessment. In addition, the phase three of IUCLID, the registration of Low Production

Table 1
Statistical information on the provisional list of active substances (provisional data)

Source	No. of active substances	Percent, %
CEFIC	915	76
Expansion of tributyltin copolymers	100	8
Additional contribution from member states to CEFIC list as of November 1998	200	17
Total	1200	100
Substances with CAS number	950	79
Overlap with PPP	160	13
Overlap with IUCLID, HPVC (more than 1000 tonnes on the market)	200	17
Overlap with IUCLID phase three (10 to 1000 tonnes on the market, registration still on-going)	60	5
Overlap with annex I of 67/548/EEC (substances which are classified and labelled)	200	17
Overlap with risk assessed HPVC	25	2

Volume Chemicals (LPVC), the submission of data on substances on the market in amounts between 10 tonnes and 1000 tonnes should include many more substances used as biocides.

Thus, as seen from the above figures, there is an important overlap between biocides and the two other directives (67/548/EEC and 91/414/EEC). The figures in Table 1 are approximate as the deadline for the first survey on biocidal substances on the market was October 1998, and the results are not available yet. For example, 159 of the 915 substances on CEFIC's list are registered as plant protection products. It has not yet been analysed how many of the about 200 additional substances from member states are registered as PPPs.

Once this list is completed it will form a provisional list of active substances used in biocidal products. Industry will be asked to provide data on these substances corresponding, as a minimum, to annex VII A of Directive 92/32/EEC, which is basic acute and repeated dose toxicological and acute ecotoxicological data. The substances, which are on the market on May 13, 2000 will then be the final list of existing active substances and the intention is to publish this final list in the Official Journal of the European Communities. The list will be the basis for priority setting for the review programme.

6. Technical notes for guidance

To ensure the smooth introduction of the Biocides Directive, technical notes for guidance (TNG) are under preparation. These notes will be discussed by technical experts before final approval by the competent authorities for implementing the Biocides Directive. They are intended for publication in the Official Journal of the European Union.

The TNGs should serve as a common guidance within the European Union for authorities and industry to facilitate the application for entering an active substance into annex I, IA or IB, and the subsequent authorisation of biocidal products.

The first three guidance notes concern:

- details on data requirements;
- conditions for entry into annex I, IA or IB; and
- evaluation of products for approval.

They are under preparation and have been circulated twice to member states, non-governmental organisations and industry for comments with subsequent revisions.

A number of other guidance documents are planned with regard to procedures for reporting the results of the tests and the summary thereof, procedures for approval of earlier studies, and others as the day to day use of the directive shows the need.

7. Data requirements of the Biocides Directive

The directive defines the data requirements both for the active substances already on the market (i.e. existing) and new ones. The data required for the active substances are: identity of substance and impurities, acute and long term toxicology data and ecotoxicol-

ogy data; fate and behaviour in the environment, physico-chemical data, analytical data, efficacy data and epidemiology data when available. In comparison with other programmes requiring data for the assessment of substances, the Biocides Directive does not go by tonnage triggers (new substances), nor are the minimum requirements relatively low (existing substances). It comes closest to the requirements for PPP under 91/414/EEC.

Annex IIA and IIB address the core data set common to all the active substances and products, respectively, and annexes IIIA and IIIB address the additional data which may be required depending on possible uses and product types. Each data required must be addressed by a laboratory report and tests of Good Laboratory Practice (GLP) standard for the assessment of the substance and the products unless a justification not to do so is given.

Before placing a biocidal product containing a new active substances on the market, the new active substance will have to meet the full data requirements as laid down in annexes IIA and IIIA, and the associated new products will have to meet the full requirements in annexes IIB and IIIB.

Existing active substances are, in principle, subject to the same data requirements, but the placing on the market can continue until a decision not to enter the substance into annex I, IA or IB has been reached.

The directive has a category of substances, which are named basic substances, where the end-points required are the same as for any other active substance for biocidal use. However, for these substances, the submission of the test results as reported in literature is sufficient.

A number of ways to assess if tests may be omitted for existing active substances is given in the guidance document on ‘data requirements’.

