COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

COUNCIL DIRECTIVE

concerning the placing of biocidal products on the market

(presented by the Commission)

EXPLANATORY MEMORANDUM

INTRODUCTION

Biocidal products comprise a wide range of products necessary for the control of organisms that are harmful to human or animal health or that cause damage to natural or manufactured products. They include such diverse groups of products as wood preservatives, insecticides, water biocides and disinfectants.

During the discussions of Directive 91/414/EEC(1) concerning the placing of plant protection products on the market, the Council of the European Communities requested that it be informed of the Commission's intention in the area of non-agricultural pesticides. (biocidal products).

Also, at the time of adoption of the Eighth Amendment to Directive 76/769/EEC(2) on 21 December 1989, the Council requested that the Commission develop a Community strategy on the marketing and use of biocidal products particularly wood preservatives.

Accordingly, Commission services reviewed the possibilities for introducing regulatory measures at the Community level for biocidal products.

The review found that biocidal products are an extremely varied group of preparations with very varied exposure scenarios and widely

(1) O.J. N° L230, 19.08.1991, p. 1
(2) O.J. N° L262, 27.09.1976, p. 201

differing regulatory controls in Member States. The Commission therefore made a statement towards the Council concerning non-agricultural pesticides (biocidal products) (doc. SEC(90) 1895) and proposing the development of a directive in this area..

What are the objectives of the action envisaged in connection with the obligations which the Community has?

The review found that biocidal products currently have a highly diverse regulatory status in the Community that could lead to barriers to trade between Member States creating unequal conditions of competition and thereby directly affecting the establishment and functioning of the internal market. Also their production and use may entail dangers for man and the environment. Details of the different regulatory approaches adopted by Member States are set out in annex I

In order that the establishment and functioning of the internal market is not affected and to ensure that there is a high level of protection for man and the environment with regard to these products, the Commission therefore consideres that there is an urgent need for Community action in this area.

Does the action envisaged fall within the exclusive competence of the Comunity or is it a competence shared with Member States?

The Commission proposes action in the form of a directive based on Article 100a of the Treaty which is concerned with the approximation of the laws, regulations and administrative provisions relating to the placing on the market of biocidal products.

The proposed Directive will ensure that a harmonised approach is taken within the Communities to placing biocidal products and their active substances onto the market. This will stop fragmentation of the EEC market in chemicals. Therefore competence in this area is exclusively for the Community.

Is a uniform regulation necessary or would a directive giving general objectives be sufficient in the case that the execution would be done by Member States and what modalities for action are at the disposal of the Community?

A Directive has been chosen as the most appropriate method of achieving the necessary harmonisation. It will enable a broad legislative framework to be established a Community level with individual Member States left to implement detailed requirements necessary to put it into effect.

The proposal follows similar principles to those laid down in Directive 91/414/EEC and is closely harmonized with it, to avoid double testing of active substances common to both plant protection products and biocidal products . A positive list approach is also proposed with requirements for inclusion onto it varying as a function of the nature of the substance and its envisaged use, taking as a base, a high level of protection for man and the environment. A regime of mutual authorisation of biocidal products between Member States is also provided for.

The Directive is concerned with preparations and substances which by their nature are designed to have detrimental effects on the organisms they are intended to control, and a large proportion of which are classified as dangerous. The Commission has therefore chosen to develop a directive which establishes a framework based on a system of authorisation of biocidal products in Member States with listing at Community level of active substances to be used in such products. It is appropriate that a clear system of refusal or acceptance is established for biocidal products to enable a high level of protection for man and the environment to be realised. Furthermore, it is appropriate for the purposes of harmonisation of this directive with Directive 91/414/EEC which establishes an authorisation scheme for plant protection products.

THE LEGISLATIVE FRAMEWORK AND SHARING OF RESPONSIBILITIES

The authorization scheme for biocidal products is to operate at the level of the Member States, unless differences arise which require referral to the Community level. In a so-called "decentralised procedure" the applicant submits his application in the form of a technical dossier to the Competent Authority in the Member State where the preparation is to be marketed. The Competent Authority will then evaluate the dossier and decide whether it fulfills the authorization conditions laid down in this Directive and propose any restrictions on the use of the preparation that appear necessary to protect man and the environment.

In general terms it is necessary that this proposal for a Directive includes authorization conditions. The conditions are designed to ensure that authorisation is given only those biocidal products which present an acceptable risk through their development, use, and disposal for man or the environment, which are sufficiently efficacious and which include active substances which are permitted to be used in biocidal products within the European Community following agreement at Community level.

If an application is accepted, the biocidal product is then authorized for use in that Member State subject to any specified use conditions. Equally important however is the provision for mutual recognition of this authorisation. According to this provision a biocidal product authorised in accordance with the directive must, upon application and in line with a Member State's obligations under the directive, also be authorized as a matter of routine in any other Member State of the Community. In order to maintain the integrity of the internal Community Market for biocidal products, this principle of mutual recognition of authorisations is expected to be upheld in the vast majority of cases, however the possibility of exceptions to this general rule are recognized in the Directive, i.e. where one of the conditions for authorization cannot be met.

Currently, there are approximately several hundred active substances on the market within Member States which serve as the biologically active components for several thousand biocidal products. For the active

substances, the Commission proposes that Authorization should be at the level of the Community in a "centralised procedure".

Essentially, the same authorization conditions and possible use restrictions will be applicable to active substances as to biocidal products. Under the terms of the Directive, following authorization, active substances are included on a positive list of active substances that may be used in biocidal products Community-wide.

The establishment of this positive list, which will be Annex I to the Directive, will mean that a clear unambiguous list of active substances for use in biocidal products is available. The list will not only facilitate the detection of those active substances placed on the market illegally, but in addition will also provide a useful checklist for formulators in the chemicals industry as to which active substances may be used.

REQUIREMENTS FOR DATA AND REVIEW OF EXISTING PRODUCTS

Authorization of biocidal products and acceptance of their active substances depends upon an evaluation of their respective technical dossiers containing information supplied according to the data requirements in Annexes II-IV to this Directive. The data required for a particular product will be closely related to and depend upon, the product's uses and the risks that are likely to arise for man and the environment from such uses. Once such data has been submitted, an evaluation is made in the light of the current scientific and technical knowledge. Taking this into account, the Commission proposes that both active substances and biocidal products should be reviewed periodically, a fixed authorization period of ten years has thus been specified for both. Provisions are also made in the Directive for the possibility of review at any time in circumstances where the original authorization criteria are no longer satisfied.

Realistically the Commission appreciates that the full implementation of the authorization scheme established in this Directive will take several years. In a ten year transitional period therefore, Member States will be entitled to permit the placing on the market in their territory of biocidal products which were on the market prior to the

implementation date of the Directive. After the adoption of the Directive, it is envisaged that the Commission will commence a programme of work to review the active substances of these existing products.

In order to promote and sustain investment in the continuing development of active substances and products, and to ensure an efficient programme of review, it is necessary to provide protection for the intellectual property (data) an applicant submits to Member States in support of applications. Such protection must apply to new data submitted, data submitted during the review period and subsequently, and to any data submitted under existing national controls on biocidal products.

The data requirements for biocidal products and their active substances are very similar to those that are required in Directive 91/414/EEC for plant protection products and their active substances. Given the diversity of the chemicals being considered here, it has been necessary for the Commission to adopt a flexible approach as to which particular data are required for each product type. Therefore certain pieces of information which are not necessary owing to the nature of the chemical or its proposed or existing uses need not be supplied. Such flexibility is particularly necessary for existing substances and products which have a long history of safe use as biocides. Conversely, the competent authority will be entitled to ask the applicant to submit further information, if the assessment of the dossier shows that additional information including further testing is necessary to evaluate the risks that placing on the market of the biocidal product entails.

Moreover, the Council in its resolution of 1 February 1993 on a Community programme of policy and action in relation to the environment and sustainable development[3], recognized that economic growth and environmental quality must be viewed as mutually dependant. Consequently, the strenghthening of environmental protection is dependant upon the economic competitiveness of industry being maintained. The directive is drafted with this in mind. Its provisions, particularly those concerned with research and development and the

3 O.J. No C 138, 17.05.1993, p. 1

protection of intellectual property, are aimed at encouraging the sustained development of biocidal products with a reduced impact for man and the environment.

This proposal concerns the placing on the market of biocidal products. The Commission recognises that, in the future, it may be necessary to provide minimum requirements for training and experience of persons using certain types of biocidal products.

PARTICULAR COMMENTS ON CERTAIN ARTICLES OF THE PROPOSED DIRECTIVE.

Article 1

Article 1 describes the purpose and the scope of this Directive. The aim of this Directive is to harmonise within the Community the placing on the market, of biocidal products and the establishment at Community level of a positive list of active substances that may be used in biocidal products.

The Directive will be applied without prejudice to other areas of existing Community law and therefore to avoid duplication of effort, harmonisation will be achieved between the current proposal and the other legislation.

Article 2

Article 2 gives the definitions of terms used in this Directive. The definitions of "biocidal products", "active substances" and "residues" are analogous but complementary to the definitions given in Directive 91/414/EEC.

Article 3

The general conditions relating to the authorization for placing on the market of biocidal products are laid down in article 3.

As a prerequisite to being placed on the market, a biocidal product must be authorized by the Competent Authority of the Member State where it is to be marketed.

Importantly, for the harmonisation of this authorization scheme, this article provides for mutual recognition between Member States. However, the Commission acknowledges that owing to differing conditions between Member States, in certain exceptional cases, a derogation from mutual recognition should be applicable. As a result, this article permits Member States to modify the biocidal product depending on the circumstances and sets out the course of action to be followed where a Member State believes it cannot authorize a product. It is stressed though that for the vast majority of cases, mutual recognition will apply.

Article 4

In order to maintain a high level of protection for man and the environment it has been necessary to ensure that certain conditions are fulfilled before a biocidal product may be authorized. These conditions are laid down in article 4.

Articles 5 and 6

Biocidal products already authorized and on the market may need to be reviewed if new information comes to light, Article 5 provides for this. Article 6 deals with cancellation or modification of an authorization and sets out the circumstances under which such changes may be made. In the case of modification of an authorization and in order to avoid unnecessary duplication of effort and additional time and cost for the applicant, the entire authorization procedure need not be followed in full every time. Instead, once any extra information requirements are supplied and the Commission, or Member State, as appropriate, is satisfied that the authorization conditions are met then the authorization may be extended to the new use.

Article 7

Article 7 is concerned with the requirements that have to be met when an application is made for the authorization of a biocidal product. The detailed information which must be supplied in the technical dossier is laid down in Annexes II, III and IV.

Article 8

Article 8 deals with the placing on the market of active substances for use exclusively in biocidal products. The article is required as such substances are excluded from the requirements of 67/548/EEC[4](7th Amendment).

Article 9

Article 9 lays down the conditions which must be fulfilled before an active substance may be included on the positive list in Annex I to the Directive; inclusion in this list being a prerequisite to use in a biocidal product.

Active substances may only be included in Annex I if, in the light of current scientific and technical knowledge and from the evaluation of the information required under Annex II, III and the relevant parts of Annex IV, the biocidal product into which the active substance is to be incorporated, during use and disposal, will not have any harmful effects on human or animal health, or any unacceptable effects on the environment.

Additionally, to further protect man and the environment, provisions are made here to allow refusal of entry of an active substance onto annex 1 if alternative substances, or methods exist which in the light of current knowledge offer significantly less danger to human health or to the environment. A proviso is made however, that such an alternative method should not present significant economic or practical

(4) O.J. N° L196, 16.08.1967, p. 1

disadvantages to the user and that an evaluation demonstrating this must be made.

Article 10

Article 10 lays down the procedure for inclusion of an active substance in Annex I. All decisions concerning the active substances' inclusion on the positive list will be decided at Community level. The Commission proposes that such decisions are most appropriately dealt with at Community level because inclusion on the positive list will mean that an active substance may subsequently be used widely in biocidal products in any of the Member States. Biocidal products, on the other hand are best dealt with at the Member State level since they will be used locally. The article sets out the procedures and timescales whereby dossiers on active substances are evaluated.

Article 11

Article 11 is an important article from the point of view of commercial data protection as it sets out rules whereby data held by Competent Authorities may be used for the benefit of other applicants.

Under Article 11, the Commission foresees that information supplied for the purposes of inclusion of an active substance in Annex 1 and authorization will be protected for certain periods. Article 11 obliges Member States not to use any such information for the advantage of any subsequent possible applicants unless prior agreement is given by the first applicant.

Article 12

Article 12 lays down provisions to avoid unnecessary testing on vertebrate animals. It provides for subsequent applicants for authorisation to make use of the first applicants data in those Member States where the data protection period has expired. Importantly for animal welfare, in circumstances where an application is made for the

Authorization of a biocidal product which is identical to a previously authorized preparation, and where data is still subject to protection the Competent Authority in that Member State can take steps to avoid unnecessary duplication of testing on vertebrate animals. One such step is to supply the name and address of the current authorization holder to the second applicant with a view to sharing the information. In the event that an agreement cannot be reached between applicants, this article permits Member States to force an agreement between concerned parties located in their territory through the introducing of national legislation to this effect.