7.1. Efficacy testing

The directive requires that the active substance is active against what it claims to be active against, i.e. effective. There are, however, only a few internationally recognised methods to test this claim and an effort from the Commission, with contribution from industry, is required to develop international criteria and testing methods in this area.

In an international context the OECD has recognised the importance of this and is launching a working group under the pesticides programme to describe, as a first step, the state of the art with regard to tests available. A second step will be, if necessary, to develop new test methods.

8. Conditions for entry into annex I, IA or IB

For an active substance (associated with a specific product type) to enter into the annexes states a risk assessment has to be performed as outlined in the technical guidance document on risk assessment for new and existing substances [17]. The first step is the hazard assessment of the active substances, which combined with an exposure assessment (of the products) leads to the risk characterisation. Depending on the risk

Table 2
Main categories and product types of active biocidal substances

(1) Disinfectants and general biocidal products
PT1: Human hygiene biocidal products
PT2: Private area and public health area disinfectant and other biocidal products
PT3: Veterinary hygiene biocidal products
PT4: Food and feed area disinfectants
PT5: Drinking water disinfectants
(2) Preservatives
PT6: In-can preservatives
PT7: Film preservatives
PT8: Wood Preservatives
PT9: Fibre, leather, rubber and polymerised materials preservatives
PT10: Masonry preservatives
PT11: Preservatives for liquid-cooling and processing systems
PT12: Slimicides
PT13: Metal working fluids
(3) Pest control
PT14: Rodenticides
PT15: Avicides
PT16: Molluscicides
PT17: Piscicides
PT18: Insecticides, acaricides and products to control other arthropods
PT19: Repellents and attractants
(4) Other biocidal products
PT20: Preservatives for food or feedstocks
PT21: Antifouling products
PT22: Embalming and taxidermist fluids
PT23: Control of other vertebrates

characterisations a risk management step may be necessary after which a decision whether to enter the substance into the annexes I or IA can be reached.

Annex IB is intended for substances which have only a minor use as biocides, as exemplified in the directive.

9. Annex VI (evaluation of products for approval)

Annex VI outlines the procedures for evaluation of the biocidal products to decide upon approval (or not) of the product. The guideline gives the general principles for

Table 3
Active substances in each main group of 1200 substances

Main group	Percent, %
(1) Disinfectants	42
(2) Preservatives	59
(3) Pest control	26
(4) Other biocidal products	11

Table 4
Active substances in main group no. 1 (of 87 disinfectants)

Product type	Percent, %
(1) Human hygiene b.p.	30
(2) Private area and public health area disinfectants and other b.p.	53
(3) Veterinary hygiene b.p.	33
(4) Food and feed area disinfectants	23
(5) Drinking water disinfectants	15

doing the evaluation, and illustrates the procedures and possible evaluation with examples.

10. Active viruses / fungi / micro-organisms

The directive also covers active substances which are fungi/micro-organisms/viruses. The number of this type of active substances is small, but nevertheless the directive contains provisions for evaluating them and enter them (or not) into annex I, IA or IB. An exact definition is needed, especially since some of these substances are dead fungi/micro-organisms/viruses and thus could be regarded as chemical substances.

11. Product types

The active substances are divided into four main categories with a total of 23 product types. Some of the product types are further classified into subgroups according to fields of use. The active substance will be approved specifically for a product type, possibly under a condition restricting the use to certain specific fields or groups of users. The product types will thus be the basis for the review programme. The four main categories and 23 product types are given in Table 2.

Table 5
Active substances in main group no. 2 (of 159 preservatives)

Product type	Percent, %
(6) In-can preservatives	14
(7) Film preservatives	14
(8) Wood preservatives	38
(9) Fibre, leather, rubber and polymerised materials preservatives	20
(10) Masonry preservatives	9
(11) Preservatives for liquid-cooling and processing systems	15
(12) Slimicides	24
(13) Metal working fluids	6

Table 6
Active substances in main group no. 3 (of 130 pest control products)

Product type	Percent, %
(14) Rodenticides	17
(15) Avicides	2
(16) Molluscicides	2
(17) Piscicides	0
(18) Insecticides, acaricides and products to control other arthropods	61
(19) Repellents and attractants	5

Table 3 indicates the distribution of the active substances and their distribution so far. The numbers are only indicative, and draw on two earlier incomplete studies, one for the Commission in 1995 [18] and the list of actives as compiled by CEFIC. The list that CEFIC supplied had the attributions: Disinfectants, Preservatives, Wood protection, Pest control, and Antifouling products.

The percentages add up to more than 100 as some substances are used in more than one main group.

Below in Tables 4–7 each main group has been analysed to indicate how the substances are distributed within the product types of that main group.

It should be noted that some of the active substances are used in many of the product types, i.e. are general biocides whereas others are used for one specific purpose. This can be illustrated by ordering the active substances according to the number of product types in which it is currently used, see Fig. 2, which is based on Ref. [14]. This study underestimates the overlaps as some of the substances are entered as a group entry, like phenolics, which are then counted only once, although more than one substance is actually involved.

12. Exposure scenarios

Each product type is believed to have its own use pattern and hence its own exposure scenario. In addition, the exposure scenario is thought to depend on the physical formulation of the product as well and the associated application pattern, e.g. the same active substance may be formulated into products sold in small spray cans, high-pressure knapsack spraying devices and dry powder, all of which have different exposure

Table 7
Active substances in main group no. 4 (of 54 other biocidal products)

Product type	Percent, %
(20) Preservatives for food or feedstocks	0
(21) Antifouling products	100
(22) Embalming and taxidermist fluids	0
(23) Control of other vertebrates	0

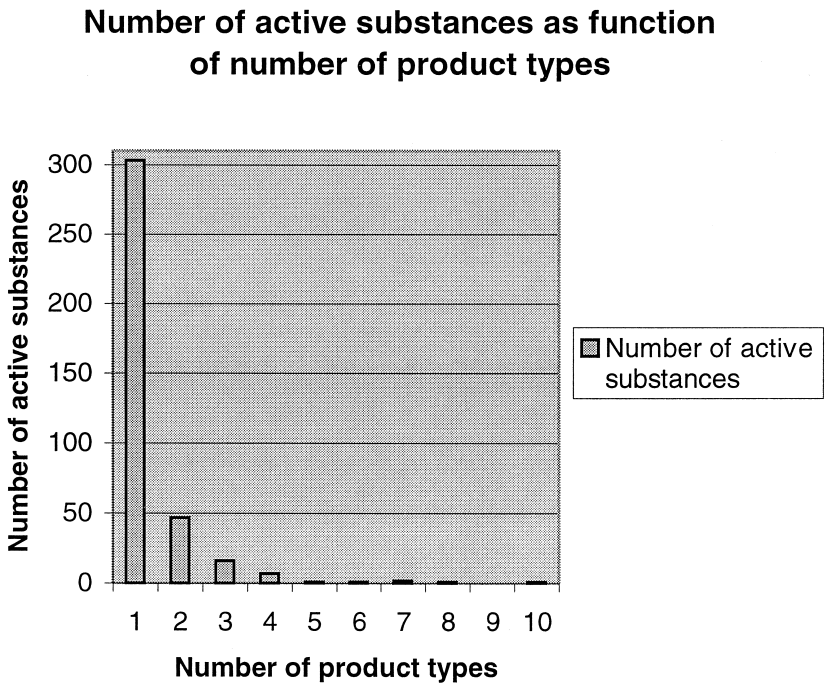

Fig. 2. Number of active substances per product types.

patterns. In addition, an effort is being made to define sub-categories of the product types, so-called fields of use, to be able to better define the exposure scenarios for some specific cases.

The exposure scenarios are divided into human exposure and environmental exposure, and are currently being developed for each product type. They are important as the data requirements partly depend on the exposure scenarios.

To better understand the mechanisms of exposure the Commission formed a working group investigating these aspects [19]. The group consisted of participants from the Health and Safety Executive, TNO, RIVM, the Commission and Industry. The final report of the group will be available from the EU.

A need for a similar group for environmental exposure has been identified.