Article 13

In the event of new information becoming available concerning the potential harmful effects of any authorized biocidal product, or any part of it, this article obliges the applicant to immediately pass this on to the Competent Authority of the Member State where the Authorization is granted. It also obliges the Member State to inform the Commission and other Member States quickly where such information becomes available.

Article 14

Article 14 is concerned with transitional measures and derogations from the normal requirements of this Directive.

In the drafting of this proposal for a Directive, the Commission has recognised that limited derogations from the full requirements of this Directive may be necessary for restricted periods. Such derogations are confined to circumstances where such a measure appears necessary because of an unforeseen danger which cannot be dealt with other than by a limited and controlled use of an unauthorized biocidal product and to provisional placing on the market where a Member State believes a product and active substance meet the requirements of the directive but entry is not yet made on Annex I.

Though such derogations are provided for in this article, it is emphasised that strict conditions will be applied to the derogations and that they will be subject to prior satisfaction of the Member States concerned that the proposed marketing will not entail harmful effects for human or animal health or have an unacceptable effect on the environment.

This article makes also provisions for a ten year transitional period after the implementation date of this Directive. To enable the chemical industry to adjust to the requirements of this Directive, during the transitional period, Member States may authorize within their territory biocidal products that contain active substances not included in the positive list. The proviso to this is that such active substances were already used in biocidal products on the market prior to the implementation of the Directive.

The Commission will initiate a work programme to gradually examine these active substances that are not included in Annex I. This programme will be harmonised with other work programmes within the framework of other Community legislation concerned with the review or authorization of substances and products. In the meantime however, Directive 76/769/EEC on the approximation of the laws; regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations will serve to provide a framework to complement, on an ad-hoc basis, as well as systematically, where necessary, the restriction or banning of the use of certain active substances or groups of these.

Article 15

To allow for research and development of new active substances and biocidal products, it introduces provisions analogous to those in 67/548/EEC (7th Amendment) for scientific and process oriented research. To maintain a high degree of protection for man and the environment if trials involving release into the environment are to take place a "trials" authorization must be obtained from the competent authority of the Member State where the trials are to take place.

Article 16

Article 16 deals with the obligations on Member States with respect of the operation of the authorization scheme for biocidal products and the flow of information between Member States following authorization.

Of particular importance, is the necessity of information exchange, periodically, between Member States and the Commission, and between themselves. Such information exchange will help to ensure that the internal market for chemicals operates effectively and that mutual recognition between Member States is upheld.

Article 17

This article is an important one for the chemicals industry since it specifically deals with confidentiality for commercial reasons of the information submitted according to this Directive. In a manner analogous to that of other EEC chemicals legislation, information submitted here may be regarded as confidential if so requested by the applicant. However, as usual, certain basic information essential to ensure the safety to the user, to the environment and information that may be important in case of an accident may not be regarded as confidential.

Articles 18.

This article is concerned with the classification, packaging and labelling of biocidal products.

In general terms the Commission believes that for the classification, packaging and labelling of biocidal products, the well established provisions of Directive 88/379/EEC(5) should apply.

(5) O.J. N° L187, 16.07.1988, p. 14

The Commission has particularly noted that for the very diverse group of preparations which biocidal products represent, Directive 88/379/EEC most comprehensively provides for their labelling, rather than the more restricted scheme under Directive 78/631/EEC(6) which is applicable to plant protection products and some types of biocidal products. Despite the applicability of Directive 88/379/EEC, in the current proposal it has nevertheless been necessary to add certain, biocide-specific labelling requirements to those of the existing labelling Directive.

Articles 19, 20 and 21

These three articles are concerned with specific safety requirements for placing biocidal products and their active substances onto the market.

Article 22

This article obliges Member States to make provisions for surveillance of the authorization scheme in their individual territories and to provide reports to the Commission.

Article 23

This article requires Member States to establish competent authorities to undertake authorizations and related work required by this directive.

Article 24

This article establishes the procedure whereby the Commission will prepare a proposal in respect of recommendations on active substances or proposals to refuse authorization.

(6) O.J. N° L206, 29.07.1978, p. 13

Article 25

This article establishes a standing committee on biocidal products and provides for decision taking on the basis of either procedure I and procedure IIIa, according to the nature of the matter to be decided.

Article 26

This article provides for the development of common principles for the evaluation of dossiers to be applied by Member States, when considering products for authorisation.

Article 27

This article provides for adaptation to technical progress.

Article 28

This article is included to ensure that persons placing biocidal products on the market cannot claim authorization as protection from civil or criminal action.

Article 29

Article 28 is an important article since it is a safeguard clause which can override the normal provisions of this Directive. The terms of the article permit any Member State which has any valid and justifiable reason(s) to suppose that a product constitutes a risk to man or the environment to restrict or prohibit the use or sale of it in its territory.

However, in order to avoid misuse of this clause and ensure a harmonized approach is taken to any such action, the Commission

proposes that such a decision will be referred to the Standing Committee described in article 25.

Article 30

This article lays down the obligation for Member States to implement this Directive and the date by which this must be achieved.

ANNEX I

Annex I is to contain the list of Community-approved active substances which, in the light of current scientific and technical knowledge when used in biocidal products, do not have any harmful effect on human or animal health or any unacceptable effect on the environment.

ANNEXES II, III AND IV.

Annexes II to IV set out the data requirements for the appraisal of biocidal products and their active substances. Owing to the diverse nature and broad range of uses which are characteristic of biocidal products, the Commission proposes that the data requirements in Annexes II to IV should be flexible. Annex II therefore provides the data requirements for active substances; and where necessary, additional, use-specific requirements are set out in Annex IV. Similarly for biocidal products , the data requirements are laid down in Annex III and the relevant parts of Annex IV. The interpretation of the data requirements will be assisted by common principles for the evaluation of technical dossiers.

Tests required under Annexes II to IV should be carried out in accordance with the provisions laid down in Directive 86/609/EEC(7) on the protection of animals used for experimental and other scientific purposes and with Directives 87/18/EEC(8) and 88/320/EEC(9) on the

(7) O.J. N° L358, 18.12.1988, p. 1
(8) O.J. N° L 15, 17.01.1987, p. 29.
(9) O.J. N° L145, 11.06.1988, p. 35

application of the principles of Good Laboratory Practice and the verification of their applications for tests on chemical substances.

ANNEX V

Annex V establishes an indicative list of product types which are considered as being biocidal products.

ANNEX I

LEGISLATION IN THE MEMBER STATES OF THE EUROPEAN COMMUNITIES

BELGIUM

The Royal decree of 5 June 1975 concerning conservation, trade and the utilisation of pesticides and phytopharmaceutical products is extended to cover certain groups of biocidal products. Namely, those pesticides which are used to eliminate or combat organisms or micro-organisms which cause a nuisance in buildings, transport means, waste sites, swimming baths and other materials or objects, prevent decay or damage to animal or plant products, to combat or eliminate ecotoparasites of small domestic animals and those which are used to treat plants, water or soil in order to combat organisms which cause illnesses to man or to animals. Notable exemptions include substances and preparations used as antiseptics or disinfectants for surgical material, additives for food and feedingstuffs and biocidal products used for research and scientific trials.

Authorization of the biocidal products and active substances thereof follow submission of technical data as for phytosanitary products. Surface disinfectants have separate requirements which are laid down by Superior Council of Public Hygiene (CSHP).

The authorization may be refused, or it may be subsequently withdrawn or suspended if this can be justified or it is for reasons of public health.

DENMARK

An approval system for pesticides was set up in Denmark with the entry into force of the Chemical Act in 1980. The approval system is applicable to both agricultural and biocidal products with fields of application in industry, private households and gardens as well as in agriculture.

Approval by the Danish National Agency of Environmental Protection (EPA) is subject to proof by the applicant that the product is not considered dangerous to health or to the environment. All relevant information is supplied concerning the formulated product and each active substance. Further tests may be required.

With the amendment of the Chemical Act in 1987, provisions were made for hazard assessment of pesticides. Criteria have been worked out to decide when pesticides should be considered dangerous or harmful to the environment and therefore cannot be approved. Additionally, alternative assessment operates such that a given pesticide may not be approved if a significantly less hazardous alternative exists which fulfills the above role.

All approvals are subject to time limits. Pesticides classified as very toxic or toxic are limited to an approval of four years, the remainder, eight years. Currently, the Danish EPA is re-evaluating the old pesticides which were on the market before 1980.

GERMANY

Comprehensive legislation for all biocidal products does not exist in Germany. Instead, a number of specific substances are regulated in different pieces of legislation (e.g. DDT, PCP, certain fumigants). Also there are some general requirements which apply for certain groups of chemicals (e.g. indoor insecticides and specific public hygiene disinfectants). Additionally, there are some standards and voluntary labelling guidelines for wood preservatives used in the construction industry.

GREECE

In Greece, pesticides for plant protection or other applications are all classified as "Agricultural" pesticides and their marketing is governed by the National Law 721/7.10.1977 (Official Journal 298/A/1977).

According to this law, a notification procedure is required and the producer or importer has to be authorized before the circulation of each product is permitted. All legally marketed products are listed in a national inventory. Certain restrictions or limitations of products from specific uses may be imposed by ministerial decisions.

Quality control of marketed products is provided by random sampling. Checks are made on the authorization, the packaging and labelling and on the active substances as compared to that which are described on the label.

SPAIN

Biocidal products are regulated by Royal Decree 3349 of 30 November 1983 which approved the health and hygiene regulations governing the manufacture, marketing and use of pesticides.

The scope of this Decree includes pesticides for domestic use by non-professionals; preparations for personal hygiene; those used in the environment including for disinfection purposes; insect and rodent control; pesticides to be applied in the foodstuffs industry and for use in stock rearing.

Use-specific registers are kept of the biocidal products that are placed on the market. Inclusion on one of the registers requires that approval must be given by the Directorate-General for Public Health following a review of data provided concerning the potential risk of the preparation to human health.

A surveillance system exists to control the marketing of biocidal products which are classified as very toxic or toxic. Such products may not be sold or stored in establishments where food products or animal feedingstuffs are on sale. In addition these preparations which are classified as very toxic may only be used by individuals or firms specifically authorized to do so. Authorization follows successful completion of training courses or examinations and the use of the biocidal products itself must be accompanied by warning signs displayed in the treated areas.

The same restrictions apply to preparations for use in the environment which are classified at least as toxic.

FRANCE

At present there is no framework legislation that requires authorization of biocidal products. Certain products however, must be authorized prior to being placed on the market.

Depending on their use, herbicides must be authorized by the Ministry of Agriculture following the law of 2 November 1943 concerning the control of antiparasite products for agricultural usage. Similarly, specific categories of disinfectants require Authorization as do pesticides that are incorporated into medicines.

Additionally, it is also possible to prevent or regulate strictly on a case-by-case basis the placing on the market of biocidal products that present specific dangers.

The labelling of biocidal products is subject to rules from the Decree of 28 March 1989 which transposed Directive 78/631/EEC into national law.

IRELAND

The Pesticide Control Unit of the Department of Agriculture and Food is the competent authority in Ireland dealing with all aspects of Regulations pertaining to pesticides, including biocidal products. Biocidal products are regulated by two Regulations : the Poison Regulations. 1983 as amended; and the European Communities (classification, packaging and Labelling of Pesticides) Regulations 1985 as amended.

The Poisons Regulations regulate the availability of pesticides. Certain preparations are only sold by pharmacies, whilst less toxic ones may be purchased through licensed outlets. Others are limited to

professional use only and in extreme cases certification of the user may be required by the local police.

Clearance, classification, packaging and labelling of biocidal products is provided for by the European Communities Regulations 1985. Clearance is granted following evaluation of a dossier containing data which approximate the requirements of Annex VII and Annex VIII of Council Directive 79/831/EEC. The preparation is then cleared for the uses specified on the label.

ITALY

Since 1954, Italian legislation has required that disinfectants for agricultural use and pesticides be registered as "medical/surgical equipment". Further Government Decrees cover the registration, as medical/surgical equipment, of rodenticides (Decree dated 26.01.76), snail-killers and insecticides for use on flowers or plants (Decree of 6.03.78), fungicides, and of insecticides and snail killers for use on flowers or plants domestically.

Registration as medical/surgical equipment, particularly of preparations containing new active substances requires certain data. Data requirements include a detailed description of the nature and dosing regime of the preparation; efficacy testing and the necessary toxicity testing to classify the preparation and to identify the risks involved with its use.

The labelling of the biocidal product should be in conformity with the preparation's main action.

LUXEMBOURG

The Statute of 20 February 1968 with the purpose of controlling pesticides and phytopharmaceutical products authorizes The Grand-Duke to regulate the manufacture, import and use of these products. The implementing Regulation of this law concerning pesticides for non-agricultural usage has not yet been adopted.

Certain biocidal products are covered at least in part by the three existing Directives (Classification and Labelling, Dangerous Substances and Limitation of Use of Certain Products). Others are covered in practice by the Regulation concerning pesticides for agricultural usage, though the boundary between the two categories is not always clear.

NETHERLANDS

The regulations for biocidal products encompass a very broad range of products. They include disinfectants, pesticides for domestic and industrial use, wood preservatives, anti-fouling paints, fumigants for stored products, ectoparasiticides and human skin insect repellants. All herbicides however are considered as agricultural pesticides.

For biocidal products, the same basic regulatory principles apply as for agricultural pesticides. Trade in and use of these products is only permitted after registration and a full dossier is provided by the applicant which includes efficacy data, public health, worker protection and environmental risk data. Specifications are laid down for each product category.

The Regulations include provisions for use : limitation of use to specified applications, user category; professional training and licensing and environmental requirements such as distance of fumigated object to surrounding buildings. Additionally, rules are laid down for publicity and advertising, waste disposal of pesticides and containers, for surveillance and for residues in foodstuffs.

PORTUGAL

Prior to being placed onto the market in Portugal all pesticides have to be registered by the National Pesticide Toxicological Commission (CTP) as one of the following : agricultural, household, industrial, a wood preservative or a pesticide for use on human beings.

The data requirements for each group are different. The requirements for agricultural pesticides are usually the most stringent, but preparations for one of the other categories which contain a new active substance, will require a toxicological evaluation similar to that of agricultural pesticides. In any case, sufficient data must be supplied by the applicant to enable a classification into one of the categories.

On approval of a particular product by the CTP the risk and safety statements for the labelling of it will then be defined.

Pesticides for use on cattle, poultry and domestic pets are considered separately and evaluated by the commission for New Medecines.

UNITED KINGDOM

Pesticides in the United Kingdom are controlled by The Food and Environment Protection Act 1985 and the Control of Pesticides Regulations 1986. Northern Ireland has its own, identical Regulations.

Under the Regulation no pesticide product may be sold, advertised, supplied, stored or used until Government Ministers give approval. Approvals are usually specific for a particular use and application method. There are three levels of approval : an experimental permit, to enable the product to be developed; a provisional approval, when the product is considered safe, but further data is required; and a full approval, when the product has been shown to be safe and effective.

To obtain an approval for a product, the applicant must submit data to the relevant registration department. For most biocidal products, this is the Health and Safety Executive, the exception being for rodenticides, for which the data must be supplied to the Ministry of Agriculture, Fisheries and Food.

In the UK, biocidal products include wood preservatives, insecticides (public hygiene and domestic use), surface biocides and anti-fouling paints. Disinfectants, substances used to treat textiles and surface water biocides are not currently covered by the Regulations but these could be in the future.

The data required for approval consists of a base set for all biocidal products and then additional data is required according to the type of product and its area of use. An evaluation of the data is made and assessed by a scientific-sub committee which then, once satisfied, refers the application to an advisory Committee (ACP) set up by the Food and Environment Protection Act. The ACP then makes its recommendations to Ministers. The approval can at any time be suspended, amended or revoked if new data becomes available which causes concern.

A review scheme is currently in operation to examine existing active substances for pesticides. All approved pesticides are published annually in a list form.

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission[1]

In cooperation with the European Parliament[2],

Having regard to the opinion of the Economic and Social Committee[3],

Whereas provisions relating to certain dangerous substances and preparations have already been laid down in Community Directives; whereas it is still necessary to establish rules in respect of other products which contain dangerous substances and which may involve risks for man and the environment.

Whereas, in 1989, at the time of the adoption of the 8th Amendment[4] to Council Directive 76/769/EEC[5] on the marketing and use of certain dangerous substances and preparations, the Council invited the Commission to develop specific measures for Community action in the field of non-agricultural pesticides;

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1 O.J. ...

2 O.J. ...

3 O.J. ...

4 O.J. No L 398, 30.12.1989, p. 19

5 O.J. No L 262, 27.09.1976, p. 201

Whereas during the discussion in the Council on Directive 91/414/EEC[6], the Council expressed concern at the lack of harmonised Community provisions for non-agricultural pesticides and invited the Commission to examine the situation in Member States and the possibility for action at Community level;

Whereas the term "non-agricultural pesticides" was formerly used to make a distinction with plant protection products which are essentially agricultural pesticides; whereas, however, biocidal product is now a more accurate and appropriate term to describe the products covered by this Directive.

Whereas biocidal products comprise a highly diverse group of products, including wood preservatives, rodenticides, insecticides, anti-foulings, surface and water biocides, disinfectants, fumigants, preservatives for technical and household materials, preservatives for works of art, and others; whereas they can give rise to exposure of man and the environment in a great variety of ways;

Whereas biocidal products are necessary for control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured products;

Whereas the Commission review showed a diverse regulatory status in the Member States; whereas there are rules in a few of the Member States governing the placing on the market for use of biocidal products and whereas these rules differ as to the conditions for such placing on the market and whereas such differences may constitute not only barriers to trade in biocidal products but also to trade in products treated with them, thereby affecting the functioning of the internal market;

Whereas in consequence the Commission concluded there was a need for action at Community level to eliminate such barriers by harmonizing the

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6 O.J. No L 230, 19.08.1991, p. 1

rules relating to the placing on the market for use of biocidal products, taking as a condition a high level of protection for man and the environment;

Whereas therefore, the Commission made a statement towards the Council proposing the development of a framework of rules; whereas, having regard to the principle of subsidiarity, decisions taken at Community level should be restricted to those necessary for the proper functioning of the Common Market and to avoid duplication of work by Member States taking into account the necessity to ensure a high degree of protection for man and the environment throughout the Community and whereas a directive on biocidal products (non-agricultural pesticides) is the most appropriate way of establishing such a framework;

Whereas such rules should provide that biocidal products should not be placed on the market for use unless they have been officially authorised;

Whereas such official authorisation is appropriate as biocidal products consist mostly of dangerous substances and are preparations designed to have detrimental effects on the organisms they are intended to control; whereas biocidal products may have consequences other than the intended effects on the target species, they were designed for and whereas, therefore, they may especially involve risks for man and the environment;

Whereas it is appropriate that an applicant should submit dossiers and whereas it is further appropriate that the dossiers shall contain only that information which is necessary to evaluate the risks that will arise from proposed uses of the product;

Whereas it is necessary, at the time when biocidal products are authorized, to make sure that, when properly used for the purpose intended, they are sufficiently effective and have no unacceptable effect on their target species (i.e. they do not cause undesirable resistance and in the case of vertebrate animals unnecessary suffering), and have in

the light of current scientific and technical knowledge no unacceptable adverse influence on the environment and, in particular, no harmful effect on human or animal health;

Whereas authorization should be limited to biocidal products containing certain active substances evaluated on the basis of their physico-chemical, toxicological and ecotoxicological properties;

Whereas it is necessary to establish a Community list of active substances permitted for inclusion in biocidal products; whereas a Community procedure must be laid down for assessing whether or not an active substance can be entered in the Community list; whereas the information that interested parties must submit with a view to admission of a substance to the list has to be specified; whereas, in the interest of safety, substances on the list should be reviewed periodically, to take account of developments in science and technology;

Whereas in the light of the diversity of both the substances and products concerned, the test requirements should allow for some flexibility to suit the individual circumstances and should result in an overall risk assessment;

Whereas it is in the interest of free circulation of biocidal products as well as of goods treated with them, that authorization granted by one Member State, and tests carried out with a view to authorization, should be recognized by other Member States;

Whereas it is therefore desirable that a system for the mutual exchange of information should be established and that Member States and the Commission should make available to each other on request the particulars and scientific documentation submitted in connection with applications for authorization of biocidal products;

Whereas, Member States must be able to authorize biocidal products not complying with the above-mentioned conditions for a limited period of time, especially in case of an unforseen danger threatening man or the environment which cannot be contained by other means; whereas such

authorization should be reviewed by the Commission in close co-operation with the Member States; whereas the Community procedure should not prevent Member States from authorizing for use in their territory for a limited period of time biocidal products containing an active substance not yet entered in the Community list, provided that a dossier meeting Community requirements has been submitted and the Member State believes that the active substance and the biocidal products satisfy the Community conditions set in regard to them;

Whereas active substances used in biocidal products may also be used in other preparations which have under other Community legislation, been tested on animals; whereas double testing on animals must be avoided; whereas, close coordination should be ensured with other Community legislation and in particular with Directive 91/414/EEC on the placing on the market of plant protection products;

Whereas, in order to ensure that the requirements laid down in respect of authorized biocidal products are satisfied when they are placed on the market, Member States must make provision for appropriate control and inspection arrangements;

Whereas the implementation of this Directive, the adaptation of its Annexes to the development of technical and scientific knowledge, and the registration of Community-approved active substances necessitate close co-operation between the Commission and the Member States and the applicant; whereas the procedure of the Standing Committee on Biocidal Products offers a suitable basis for this co-operation; whereas this entails transparency of the administrative procedures;

Whereas the full implementation of this Directive and especially of Article 14 (4) will not be achieved for several years, Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations can provide for a framework to complement the development of the positive list by limitations of the marketing and use of certain active substances

and products or groups of these;

Whereas the Council in its resolution of 1 February 1993[7] on a Community programme of policy and action in relation to the environment and sustainable development has approved the general approach and strategy of the programme presented by the Commission which states that economic growth and environmental quality must be viewed as mutually dependant; whereas therefore the strengthening of environmental protection requires the maintenance of the economic competitiveness of industry;

Whereas the review of active substances shall need to take account of other work programmes within the framework of other community legislations concerned with the review or authorisation of substances and products;

Whereas minimum rules concerning the use of biocidal products at work are already laid down under directives on health and safety at work : whereas it is desirable to develop further these rules;

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7 O.J. No C 138, 17.05.1993, p. 1

HAS ADOPTED THIS DIRECTIVE:

Article 1

Scope of applicability

1. This Directive concerns

   (a) the authorization and the placing on the market for use of biocidal products within the Member States;

   (b) the mutual acceptance of authorizations within the Community;

   (c) the establishment at Community level of a positive list of active substances which may be used in biocidal products.

2. This directive shall apply to biocidal products as defined in Article 2, 1 (a) but shall exclude products where they are covered by the following directives for the purposes of these directives:

   (a) Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products[8] ,

   (b) Directives 70/524/EEC[9] and 82/471/EEC[10] or additives and substances for exclusive use in animal feedingstuffs,

   (c) Directive 76/768/EEC[11] on cosmetic products,

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8 O.J. No 22, 09.12.1965, p. 369

9 O.J. No L 270, 14.12.1970, p. 1

10 O.J. No L 213, 21.07.1982, p. 8

11 O.J. No L 262, 27.09.1976, p. 169

(d) Directive 89/107/EEC[12] on substances used exclusively as additives to foodstuffs and Directive 88/388/EEC[13] on substances used exclusively as flavourings in foodstuffs,

(e) Directive 91/414/EEC[14] concerning the placing of plant protection products on the market.

(f) Directive ../.../EEC[15] concerning medical devices.

3. This Directive shall apply without prejudice to the provisions of:

(a) Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations,

(b) Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances[16],

(c) Regulation (EEC) No 1734/88 on the export from and import into the Community of certain dangerous chemicals[17],

(d) Directive 80/1107/EEC on the protection of workers against dangers from exposure to chemical, physical and biological agents at work[18], and Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work[19] and individual Directives based on these Directives.

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12 O.J. No L 040, 12.02.1989, p. 27

13 O.J. No L 184, 15.07.1988, p. 61

14 O.J. No L 230, 19.08.1991, p. 1

15 O.J. No .....

16 O.J. No L 33, 08.02.1979, p. 36

17 O.J. No L 155, 22.6.1988, p. 2

18 O.J. No L 327, 03.12.1980, p. 8

19 O.J. No L 183, 29.06.1989, p. 1

(e) Directive 90/679/EEC[20] on the protection of workers from risks related to exposure to biological agents at work (7th individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC).

4. Article 18 does not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

Article 2

Definitions

1. For the purposes of this directive the following definitions shall apply:

a) Biocidal products :

active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism.

An indicative list of product types is at Annex V.

b) Active Substances

substances, fungi and micro organisms including viruses having general or specific action on or against harmful organisms.

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20 O.J. No L 374, 31.12.1990, p. 1

c) Harmful organism

any organism which has an unwanted presence or a detrimental effect for man, his activities or the products he uses or produces, or for animals or for the environment.

d) Placing on the market

any supply, whether in return for payment or free of charge, other than for storage followed by consignement from the territory of the Community or disposal. Importation of a biocidal product into the territory of the Community shall be deemed to constitute placing on the market for the purposes of this directive.

e) Authorisation

administrative act by which the competent authority of a member state authorises, following an application submitted by an applicant, the placing on the market of a biocidal product in its territory or in a part thereof.

f) Residues

One or more of the substances present in a biocidal product which remains as a result of its use including the metabolites of such substances and products resulting from their degradation or reaction.

2. For the purposes of this Directive the definitions for

(a) substances,

(b) preparations,

(c) scientific research and development,

(d) process-orientated research and development

laid down in Article 2 of Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances[21] shall apply.