13. Review programme

Through the current effort to identify active substances used in biocidal products described earlier, a list of active substances is being compiled. This list will be the list of existing active substances as of May 13, 2000. New active substances are by definition those placed on the market after that date. This differentiation is important as new active substances have to be approved before being placed on the market whereas the existing ones will be reviewed product type by product type over a 10-year period.

The review of the existing substances is expected to be the major effort associated with biocides; experience from a similar programme in the USA showed that almost no new active substances have been applied for.

For the review programme consideration will be made of previous conclusions on the active substances evaluations under other Commission directives to determine whether it can be re-used for the biocides regulation.

The directive itself does not contain details on the review of the existing active substances and to meet the need for more details concerning this aspect, a regulation [2] on the review programme is now under discussion between the Commission and the member states.

The review programme is planned to run in four phases:

(a) data collection step A (available test results),
(b) priority setting,
(c) data collection step B (full data set, full reports), and
(d) evaluation of the active substance and associated products.

13.1. Data collection

The data collection will be in two steps: firstly the available information will be surveyed, the end-point (test results) information must be submitted (Step A). Then for the evaluation of the active substance a full data set must be submitted (step B).

It is planned in the first phase to collect some minimum information corresponding to the information called the 'base-set' for existing substances and annex VII A data for new substances.

The initial data collection for the priority setting will be done through a system similar to the IUCLID system used for the existing substances programme.

13.2. Priority setting

The priority setting will be based on the approach used in EURAM [20] where substances are ranked based on a combination of their hazardous properties and the exposure, taking into account both toxicological and environmental aspects.

The resulting priority lists will be published in the Official Journal allowing industry to time plan the testing programme to obtain test results for missing data.

13.3. Substance and product evaluation

The final step for each substance is the evaluation of the data with the end-result of annex I entry (or non-entry) of the active substance for the proposed product category,

[2] The difference between a regulation and a directive is that the Commission is responsible for a regulation and it enters into force immediately in the member states without integration into national legislation, whereas directives are under the responsibility of the member states and need to be integrated into national legislation. Member states are given adequate time to integrate the directives.

as the review is planned product type by product type. This means that in theory a substance can be reviewed 23 times if it is used in all 23 product types. However, due consideration of earlier reviews will be taken into account.

14. Discussion and conclusions

The directive on the placing on the market of biocidal products (98/8/EC) addresses the dangerous properties of a specific subset of chemicals, which are used against unwanted biological organisms.

A key concept in the directive is the 'active substance' which needs to be approved according to the directive, together with the product in which the active substance is sold on the market.

There are an estimated 1200 active substances on the market at the moment. An indicative statistic analysis shows that most substances are used in one product type only; however at least 20% of the substances are used in two or more product types.

The directive foresees that these biocides will be placed on acceptance lists (annexes I, IA and IB), and reviewed periodically. Currently, guidance documents are in preparation to clarify the data requirements and their dependence on the product type(s) in which the substance is used.

In addition, guidelines on the entry into the annexes I, IA and IB, and guidance on the evaluation of the risk(s) associated with the products are being produced.

The existing programmes on risk assessment of chemicals can efficiently be used as a starting point for the biocides review.

The directive requires that the active substances must be effective against what it claims to be active against. There are, however, only a few internationally recognised methods to test this efficacy claim. OECD is setting up a working group to get an overview of available methods and future needs for method and criteria developments.

The active substances on the market on May 13, 2000 are existing active substances and will go through a review programme, which will last 10 years. Substances placed on the market after that date are new active substances and will be sent to the evaluation procedures immediately, before being placed on the market.

For the Biocides Directive the exposure scenarios will be very important for estimating the risk and a working group was set up to collect available human exposure information and to look at future needs. It is expensive to measure human exposure in the field and data should be extrapolated as far as possible, and available models used.

A similar effort is needed to investigate the environmental exposure.

In comparison with other programmes requiring data for the assessment of substances the Biocides Directive does not go by tonnage triggers (new substances), nor does it put in a 'low' minimum requirement (existing). It comes closest to the requirements for the placing on the market of plant protection products (Directive 91/414/EEC).

Current surveys of active substances show that a large number of these are covered by other existing legislation. As much information as possible will be extracted from the existing data collections, in order to minimise the cost and effort needed to implement the Biocides Directive.

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