Article 3

Authorization for placing on the market of biocidal products

1. Member States shall prescribe that a biocidal product shall not be placed on the market and used in their territory unless it has been authorized in accordance with this Directive.

2. Every application for authorization shall be decided upon within a reasonable period.

3. A biocidal product that has already been authorized in one Member State shall be authorized, in another Member State within 60 days of an application being received by the other Member State, providing that the active substance of the biocidal product conforms to the entry in Annex 1.

4. If in complying with Article 4 a Member State establishes that :

   (a) unacceptable resistance of the target organism to the biocidal product is proven or

   (b) the relevant circumstances of use, such as climate or breeding period of the target species, differ significantly from those in the Member State where biocidal product was first authorized, and an unchanged

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21 O.J. No L 196, 16.08.1967, p. 1 (as amended)

authorization may therefore present unacceptable risks to man or the environment,

the Member State may request that the directions for use and the dose rate referred to in Article 18 (3) (e) are adjusted to the different circumstances, or, if the risk can not be prevented in any other way, the Member State may request changes to be made to the biocidal product itself so that conditions for issue of an authorisation provided for in article 4 are satisfied.

5. Notwithstanding paragraph 4 where a Member State believes a biocidal product cannot meet the conditions set out under Article 4 and consequently proposes to refuse authorization, it shall notify the Commission, other Member States and the applicant and shall provide them with an explanatory document giving details of the product and setting out the grounds on which it proposes to refuse the authorization.

The Commission shall prepare a proposal on these matters in accordance with Article 24 for decision in accordance with the procedure laid down in Article 25(3).

6. Member States shall prescribe that biocidal products shall be classified, packaged and labelled in accordance with the provisions of this Directive.

7. Authorizations shall be granted for a fixed period of 10 years from the date of first entry of the active substance onto Annex 1; they may be renewed after verification that the conditions imposed in paragraphs 1 and 2 are still satisfied. Renewal may, where necessary, be granted only for the period necessary to allow the competent authorities of the Member States, to make such verification, where an application for renewal has been made.

8. Member States shall prescribe that biocidal products must be properly used. Proper use shall include compliance with conditions

established under Article 4 and specified under the labelling provisions of this directive. Proper use shall also involve the rational application of a combination of physical, biological, chemical or other measures as appropriate whereby the use of biocidal products is limited to the minimum necessary. Where biocidal products are used at work use shall also be in accordance with the requirements of directives for the protection of workers.

Article 4

Conditions for issue of an authorization

1. Member States shall authorise a biocidal product only if

(a) the active substance(s) included therein are listed in Annex I and any conditions laid down in the Annex are fulfilled;

(b) it is established, in the light of current scientific and technical knowledge and it is shown from appraisal of the dossier provided for in Annex III and, where specified, the relevant parts of Annex IV according to the common principles for the evaluation of dossiers, that when used as authorised and having regard to :

- all normal conditions under which the biocidal product may be used,
- how the material treated with it may be used,
- the consequences from use and disposal,

the biocidal product

(i) is sufficiently effective,

(ii) has no unacceptable effect on the target organism,

(iii) has no harmful effects itself or as a result of its residues, on human or animal health, directly or indirectly (eg through drinking water, food or feed) or on groundwater,

(iv) has no unacceptable effect on the environment having particular regard to the following considerations :

- its fate and distribution in the environment; particularly contamination of water including drinking water and groundwater,

- its impact on non-target organisms,

(v) does not cause unnecessary suffering and pain to vertebrates to be controlled,

(c) the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants, and its residues of toxicological or environmental significance, which result from authorized uses, can be determined according to the relevant requirements in Annexes II, III and IV;

(d) its physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use, storage and transport of the product;

2. A biocidal product classified according to Article 18 (1) as very toxic or as a category 1 or 2 carcinogen, or mutagen or classified as toxic for reproduction category 1 or 2, shall not be authorized for marketing to, or use by the general public.

3. Authorization may be conditional on requirements relating to marketing and use necessary to ensure compliance with the provisions of paragraph 1.

4. Where other Community provisions impose requirements relevant to the conditions for the issue of an authorisation and particularly where these are intended to protect the health of distributors, users, workers and consumers or animal health or the environment, the competent authority shall take these into account when issuing an authorisation and where necessary shall issue the authorisation subject to those requirements.

Article 5

Review of an authorization

Authorization may be reviewed at any time if there are indications that any of the requirements referred to in Article 4 are no longer satisfied. In such instances the Member States may require the applicant for authorization or the applicant to whom a modification of authorization has been granted in accordance with Article 6 to submit further information necessary for the review. Renewal may, where necessary, be granted only for the period necessary to complete a review, and shall be granted for the period necessary to provide such further information.

Article 6

Cancellation or modification of an authorization

1. An authorization shall be cancelled if :

(a) the active substance is no longer included in Annex I;

(b) the conditions under Article 4 (1) for obtaining the authorization are no longer satisfied;

(c) it is discovered that false or misleading particulars were supplied concerning the facts on the basis of which the authorization was granted;

2. An authorization may also be cancelled if the authorization holder requests it and states the reasons for the cancellation.

3. Where a Member State cancels an authorization, it shall inform the authorisation holder and it may grant a period of grace for the disposal or for storage, marketing and use of existing stocks, of a length in accordance with the reason for the cancellation without prejudice to any period provided for by decision taken under Directive 76/769/EEC or in connection with paragraph 1 (a).

4. An authorization shall be modified if, on the basis of developments in scientific and technical knowledge, the conditions of use and, in particular, manner of use or amounts used can be modified.

5. An authorization may also be modified if the authorization holder requests it and states the reasons for the modification.

6. Where a proposed modification concerns an extention of uses, Member State shall extend the authorization subject to the particular conditions placed on the active substance in Annex I.

7. Where a proposed modification of an authorization involves changes to the particular conditions placed on the active substance in Annex I, these can be made only after evaluation of the active substance, with regard to the proposed changes, in accordance with the procedures laid down in Article 10.

8. Modifications shall only be granted if it is established that the conditions under Article 4 continue to be satisfied.

Article 7

Requirements for authorization

1. Application for authorisation shall be made by or on behalf of the person who will be responsible for the first placing on the market of a biocidal product in a particular Member State and shall be to the competent authority of that Member State. Every applicant shall be required to have a permanent office within the Community.

2. Member States shall require that applicants for authorization of a biocidal product shall submit to the competent authority :

   (a) a dossier on the biocidal product satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex III and, where specified, the relevant parts of Annex IV, and

   (b) for each active substance in the biocidal product, a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex II and, where specified, the relevant parts of Annex IV.

3. The dossiers shall include a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods. The information in the dossiers supplied according to Article 7(2) shall be sufficient for an evaluation to be made of the effects and properties referred to in Article 4 (1)(b), (c) and (d). It shall be submitted to the competent authority in the form of technical dossiers, containing the information and results of the studies referred to in Annex II and III and, where specified, the relevant parts of Annex IV.

4. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted.

5. If the evaluation of the dossier shows that further information including information and results from further testing is necessary to evaluate the risks of the biocidal product, the competent authority shall ask the applicant to submit such information.

6. The name of an active substance must be given as registered in the list contained in Annex I to Directive 67/548/EEC or, if not included therein, as given in the European Inventory of Existing Chemical Substances (EINECS)[22], or if not included therein, it must be given its ISO common name. If the latter is not available, the substance must be designated by its chemical designation according to IUPAC rules.

7. Tests must be conducted according to the methods described in Annex V of Directive 67/548/EEC. In the event of a method being inappropriate or not described, other methods used should, whenever possible, be internationally recognized and must be justified. Tests must be conducted in accordance with the provisions laid down in Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes and Directive 87/18/EEC[23] on the application of the principles of Good Laboratory Practice and the verification of their applications for tests on chemical substances.

8. Competent Authorities as referred to under Article 23 shall ensure that a file is compiled on each application. Each file shall

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22 O.J. No. C146, 15.6.1990, p. 1

23 O.J. No L 15, 17.1.1987, p. 29

contain at least a copy of the application, a record of the administrative decisions taken by the Member State concerning the application and concerning the dossiers submitted in accordance with paragraph 2 together with a summary of the latter. Member States shall on request make available to the other Competent Authorities and to the Commission the files provided for in this paragraph; they shall supply to them on request all information necessary for full comprehension of applications, and shall where requested ensure that applicants provide a copy of the technical documentation laid down in article 7.

9. Member States may require that samples of the preparation and of its ingredients be provided.

Article 8

Placing on the market of active substances

1. Member States shall prescribe that where a substance is an active substance for use in biocidal products it may not be placed on the market for such use unless

(a) where the active substance was not on the market before the date of entry into force of this Directive, a dossier has been forwarded to a Member State, which satisfies the requirements of Article 10 (1), and is accompanied by the declaration that the active substance is intended for inclusion in a biocidal product. This shall not apply to substances for use under Article 15.

(b) it is classified, packaged and labelled in accordance with the provisions of Directive 67/548/EEC.

Article 9

Inclusion of an active substance in Annex I

1. In the light of current scientific and technical knowledge, an active substance shall be included in Annex 1 for an initial period not exceeding 10 years if it may be expected that biocidal products containing the active substance will fulfil the conditions laid down in Article 4 1 (b), (c) and (d).

2. Inclusion of an active substance in Annex I shall, where appropriate, be subject to the following :

(1) requirements on :

(a) the minimum degree of purity of the active substance;

(b) the nature and maximum content of certain impurities;

(c) product type in which it may be used;

(d) manner of use;

(e) designation of categories of users (e.g. industrial, professional or non-professional);

(f) other particular conditions from the evaluation of the information referred to in Article 10 (2);

(ii) the establishment of the following :

(a) a suitable standard of user protection,

(b) where relevant, an acceptable daily intake for man (ADI),

(c) fate and behaviour in the environment and impact on non-target organisms.

3. The inclusion in Annex I of an active substance shall be restricted to those product types in Annex V for which acceptable data have been submitted in accordance with Article 7.

4. The inclusion of a substance in Annex I may be renewed on one or more occasions for periods not exceeding 10 years. The initial inclusion as well as any renewed inclusion may be reviewed at any time if there are indications that any of the requirements referred to in paragraph 1 are no longer satisfied. Renewal may, where necessary, be granted only for the period necessary to complete a review, where an application has been made for such renewal and shall be granted for the period necessary to provide information requested in accordance with Article 10 (2).

5. The inclusion of an active substance in Annex I may be refused or reviewed, if there is another active substance on Annex I for the same product type, or another method of control exists, which in the light of scientific or technical knowledge present significantly less risk to health or to the environment. When considering such a refusal, an evaluation of the alternative active substances or methods shall be produced in accordance with common principles for the evaluation of dossiers, to demonstrate they can be used with the same effect on the target organism without significant economic and practical disadvantages to the user. The evaluation shall be circulated in accordance with the procedures in Article 10(2) for decision in accordance with the procedures laid down in Articles 24 and 25(3).

Article 10

Procedure for inclusion of an active substance in Annex I

1. An active substance will be considered for inclusion in Annex I, and any changes to Annex I will be considered when :

(a) an applicant has forwarded to the competent authority of one of the Member States

(i) a dossier for the active substance satisfying the requirements of Annex II and, where specified, the relevant parts of Annex IV;

(ii) a dossier for at least one biocidal product containing the active substance satisfying the requirements of Annex III and, where specified, the relevant parts of Annex IV;

(b) the receiving competent authority has checked the dossiers and believes them to satisfy the requirements of Annex II and Annex III and where relevant Annex IV, accepts them and agrees to the applicant forwarding a summary of the dossiers to the Commission and the other Member States.

2. The receiving Competent Authority shall, within 6 months of accepting the dossiers carry out an evaluation thereof. A copy of the evaluation shall be sent by the Competent Authority to the Commission, the other Member States and to the applicant, together with a recommendation for the inclusion, or otherwise, of the active substance in Annex I.

If during the evaluation of the dossiers it appears that further information is necessary for full evaluation to be made, the receiving Competent Authority shall ask that the applicant submit

such information. The 6 month period shall be suspended from the date of issue of the competent authority's request until the date the information is received. The competent authority shall inform the other Member States and the Commission of its action at the same time as it informs the applicant.

3. On receipt of the evaluation, the Commission shall, in accordance with in Article 24, prepare a proposal without undue delay for decision in accordance with the procedures laid down in Article 25(3). The decision shall be taken at the latest 15 months after the receipt by the Commission of the evaluation referred to in paragraph 2.

Article 11

Use of data held by Competent Authorities for other applicants

1. Member States shall not make use of the information referred to in Annex II and the relevant parts of Annex IV for the benefit of a second or subsequent applicant :

   a) unless the second or subsequent applicant has the written agreement of the first applicant that use may be made of such information, or

   b) in the case of an active substance not on the market on the date of coming into force of this directive, for a period of 15 years from the date of first inclusion in Annex I or;

   c) in the case of an active substance already on the market on the date of coming into force of this directive;

      (i) for a period of 10 years from the date of coming into force of this directive for any information submitted for the purposes of this directive except where such

information is already protected under existing national rules relating to biocidal products. In such cases the information shall continue to be protected in that Member State until the expiry of any remaining period of data protection provided for under national rules, up to a maximum of 10 years from the date or coming into force of this directive;

ii) for a period of 10 years from the date of entry of an active substance onto Annex I for information submitted for the first time in support of the first inclusion in Annex I of either the active substance or an additional product type for that active substance.

d) in the case of any further information submitted for the first time for any of the following :

(i) variation of the conditions of the entry on Annex I;

(ii) maintenance of the entry on Annex I

for period of 5 years from the date of decision following receipt of further information unless the 5 year period expires before the period provided for in paragraph 1 (b) & (c), in which case the period of 5 years shall be extended so as to expire on the same data as those periods.

Where an active substance is included in Annex I of this directive and also in Annex I of directive 91/414/EEC, the information referred to in Annex II and relevant parts of Annex IV, which is required under both directives and has been provided under both directives, shall benefit only from the periods of data protection provided for under directive 91/414/EEC.

2. Member States shall not make use of the information referred to in Annex III and the relevant parts of Annex IV, for the benefit of a second or subsequent applicants :

a) unless the second or subsequent applicant has the written agreement of the first applicant that use may be made of such information, or

b) in the case of a biocidal product containing an active substance not on the market on the date of coming into force of this directive; for a period of 10 years from the date of first authorization in any Member State; or;

c) in the case of a biocidal product containing an active substance already on the market on the date of coming into force of this directive;

(i) for a period of 10 years from the date of coming into force of this directive for any information submitted for the purposes of this directive, except in the case where data are already protected according to existing national rules relating to biocidal products, in which case such data shall be protected in that Member State until the expiry of any remaining period of data protection provided for under those national rules, up to a maximum of 10 years from the date of coming into force of this directive;

(ii) for a period of 10 years from the date of entry of an active substance onto Annex I, for information which is submitted for the first time in support of the inclusion in annex I either of the active substance or of an additional product type for that active substance.

d) in the case of any data submitted for the first time for either of the following :

(i) variation of the conditions of authorisation of a biocidal product;

(ii) submission of data necessary to maintain entry of an active substance onto Annex I

for a period of 5 years from the date of first receipt of further information unless the 5 years period expires before the period in Paragraph 2 (b) and (c) above in which case the period of 5 years shall be extended so as to expire on the same date as those periods.

Where a biocidal product contains an active substance which is included in Annex I of this directive and also in Annex I of Directive 91/414/EEC, the information referred to in Annex III and relevant parts of Annex IV, which is required under both directives and has been provided under both directives, shall benefit only from the periods of data protection provided for under directive 91/414/EEC.

Article 12

Second and subsequent applications for authorization

1. In the case of a biocidal product which has already been authorized in accordance with Articles 3 and 4, and without prejudice to the obligations imposed under Article 11, the Competent Authority may agree that a second or subsequent applicant for authorization may refer to data provided by the first applicant insofar as the second or subsequent applicant can provide evidence that the biocidal product and its active substances is the same as the one previously authorized, including degree of purity and nature of impurities.

2. Notwithstanding Article 7, paragraph 2, where the active substance is listed in Annex I :

(a) applicants for authorization of biocidal products shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority of the Member State to which they intend making application :

- whether the biocidal product for which an application is to be made is the same as a biocidal product for which authorization has been granted; and

- as to the name and address of the holder or holders of the authorization or authorizations.

The enquiry shall be supported by evidence that the prospective applicant intends to apply for authorization on his own behalf and that the other information specified in Article 7(2) is available.

(b) the competent authority of the Member State, if satisfied that the applicant intends to apply, shall provide the name and address of the holder or holders of previous relevant authorizations and shall at the time inform the holders of the authorizations of the name and address of the applicant.

The holder or holders of previous authorizations and the applicant shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.

Where data is requested with a view to inclusion in Annex I of an active substance already on the market on the date of entry into force of this Directive, the competent authorities of the Member States shall encourage data holders to cooperate in the provision of the requested data, with a view to limiting the

duplication of testing on vertebrate animals.

If the applicant and holders of previous authorizations of the same product can still not reach an agreement on the sharing of data, Member States may introduce national measures obliging the applicant and holders of previous authorizations located within their territory to share the data with a view to avoiding duplicative testing on vertebrate animals and determine both the procedure for utilizing information, and the reasonable balance of the interests of the parties concerned.

Article 13

New information

1. Member States shall prescribe that the holder of an authorisation for a biocidal product shall immediately notify the competent authority of information which they may reasonably be expected to be aware concerning an active substance or a biocidal product containing it and which may affect continuing authorization. In particular the following shall be notified :

- new knowledge or information on the effects of the active substance or biocidal product for man or the environment;

- changes in the source or composition of active substance;

- changes in composition of a biocidal product

2. Member States shall immediately notify other Member States and the Commission any such information they receive concerning potentially harmful effects for man or the environment of a biocidal product, its active substances, impurities, co-formulants or residues.

Article 14

Transitional measures and derogations from the requirements

1. By way of derogation from Article 3 and 4, a Member State may authorize temporarily for a period not exceeding 120 days the placing on the market of biocidal products not complying with the provisions of this Directive for a limited and controlled use if such a measure appears necessary because of an unforseen danger which cannot be contained by other means. In this case, the Member State concerned shall immediately inform the other Member States and the Commission of its action and the justification for it. The Commission shall make a proposal and it shall be decided without delay, in accordance with the procedure laid down in Article 25, whether and under which conditions the action taken by the Member State may be extended for a period to be determined, be repeated, or be revoked.

2. By way of derogation from Article 4 (1) (a) and until an active substance is listed in annex 1 a Member State may authorize provisionally, for a period not exceeding three years, the placing on the market of a biocidal product containing an active substance not listed in Annex I and not yet available on the market on the date of coming into force of this Directive. Such an authorisation may only be issued if, after evaluation of dossiers in accordance with the Article 10 the Member State believes that :

   - the active substance satisfies the requirements of Article 9 and;

   - the biocidal product may be expected to satisfy the conditions of Article 4(1) (b), (c) and (d),

   and no other Member State, on the basis of the summary it receives, makes legitimate objection in accordance with Article 16 (2) to the

completeness of the dossiers. Where an objection is made a decision on the completeness of dossiers shall be taken in accordance with the procedures laid down in Article 25(3) without undue delay.

If following the procedures laid down in Article 24 and 25(3), it is decided, that the active substance does not satisfy the requirements specified in Article 9, the Member State shall ensure that the provisional authorization is cancelled.

In cases where evaluation of dossiers for the purposes of inclusion of an active substance in Annex I is not completed when the period of 3 years expires, the competent authority may further provisionally authorize the product for a period not exceeding 1 year, providing there are good reasons to believe the active substance will satisfy the requirements of Article 9. Member States shall inform other member states and the Commission of such action.

3. By way of further derogation from Article 4(1), Article 7(2) and Article 7(3) and without prejudice to paragraph 4 and paragraph 6, a Member State may, for a period of 10 years from the date of entry into force of this Directive, authorize the placing on the market in its territory of a biocidal product containing active substances not listed in Annex I that are on the market on the date of entry into force of this Directive.

4. Following the adoption of this Directive, the Commission shall commence a 10 year programme of work for the systematic examination of active substances not on Annex I. A Regulation, adopted according to the procedure laid down in Article 25(2), will provide for all provisions necessary for the establishment and implementation of the programme. No later than two years before completion of the work programme, the Commission shall forward to the Council and the European Parliament a report on the progress achieved with the programme.

During this 10 year period, it may be decided under the procedure laid down in Article 25(3) that an active substance shall be included in Annex I and under which conditions, or, in cases where the requirements of Article 9 are not satisfied or the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Annex I.

Following a decision, the Member States shall ensure that authorizations for biocidal products containing the active substances are modified or cancelled as appropriate.

5. Where following a review of an active substance it is concluded that the substance does not meet the requirements of Article 9 and consequently cannot be included in Annex I, the Commission shall bring forward proposals for restricting the marketing and use of that substance in accordance with directive 76/769/EEC.

6. When authorizing biocidal products containing an active substance to be reviewed in accordance with paragraph 4 and before such review has taken place, Member States shall apply the conditions in Article 4 (1) (b), (c) and (d) on the basis of dossiers which address the requirements in Annex II and III.

Article 15

Research and development

1. Member States shall prescribe that any experiment or test for the purposes of research or development involving placing on the market of an unauthorized biocidal product or an active substance intended exclusively for use in a biocidal product shall not take place unless :

(a) in the case of scientific research and development the persons concerned draw up and maintain written records detailing the

identity of the product or substance, labelling data, quantities supplied and the names and addresses of those persons receiving the product or substance and compiles a dossier containing all available data on possible effects on human or animal health or impact on the environment. This information shall, as requested, be made available to the Competent Authority.

(b) in the case of process orientated research and development the information required in (a) is notified to the Competent Authority where and before placing on the market occurs and to the Competent Authority of the Member State where the experiment or test is to be conducted.

2. Member States shall prescribe that an unauthorized biocidal product or an active substance for exclusive use in a biocidal product may not be placed on the market for the purpose of trials which may involve or result in release into the environment unless the Competent Authority has assessed the available data and issued an authorization for trials purposes which limits the quantities to be used and the areas to be treated and may impose further conditions.

3. Where trials take place in a Member State other than the Member State where placing on the market occurs, the applicant shall obtain trials authorization from the Competent authority of the Member State in whose territory the trials are to be conducted.

If the proposed experiments or tests referred to in paragraph 1 and 2 are liable to have harmful effects on human or animal health or to have an unacceptable adverse influence on the environment, the Member State concerned may either prohibit them or only permit them subject to such conditions as it considers necessary to prevent those consequences.

4. Paragraph 2 shall not apply if the Member State has granted the person concerned the right to undertake certain experiments and

tests and has determined the conditions under which the experiments and tests have to be undertaken.

5. Common conditions for the application of this Article, in particular the maximum quantities of active substances or biocidal products that may be released during experiments, and the minimum data to be submitted in accordance with paragraph 2, shall be adopted in accordance with the procedure laid down in Article 25(3).

Article 16
Information exchange

1. Within a period of one month from the end of each quarter Member States shall inform each other and the Commission of any biocidal products which have been authorized within their territory or for which an authorization has been refused, modified, renewed or cancelled, indicating at least :

(a) the name or business name of the holder of the authorization;

(b) the trade name of the biocidal product;

(c) the name and amount of each active substance which it contains;

(d) the product type and the use or uses for which it is authorized;

(e) the type of formulation;

(f) any proposed limits on residues which have been established;

(g) limitations, conditions and requirements of the authorisation and where relevant, the reasons for the modification or cancellation of an authorization.

2. Where a Member State receives a summary of the dossiers in accordance with Article 10 (1) (b) and has legitimate reason to believe the dossiers are incomplete it shall immediately communicate its concerns to the competent authority responsible for the evaluation of the dossiers and shall immediately inform the Commission and other Member States of its concerns.

3. Each Member State shall draw up an annual list of the biocidal products authorized in its territory and shall communicate that list to the other Member States and the Commission.

4. In accordance with the procedure laid down in Article 25(2) a standardised information system shall be set up to facilitate the application of paragraphs 1 and 2.

Article 17

Confidentiality

1. Without prejudice to Council Directive 90/313/EEC on the freedom of access to information on the environment[24] an applicant may indicate to the Competent Authority the information which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially and which he therefore wishes to be kept confidential from all persons other than the competent authorities and the Commission. Full justification will be required in each case.

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24 O.J. No L158, 23.06.1990, p. 56

2. The competent authority receiving the application shall decide which information shall be confidential within the terms of paragraph 1.

Information accepted as being confidential by the receiving competent authority shall be treated as being confidential by the other Competent Authorities, Member States and the Commission.

3. Confidentiality shall not in any case apply to:

(a) the name of the applicant

(b) the name of the biocidal product manufacturer

(c) the name of the active substance manufacturer

(d) the names and content of the active substance or substances in the biocidal product and the name of the biocidal product;

(e) the name of other substances which are regarded as dangerous under Directives 67/548/EEC and contribute to the classification of the product;

(f) physico-chemical data concerning the active substance and biocidal product;

(g) any ways of rendering the active substance or biocidal product harmless;

(h) a summary of the results of the tests required under Article 7 to establish the substance's or product's efficacy and effects on humans, animals and the environment;

(i) recommended methods and precautions to reduce dangers from handling, storage, transport and use as well as from fire or other hazards;

(j) methods of analysis referred to in Article 4(1) (c) ;

(k) methods of disposal of the product and of its packaging;

(l) decontamination procedures to be followed in the case of accidental spillage or leakage;

(m) first aid and medical treatment to be given in the case of injury to persons.

If the applicant or manufacturer or importer of the biocidal product or active substance should later disclose previously confidential information, the Competent Authority shall be informed accordingly.

4. The detailed provisions and format for making information publically available shall be decided in accordance with the procedures set out in Article 25(2).

Article 18

Classification, packaging and labelling of biocidal products

1. Biocidal products shall be classified according to the provisions relating to classification in Directive 88/379/EEC on the classification, packaging and labelling of dangerous preparations[25].

2. Biocidal products shall be packaged according to Article 6 of Directive 88/379/EEC. In addition :

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25 O.J. No L187, 16.07.1988, p. 14

a) products which may be mistaken for food or drink shall be packaged to minimise the likelihood of such a mistake being made;

b) products available to the general public which may be mistaken for food or drink shall contain components to discourage their consumption.

3. Biocidal products shall be labelled according to the provisions of Directive 88/379/EEC concerning labelling. In addition the label must show clearly and indelibly the following:

(a) the identity of the active substance and its concentration in metric units

(b) the authorization number allocated to the biocidal product by the competent Authority;

(c) the type of preparation (e.g. liquid concentrates, granules, powders, solids, etc.);

(d) the uses for which the biocidal product is authorized (e.g. wood preservation, disinfection, surface biocide, anti-fouling, etc);

(e) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorization;

(f) particulars of likely direct or indirect adverse side effects and any directions for first aid;

(g) if accompanied by a leaflet the sentence "Read attached instructions before use";

(h) directions for safe disposal of the biocidal product and its packaging; including where relevant any prohibition on re-use of packaging;

(i) the formulation batch number or designation and the expiry date relevant to normal conditions of storage;

and where applicable :

(j) the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by man or animals to the area where the biocidal product has been used;

(k) the categories of users to which the biocidal product is restricted;

(l) information on any specific dangers to the environment particularly concerning protection of non-target species and avoidance of contamination of water.

Member States shall require that items 3 (a), (b), (d) and where applicable (g) and (k) always be carried on the label of the product.

Member States shall permit items 3 (c), (e), (f), (h), (i), (j) and (l) to be carried elsewhere on the packaging or on an accompanying leaflet integral to the packaging. These items of information shall be regarded as label information for the purposes of this directive.

4. By way of derogation from paragraphs 1 and 2 and the first sentence of paragraph 3; Biocidal products authorised as insecticides, acaricides, rodenticides, avicides or molluscicides shall be classified packaged and labelled in accordance with directive

78/631/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides)[26] insofar as there is no other Community provisions specifically covering these matters for such products.

5. Where a biocidal product identified in paragraph 4 is authorised under this directive and is also subject to classification, packaging and labelling according to Directive 78/631/EEC by virtue of other Community provisions; Member States shall permit changes to the packaging and labelling of that product which may be required as a consequence of those provisions, insofar as they do not conflict with the requirements of an authorisation issued under this directive.

6. Member States may require the provision of samples, models or drafts of the packaging, labelling and leaflets.

Article 19

Safety Data Sheets

Member States shall ensure that a system of specific information (in safety-data-sheet form) is established to enable professional and industrial users of biocidal products to take the necessary measure for the protection of the environment and health safety at the workplace.

For active substances used exclusively in biocidal products safety data sheets shall be prepared in accordance with the requirements of Article 27 of Directive 67/548/EEC.

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26 O.J. No L 206, 29.7.78, p. 13

For biocidal products safety data sheets shall be prepared in accordance with Article 10 of Directive 88/379/EEC.

Article 20

Advertising

1. Member States shall require that every advertisement for a biocidal product is accompanied by the sentences "Use biocides safely. Always read the label and product information before use".

   The sentences shall be clearly distinguishable in relation to the whole advertisement.

   Member States shall prescribe that advertisers may replace the word "Biocides" in the prescribed sentences with an accurate description of the product type being advertised e.g. wood preservatives, disinfectants, surface biocides, anti-fouling products, etc.

2. Member States shall require that advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the effects of the substance on man or the environment.

Article 21

Poison Control

Member States shall appoint the body or bodies responsible for receiving information on biocidal products which have been placed on the market, including information on the chemical composition, of such products, and

for making such information available in cases where suspected poisoning arises from the use of biocidal products. Such information may only be used to meet any medical demand by formulating preventive and curative measures, in particular in emergencies. Member States shall ensure that the information is not used for other purposes.

Member States shall take the necessary steps to ensure that the appointed bodies provide all the requisite guarantees for maintaining the confidentiality of the information received. Member States shall ensure that the appointed bodies shall have at their disposal all the information required to carry out the tasks for which they are responsible from the manufacturers or persons responsible for marketing.

For biocidal products already on the market, Member States shall take measures to comply with this Directive within three years from the adoption thereof.

Article 22

Compliance with requirements

Member States shall make suitable arrangements for biocidal products which have been placed on the market to be officially monitored to establish whether they comply with the requirements of this Directive.

Every three years after the entry into force of this directive, Member States shall forward to the Commission by the 30 November of the third year a report on their action in these matters together with information on any poisonings involving biocidal products. The Commission shall within 1 year of receipt of this information prepare and publish a composite report.

Article 23

Competent Authorities

1. Member States shall designate a competent authority responsible for carrying out the duties imposed on Member States under this Directive.

2. Member States shall inform the Commission of the identity of their competent authority 6 months before the entry into force of this Directive.

Article 24

Commission Procedures

1. When the Commission receives from a Member State either :

   (a) an evaluation and recommendations concerning an active substance as foreseen in Article 10 (2) and Article 9 (5) or

   (b) a proposal to refuse an authorization and an explanatory document as foreseen in Article 3 (5);

   it shall allow a period of 45 days during which other Member States and the applicant may submit comments to it in writing.

2. At the end of the period for comment, the Commission shall, on the basis of :

   - the documents received from the member state evaluating the dossiers and ;

- any advice obtained from advisory committees in particular the Scientific Advisory Committee on the toxicology and ecotoxicology of chemical substances as established by Commission decision 78/618/EEC[27] and in the case of active substances included in insecticides, acaricides, rodenticides, avicides and molluscicides which are also authorised under the requirements of Directive 91/414/EEC, the Scientific Committee for Pesticides, as established by Commission decision 78/436/EEC[28]

- comments received from other member States and the applicants and;

- any other relevant information ;

prepare a proposal for decision in accordance with the procedures laid down in Article 25(3).

3. The applicant or his authorized representative may be asked by the Commission to submit remarks to it, in particular whenever an unfavourable decision is envisaged.

Article 25

Committees and procedures

1. The Commission shall establish a Standing Committee on Biocidal products (the Standing Committee) to assist it. The Standing Committee shall be composed of representatives of the Member States and chaired by a representative of the Commission. The standing committee shall adopt its own rules of procedure.

27 O.J. N. L 198, 22.07.1978, p. 17

28 O.J. N L 124, 12.05.1978, p. 16

2. For matters referred to the Standing Committee by virtue of Articles 14(4) first paragraph, 16(4) and 17(4) the representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

3. For all other matters referred to the committee in accordance with the requirements of this directive the representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of 30 days the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 26

Common principles for the evaluation of dossiers

The common principles for evaluation of dossiers referred to in Article 4 (1) (b) above, shall be adopted in accordance with the procedure laid down in Article 25(3). These principles shall be regularly reviewed and where appropriate revised, in accordance with the same procedure.

Article 27

Adaptation to technical progress

The amendments necessary for adapting Annexes II, III, IV and V to technical progress shall be adopted in accordance with the procedure laid down in Article 25(3).

Article 28

Civil and Criminal Liability

The granting of authorization and all other measures in conformity with this Directive shall be without prejudice to general civil and criminal liability in the Member States of the manufacturer and, where applicable,

of the person responsible for placing the biocidal product on the market or using it.

Article 29

Safeguard clause

Where a Member State has valid reasons to consider that a biocidal product which it has authorized or is bound to authorize under Article 3 constitutes an unacceptable risk to human or animal health or the environment, it may provisionally restrict or prohibit the use or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision. A decision shall be taken on the matter within 90 days in accordance with the procedure laid down in Article 25(3).

Article 30

Implementation of the Directive

1. Not later than 18 months after the date of the adoption of the Directive Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

2. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 31

This Directive is addressed to the Member States.

Done at Brussels,

For the Council,

The President

ANNEX I

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL FOR INCLUSION IN BIOCIDAL PRODUCTS

ANNEX II

Requirements for The Dossier To Be Introduced for the Inclusion of An Active Substance In Annex I

PART A

CHEMICAL SUBSTANCES

1. Dossiers on active substances are required to address at least all the points listed under "Dossier requirements". Responses are required to be supported by data.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted.

Dossier requirements

(i) Applicant

(ii) Identity of the active substance

(iii) Physical and chemical properties of the active substance

(iv) Methods of detection and identification

(v) Effectiveness against target organisms and intended uses

(vi) Toxicological profile for man and animals including metabolism

(vii) Ecotoxicological profile including environmental fate and behaviour

(viii) Measures necessary to protect man, animals and the environment

(ix) Classification and labelling

(x) Summary and evaluation of (ii) - (ix)

The following data will be required to support submission on the above points.

I. APPLICANT

1.1 Name + address

1.2 Active substance manufacturer (name, address, location of plant)

II. IDENTITY OF THE ACTIVE SUBSTANCE

2.1 Common name proposed or accepted by ISO and synonyms

2.2 Chemical name (IUPAC nomenclature)

2.3 Manufacturer's development code number(s)

2.4 CAS and EEC numbers (if available)

2.5 Empirical and structural formula (including full details of any isomeric composition), molecular mass

2.6 Method of manufacture (synthesis pathway in brief terms) of active substance

2.7 Specification of purity of the active substance in g/kg or g/l, as appropriate

2.8 Identity of impurities and additives (eg stabilisers), together with the structural formula and the possible range expressed as g/kg or g/l, as appropriate

2.9 The origin of the natural active substance or the precursor(s) of the active substance, eg an extract of a flower

III. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

3.1 Melting point, boiling point, relative density(1)

3.2 Vapour pressure (in Pa) (1)

3.3 Appearance (physical state, colour)(2)

3.4 Absorption spectra (UV/VIS, IR, NMR), and a mass spectrum, molar extinction at relevant wavelengths, where relevant(1)

3.5 Solubility in water including effect of pH (5 to 9) and temperature on solubility, where relevant(1)

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(1) These data must be submitted for the purified active substance of stated specification.

(2) These data must be submitted for the active substance of stated specification.

3.6 Solubility in organic solvents, including effect of temperature on solubility (1)

3.7 Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature (1)

3.8 Stability in organic solvents used in preparations and identity of relevant breakdown products (2)

3.9 Thermal stability, identity of relevant breakdown products

3.10 Flammability including auto-flammability and identity of combustion products

3.11 Flashpoint

3.12 Surface tension

3.13 Explosive properties

3.14 Oxidising properties

3.15 Reactivity towards container material

IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

4.1 Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of the active substance and additives (eg stabilisers)

4.2 Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:

a) Soil

b) Air

c) Water : the applicant should confirm that the substance itself and any of its degradation products which fall within the definition of pesticides given for parameter 55 in Annex I of Directive 80/778/EEC on the quality of water intended for human consumption (O.J. No. L229, 30.8.1980, p. 11) can be estimated with adequate reliability at the MAC specified in that Directive for individual pesticides.

d) Animal and human body fluids and tissues

e) Food or feedingstuffs and other products where relevant

V. EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES

5.1 Function, eg fungicide, rodenticide, insecticide, bacteriocide

5.2 Organism(s) controlled and products, organisms or objects to be protected

5.3 Effects on target organisms, eg contact, inhalation or stomach poison, fungitoxic, or fungistatic

5.4 Mode of action

5.5 Field of use envisaged

5.6 User, professional or non-professional, general public

5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies

5.8 Likely, tonnage to be placed on the market per year

5.9 Observations on undesirable or unintended side-effects, eg on beneficial and other non-target organisms

VI. TOXICOLOGICAL AND METABOLIC STUDIES

6.1 Acute Toxicity

6.1.1 Oral

6.1.2 Dermal

6.1.3 Inhalation

6.1.4 Skin and eye irritation

6.1.5 Skin sensitisation

6.2 Metabolism studies in mammals
Basic toxicokinetics, including a dermal absorption study

For the following studies 6.3 (where necessary), 6.4, 6.5, 6.7 and 6.8, the required route of administration is the oral route unless it can be justified that an alternative route is more appropriate.

6.3 Short term repeated dose toxicity (28 days)
This study is not required when a sub-chronic toxicity study is available in a rodent

6.4 Subchronic toxicity
90-day study, 2 species, one rodent and one non-rodent

6.5 Chronic toxicity
One rodent and one other mammalian species

6.6 Mutagenicity studies

6.6.1 *In vitro* gene mutation study in bacteria

6.6.2 *In vitro* cytogenicity study in mammalian cells

6.6.3 *In vitro* gene mutation assay in mammalian cells

6.6.4 If positive in 6.6.1, 6.6.2 or 6.6.3, then an *in vivo* mutagenicity study will be required (bone marrow assay for chromosomal damage or a micronucleus test)

6.6.5 If negative in 6.6.4 but positive *in vitro* tests then undertake a second *in vivo* study to examine whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow

6.6.6 If positive in 6.6.4 then a test to assess possible germ cell effects may be required

6.7 Carcinogenicity study
One rodent and one other mammalian species. These studies may be combined with those in 6.5

6.8 Reproductive toxicity

6.8.1 Teratogenicity test - rabbit and one rodent species.

6.8.2 Fertility study - at least two generations, one species, male and female

6.9 Neurotoxicity study
If the active substance is an organophosphorus compound or if there are any other indications that the test substance may have neurotoxic properties then neurotoxicity studies will be required. The test species is the adult hen unless another species is justified to be more appropriate. If appropriate, delayed neurotoxicity tests will be required. If anticholine esterase activity is detected, a test for response to reactivating agents should be considered.

6.10 Toxic effects on livestock and pets

6.11 Studies related to the exposure of the active substance to man

6.11.1 Food and feedingstuffs - if the active substance is to be used in preparations for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored the tests referred to in Annex IV, Part A, point 1 shall be required.

6.11.2 If any other tests related to the exposure of the active substance to man, in its proposed preparations, are considered necessary, then the test(s) in Annex IV, Part A , Point 2 shall be required

6.12 Supplementary studies

6.12.1 If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required

6.12.2 Mechanistic study - any studies necessary to clarify effects reported in toxicity studies

6.13 Medical data in anonymous form

6.13.1 Medical surveillance data on manufacturing plant personnel if available

6.13.2 Direct observation eg clinical cases, poisoning incidents if available

6.13.3 Health records, both from industry and any other available sources

6.13.4 Epidemiological studies on the general population, if available

6.13.5 Diagnosis of poisoning (determination of active substance, metabolites in body fluids or exhaled air) specific signs of poisoning, clinical tests.

6.13.6 Sensitisation/allergenicity observations, if available

6.13.7 Proposed treatment: first aid measures, antidotes, medical treatment

6.13.8 Prognosis following poisoning

6.14 Summary of mammalian toxicology and conclusions, including no observable adverse effect level (NOAEL), no observable effect level (NOEL), overall evaluation with regard to all toxicological data and any other information concerning active substance. Where possible any suggested worker protection measures should be included in summary form.

VII. ECOTOXICOLOGICAL STUDIES ON THE ACTIVE SUBSTANCE

7.1 Acute toxicity to fish

7.2 Acute toxicity to Daphnia magna

7.3 Growth inhibition test on algae

7.4 Acute toxicity test on one other, non-aquatic, non-target organism

7.5 If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in Annex IV, Parts B and C, shall be required.

Fate and Behaviour in The Environment

7.6 Degradation

7.6.1 Biotic

7.6.1.1 Ready biodegradability

7.6.1.2 Inherent biodegradability, where appropriate

7.6.1.3 If the result of the test in 7.6.1.2 is negative and if the likely route of disposal of the active substance and its preparations is by sewage treatment, then the test described in Annex IV, Part C, Point 4.1 shall be required

7.6.1.4 Any other biodegradability tests that are relevant from the results in 7.6.1.1 and 7.6.1.2

7.6.2 Abiotic

7.6.2.1 Hydrolysis as a function of pH and identification of breakdown product(s)

7.6.2.2 Phototransformation in water including identity of the products of transformation(1)

7.6.2.3 Phototransformation in air (estimation method), including identification of breakdown products (1)

7.6.3 If the results of 7.6.1.2 or 7.6.1.4 indicate the need to do so, or the active substance has an overall low or absent abiotic degradation, then the tests described in Annex IV, Part B, Points 1.1 and 2.1, and where appropriate the tests described in Annex IV, Part B, Point 3 shall be required.

7.7 Adsorption/desorption screening test

Where the results of this test indicate the need to do so, the test described in Annex IV, Part B, Point 1.2 shall be required, and/or the test described in Annex IV, Part B, Point 2.2.

7.8 Summary of ecotoxicological effects and fate + behaviour in the environment

VIII. MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire

8.2 In case of fire, nature of reaction products, combustion gases etc...

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(1) These data must be submitted for the purified active substance of stated specification

8.3 Emergency measures in case of an accident

8.4 Possibility of destruction or de-contamination following release in or on the following:

a) Air

b) Water, including drinking water

c) Soil

8.5 Substances falling within the scope of List I or List II of the annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (O.J. No. L20, 26.1.1980, p.43)

8.6 Procedures for waste management of the active substance for industry or professional users

8.6.1 Possibility of re-use or recycling

8.6.2 Possibility of neutralisation

8.6.3 Conditions for controlled discharge including leachate qualities on disposal.

8.6.4 Conditions for controlled incineration

8.6.5 Others, if appropriate

IX. CLASSIFICATION AND LABELLING

Proposals including justification for the proposals for the classification and labelling of the active substance according to Directive 67/548/EEC

- Hazard symbol(s)
  Indications of danger
  Risk phrases
  Safety phrases

X. SUMMARY AND EVALUATION OF (II - Ix)

PART B

FUNGI, MICRO-ORGANISMS AND VIRUSES

1. Dossiers on active organisms are required to address at least all the points listed under "Dossier requirements" below. Responses are required to be supported by data.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted.

Dossier Requirements

(i) Applicants details

(ii) Identity of active organism

(iii) Source of active organism

(iv) Methods of detection and identification

(v) Biological properties of active organism including pathogenicity and infectivity for target and non target organisms including man

(vi) Effectiveness and intended uses

(vii) Toxicological profile for man and animals including metabolism of toxins

(viii) Ecotoxicological profile including environmental fate and behaviour of the organisms and of toxins it produces

(ix) Measures necessary to protect man, non-target organism and the environment

(x) Classification and labelling

(xi) Summary and evaluation of (ii) - (x)

The following data will be required to support submissions on the above points.

I. APPLICANT

1.1 Applicant (name, address, etc.)

1.2 Manufacturer (name, address, plant location)

II. IDENTITY OF THE ORGANISM

2.1 Common name of organism (including alternative and superseded names)

2.2 Taxonomic name and strain indicating whether it is a stock variant or a mutant strain; for viruses, taxonomic designation of the agent, serotype, strain or mutant

2.3 Collection and culture reference number where the culture is deposited

2.4 Methods, procedures and criteria used to establish the presence and identity of the organism (e.g. morphology, biochemistry, serology, etc.)

III. SOURCE OF THE ORGANISM

3.1 Occurance in nature or otherwise

3.2 Isolation methods for organism or active strain

3.3 Culture methods

3.4 Production methods including details of containment and procedure to maintain quality and ensure a uniform source of active organism. For mutant strains detailed information should be provided on production and isolation, together with all known differences between the mutant strains and parent and naturally occurring strains.

3.5 Composition of the final active organism material i.e. nature, purity, identity, properties, content of any impurities and extraneous organisms

3.6 Methods to prevent contamination of seed stock and loss of virulence of seed stock

3.7 Procedures for waste management

IV. METHODS OF DETECTION + IDENTIFICATION

4.1 Methods for establishing the presence and identity of the organism

4.2 Methods for establishing the identity and purity of seed stock from which batches are produced and results obtained, including information on variability

4.3 Methods to show microbiological purity of the final product and showing that contaminants have been controlled to an acceptable level, results obtained and information on variability

4.4 Methods used to show that there are no human or other mammalian pathogens as contaminants in the active agent, including in the case of protozoa and fungi, the effects of temperature (35°C and other relevant temperatures)

4.5 Methods to determine viable and non-viable (e.g. toxins) residues in or on treated products, foodstuffs, feedingstuffs, animal and human body fluids and tissues, soil, water and air, where relevant

V. BIOLOGICAL PROPERTIES OF THE ORGANISM

5.1 History of the organism and its uses including as far as is known its general natural history and if relevant its geographical distribution

5.2 Relationship to existing pathogens of vertebrates, invertebrates, plants or other organisms

5.3 Effects on target organism. Pathogenicity or kind of antagonism to the host. Details of host specificity range should be included.

5.4 Transmissibility, infective dose and mode of action including information on presence, absence or production of toxics with, if appropriate, information on their nature, identity, chemical structure and stability and potency

5.5 Possible effects on non-target organisms closely related to the target organism including infectivity, pathogenicity, transmissibility

5.6 Transmissibility to other non-target organisms

5.7 Any other biological effects on non-target organisms when properly used

5.8 Infectivity and physical stability when properly used

5.9 Genetic stability under environmental conditions of proposed use

5.10 Any pathogenicity and infectivity to man + animals under conditions of immunosuppression.

5.11 Pathogenicity and infectivity for known parasites/predators of the target species.

VI. EFFECTIVENESS AND INTENDED USES

6.1 Harmful organisms controlled and materials, substances, organisms or products to be treated or protected

6.2 Uses envisaged e.g. insecticide disinfectant, anti-fouling biocide, etc

6.3 Information or observations on undesirable or unintended side effects

6.4 Information on the occurrence or possible occurrence of the development of resistance and possible management strategies to deal with this

6.5 Effects on target organisms

6.6 Category of user

VII. TOXICOLOGICAL AND METABOLIC STUDIES

7.1 Acute toxicity

In cases where a single dose is not appropriate, a set of range finding tests must be carried out to reveal highly toxic agents and infectivity.

(1) oral
(2) dermal
(3) inhalation
(4) skin and where necessary eye irritation
(5) skin sensitization and where necessary respiratory sentization and
(6) for viruses and viroids, cell culture studies using purified infective virus and primary cell cultures of mammalian, avian and fish cells

7.2 Sub chronic toxicity

40 day study, 2 species, one rodent, one non-rodent

(1) oral administration
(2) other routes (inhalation, dermal) as appropriate and
(3) for viruses and viroids test for infectivity carried out by bio assay or on a suitable cell culture at least 7 days after administration to test animals.

7.3 Chronic toxicity

2 species, rodent and one other mammal, oral administration unless other route more appropriate

7.4 Carcinogenicity study

May be combined with studies in 6.3. One rodent and on other mammal

7.5 Mutagenicity studies

As specified in PART A / 6.6

7.6 Reproductive toxicity

Teratogenicity test - rabbit + one rodent species.
Fertility study - 1 species, min 2 generations, male + female

7.7 Metabolism studies

Basic toxicokinetics, absorption (including dermal absorption) distribution and excretion in mammals including elucidation of metabolic pathways.

7.8 Neurotoxicity studies : required where there is any indication of anticholinerterase activity or other neurotoxic effects. Delayed neurotoxicity tests using adult hens should be performed where appropriate.

7.9 Immunotoxicity studies e.g. allergenicity

7.10 Incidental exposure studies : required where the active substance will be in products for use where human food or animal feedingstuffs are prepared, consumed or stored and where humans livestock or pets are likely to be exposed to treated areas or materials

7.11 Human exposure data including :

(1) Medical data in anonymous form (if available)
(2) Health records, medical surveillance data on manufacturing plants personnel (if available)
(3) Epidemiological data (if available)
(4) Poisoning incidents data
(5) Poisoning diagnosis (signs, symptoms) including details of any analytical tests
(6) Proposed treatment of poisoning + prognoses.

7.12 Summary of mammalian toxicology - conclusions (including NOAEL NOEL and if appropriate ADI) overall evaluation with regard to all toxicological, pathogenicity and infectivity data and any other information concerning the active organism. Where possible suggested user protection measures should be included in summary form.

VIII. ECOTOXICOLOGICAL STUDIES

8.1 Acute toxicity to fish

8.2 Acute toxicity to Daphnia magna

8.3 Effects on algal growth (inhibition test)

8.4 Acute toxicity on one other, non-aquatic, non-target organism.

8.5 Pathogenicity and infectivity for honeybees and earthworms

8.6 Acute toxicity and/or pathogenicity and infectivity for other non-target organisms believed to be at risk

8.7 Effects (if any) on other flora & fauna

8.8 Potential for indirect contamination of areas adjacent to treatment areas.

8.9 In cases where toxins are produced, data as outlined in Annex II, Part A, VII 7.1-7.5 should be produced.

Fate + behaviour in the environment

8.10 Spread, mobility, multiplication and persistence in air, soil and water.

8.11 In cases where toxins are produced, data as outlined in Annex II, Part A, VII 7.6-7.8

IX. MEASURES NECESSARY TO PROTECT MAN, NON-TARGET ORGANISMS AND THE ENVIRONMENT.

9.1 Methods and precautions, to be taken for storage, handling, transport and use; or in event of fire on other likely incident

9.2 Any circumstances or environmental conditions under which the active organism should not be used

9.3 The possibility of rendering the active organism uninfective and any method for doing this.

9.4 Consequences of the contamination of air, soil and water, particularly drinking water

9.5 Emergency measures in case of accident

9.6 Procedures for waste management of the active organism including leachate qualities on disposal

9.7 Possibility of destruction or decontamination following release in or into the following : air, water, soil, others if appropriate.

X. CLASSIFICATION AND LABELLING

Proposals for allocation to one of the risk groups outlined in Article 2 (d) of Directive 90/679/EEC[29] with justifications for the proposal. Together with indications on the need for products to carry the biohazard sign specified in annex II of 90/679/EEC.

XI. SUMMARY AND EVALUATION OF (i) - (x)

(29) OJ No L 374, 31.12.90, p.1

ANNEX III

Requirements For The Dossier To Be Introduced For The Authorisation of A Biocidal Product

PART A

CHEMICAL PRODUCTS

1. Dossiers on biocidal products are required to address at least all the points listed under "Dossiers requirements". Responses are required to be supported by data.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted.

Dossier requirements

(i) Applicant

(ii) Identity and composition of the biocidal product

(iii) Physical, chemical and technical properties of the biocidal product

(iv) Methods for identification and analysis of the biocidal product

(v) Intended uses of the product and efficacy for these uses

(vi) Toxicology data for the biocidal products (additional to that for the active substance)

(vii) Ecotoxicological data for the biocidal products (additional to that for the active substance)

(viii) Measures to be adopted to protect man, animals and the environment

(ix) Classification, packaging and labelling of the biocidal product

(x) Summary and evaluation of (ii) -> (ix)

The following data will be required to support submissions on the above points.

I. APPLICANT

1.1 Applicant (name and address etc.)

1.2 Manufacturer of the preparation and the active substance(s) (names and addresses, including location of plant(s)).

II. IDENTITY OF THE BIOCIDAL PRODUCT

2.1 Trade name or proposed trade name, and manufacturer's development code number of the preparation, if appropriate

2.2 Detailed quantitative and qualitative information on the composition of the preparation eg active substance(s), impurities, adjuvants, inert components

2.3 Physical state and nature of the preparation eg emulsifiable concentrate, wettable powder, solution

III. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT

3.1 Appearance (physical state, colour)

3.2 Explosive properties

3.3 Oxidising properties

3.4 Flash point and other indications of flammability or spontaneous ignition

3.5 Acidity/alkalinity and if necessary pH value (1% in water)

3.6 Relative density

3.7 Storage stability - stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the biocidal product

3.8 Technical characteristics of the preparation

3.8.1 Wettability

3.8.2 Persistent foaming

3.8.3 Flowability, pourability and dustability

3.8.4 Suspensibility and suspension stability

3.8.5 Wet sieve test and dry sieve test

3.8.6 Particle size distribution, content of dust/fines, attrition and friability

3.8.7 In the case of granules, sieve test and indication of weight distribution of the granules, at least of the fraction with particle sizes bigger than 1mm

3.8.8 Emulsifiability, re-emulsifiability, emulsion stability

3.8.9 Wetting, adherence and distribution to target organisms

3.9 Physical and chemical compatibility with other products including other Biocidal Products with which its use is to be authorised

3.10 If the Biocidal Product is to be used in the form of a bait or granules, then specify any repellants or poison control measures included with the preparation that are present to prevent action against non target organisms

IV. METHODS OF IDENTIFICATION AND ANALYSIS

4.1 Analytical method for determining the composition of the biocidal product

4.2 In so far as not covered by Annex II, point 4.2 analytical methods including recovery rates and the limits of determination for toxicologically and ecotoxicologically relevant components of the Biocidal Product and/or residues thereof, where relevant in or on the following:

a) Soil

b) Air

c) Water (including drinking water)

d) Animal and human body fluids and tissues

e) Treated food or feedingstuffs

V. INTENDED USES AND EFFICACY

5.1 Field of use envisaged

5.2 Method of application

5.3 Application rate and if appropriate, the final concentration of biocidal product and active substance in system in which the preparation is to be used, eg cooling water, surface water, water used for heating purposes.

5.4 Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and livestock

5.5 Any other necessary information

5.6 Function, eg fungicide, rodenticide, insecticide, bacteriocide

5.7 Pest organism(s) controlled and products, organisms or objects to be protected

5.8 Effects on target organisms, eg contact, ingestion or stomach poison, fungitoxic, fungistatic

5.9 Mode of action in so far as not covered by Annex II, Point 5.4

5.10 User, professional or non-professional

5.11 Observations on undesirable or unintended side-effects, eg on beneficial and other non-target organisms

Efficacy Data

5.12 Data to support the efficacy claims of the preparation label, including any available standard protocols used, laboratory tests, or where appropriate field trials. For each application a reasoned case will be required.

5.13 The effect of factors such as climate, temperature, humidity, precipitation etc. insofar as not covered by Point 5.4

5.14 Compatibility with different cultural practices and other measures that may be used against the target organism under the conditions of use envisaged

5.15 Any other known limitations on efficacy

5.16 Relative advantages of the preparation or its intended use compared to any existing preparations or treatment methods

5.17 Summary and evaluation of data presented under 5.12 to 5.17

VI. TOXICOLOGICAL STUDIES

6.1 Acute toxicity

6.1.1 Oral

6.1.2 Dermal

6.1.3 Inhalation

6.1.4 Skin and eye irritation

6.1.5 For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of preparations, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate

6.2 Dermal absorption test, where necessary

6.3 Available toxicological data relating to toxicologically relevant non-active substances

6.4 Studies related to the exposure of the preparation to man

Where necessary, the test(s) described in Annex IV, Part A shall be required for the toxicologically relevant non-active substances of the preparation

6.5 If the biocidal product is in the form of a bait or granules, pet or livestock acceptance studies may be required

6.6 Summary and evaluation of data presented in 6.1 to 6.6, including where possible any suggested worker protection measures in summary form

VII. ECOTOXICOLOGICAL STUDIES ON THE BIOCIDAL PRODUCT

7.1 The information provided must, where relevant, include that referred to in Annex II, point 7.1 to 7.4.

7.2 If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in Annex IV, Parts D and E shall be required

Fate And Behaviour In The Environment

7.3 The information provided must, where relevant, include that referred to in Annex II, point 7.6.

VIII. MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire

8.2 Emergency measures in case of an accident

8.3 Procedures, if any, for cleaning application equipment

8.4 Possible routes of entry into the environment

8.5 Identity of relevant combustion products in cases of fire

8.6 Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public

8.6.1 Possibility of re-use or recycling

8.6.2 Possibility of neutralisation

8.6.3 Conditions for controlled discharge

8.6.4 Conditions for controlled incineration

8.6.5 Others, if appropriate

8.7 Possibility of destruction or de-contamination following release in or on the following:

a) Air

b) Water, including drinking water

c) Soil

8.8 Leachate qualities on disposal, in so far as not covered by point 8.6.3 of Annex II

8.9 Any information on authorisation in other countries

IX. CLASSIFICATION, PACKAGING AND LABELLING

Proposals including justification for the classification and labelling according to Directive 88/379/EEC or, in the case of rodenticides, insecticides/acaricides, avicides and molluscicides Directive 78/631/EEC

- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases
- Instructions for use.
- Packaging (type, materials, size etc.), compatibility of the preparation with proposed packaging materials to include.
- Specimens of the proposed packaging and of the proposed label(s) if so required

X. SUMMARY AND EVALUATION OF ALL ANNEX III INFORMATION AND REQUIREMENTS

PART B

FUNGI, MICRO-ORGANISMS AND VIRUSES

1. Dossiers on biocidal products are required to address at least all the points listed under "Dossier requirements". Responses are required to be supported by data.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted.

Dossier requirements

(i) Applicant

(ii) Identity and composition of the biocidal product

(iii) Technical properties of the biocidal product and any biocidal properties additional to those of the active organism.

(iv) Methods for identification + analysis of the biocidal product

(v) Intended uses and efficacy for those uses

(vi) Toxicological information (additional to that for the active organism)

(vii) Ecotoxicological information
(additional to that for the active organism)

(viii) Measures to be adopted to protect man, non-target organisms + the environment

(ix) Classification, packaging and labelling of the biocidal product

(x) Summary of (ii) -> (ix)

The following data will be required to support submission on the above points.

I. APPLICANT

1.1 Name and address etc.

1.2. Manufacturers of biocidal products and active organisms including location of plants

II. IDENTITY OF BIOCIDAL PRODUCT

2.1 Trade name or proposed trade name and manufacturer's development code number for the biocidal product, if appropriate.

2.2 Detailed quantitative and qualitative information on the composition of the biocidal product (active organisms, inert components, extraneous organisms, etc.)

2.3 Physical state and nature of the biocidal product (emulsifiable concentrate, wettable powder, etc.)

2.4 Concentration of active organism in material used

III. TECHNICAL + BIOLOGICAL PROPERTIES

3.1 Appearance (colour and odour)

3.2 Storage - stability and shelf-life. Effects of temperature, method of packaging and storage, etc. on retention of biological activity

3.3 Methods for establishing storage and shelf-life stability

3.4 Technical characteristics of the preparation

3.4.1 Wettability

3.4.2 Persistent foaming

3.4.3 Suspensibility and suspension stability

3.4.4 Wet sieve test and dry sieve test

3.4.5 Particle size distribution, content of dust/fines, attrition and friability

3.4.6 In the case of granules, sieve test and indications of weight distribution of the granules, at least of the fraction with particle sizes bigger than 1 mm

3.4.7 Content of active substance in or on bait particles, granules or treated material

3.4.8 Emulsinability, re-emulsifiability, emulsion stability

3.4.9 Flowability, pourability and dustability

3.5 Physical and chemical compatibility with other products including biocidal products with which its use is to be authorized

3.6 Wetting, adherence and distribution following application

3.7 Any changes to biological properties of the organism is a result of formulation. In particular changes in pathogenicity on infectivity

IV. METHOD FOR IDENTIFICATION + ANALYSIS OF THE BIOCIDAL PRODUCT

4.1 Analytical methods for determining the composition of the biocidal product

4.2 Methods for determining residues (e.g. biotest)

4.3 Methods used to show microbiological purity of the biocidal product

4.4 Methods used to show the biocidal product to be free from any human and other mammalian pathogens or, if need be, from pathogens harmful to non-target organisms and the environment

4.5 Techniques used to ensure a uniform product and assay methods for its standardization

V. INTENDED USES AND EFFICACY FOR THESE USES

5.1 Use
Product type (e.g. wood preservative, public hygiene biocide etc.)

5.2 Details of intended use, e.g. types of harmful organism controlled, materials to be treated etc.

5.3 Application rate

5.4 Where necessary, in the light of the test results, any specific circumstances or environmental conditions under which the product may or may not be used.

5.5 Method of application

5.6 Number and timing of applications

5.7 Proposed instructions for use

Efficacy data

5.8 Preliminary range-finding tests

5.9 Field experimentation

5.10 Information on the possible occurence of the development of resistance

5.11 Effects on the quality of materials or products treated

VI. TOXICITY INFORMATION ADDITIONAL TO THAT REQUIRED FOR THE ACTIVE ORGANISM

6.1 Oral single dose

6.2 Percutaneous single dose

6.3 Inhalation

6.4 Skin and where relevant eye irritation

6.5 Skin sensitization

6.6 Available toxicological data relating to non-active substances

6.7 Operator exposure

6.7.1 Percutaneous absorption/inhalation depending on formulation and method of application

6.7.2 Likely operator exposure under field conditions, including where relevant quantitative analysis of operator exposure

VII. ECOTOXICITY INFORMATION ADDITIONAL TO THAT REQUIRED FOR THE ACTIVE ORGANISM

7.1 Observations concerning undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms or persistence in the environment

VIII. MEASURES TO BE ADOPTED TO PROTECT MAN, NON-TARGET ORGANISMS AND THE ENVIRONMENT

8.1 Recommended methods and precautions concerning handling, storage, transport and use

8.2 Re-entry periods, necessary waiting periods or other precautions to protect humans and animals

8.3 Emergency measures in case of an accident

8.4 Procedures for destruction or decontamination of the biocidal product and its packaging

8.5 Procedures for cleaning application equipment

8.6 Procedures for safe disposal of the concentrated biocidal product or diluted product

IX. CLASSIFICATION, PACKAGING AND LABELLING

9.1 Proposals including justification for the classification, packaging and labelling

(i) with regard to non-biological components of the product in accordance with Directive 88/379/EEC

- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases

(ii) with regard to the active organisms labelling with the appropriate risk group as outlined in Article 2 (d) of Directive 90/679/EEC together with the biohazard sign specified in that directive if appropriate

9.2 Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials

9.3 Specimens of proposed packaging

X. SUMMARY OF (ii) -(ix)

ANNEX IV

Further Requirements For the Dossiers To Be Introduced For the Authorisation Of Biocidal Products

ANNEX IV
PART A

Further Human Health Related Studies On The Active Substance And/Or The Preparation

1. Food and Feedingstuffs Studies

1.1 Identification of degradation and reaction products and of metabolites of the active substance in treated or contaminated foods or feedstuffs

1.2 Behaviour of the residue of the active substance, its degradation products and where relevant its metabolites on the treated or contaminated food or feedstuffs including the kinetics of disappearance

1.3 Overall material balance for the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from proposed use would not be of concern for human or animal health

1.4 Estimation of potential or actual exposure of the active substance to humans through diet and other means

1.5 If the residue of the Biocidal Product remains on feedingstuffs for a significant period of time then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin

1.6 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residue of the biocidal product or active substance

1.7 Proposed acceptable residues and the justification of their acceptability

1.8 Any other available information that is relevant

1.9 Summary and evaluation of data submitted under 1.1 to 1.8

2. Other Test(s) Related To The Exposure To Man

Suitable test(s) and a reasoned case will be required for the active substance or the preparation, as appropriate

ANNEX IV
PART B

Further Studies On The Fate And Behaviour Of The Active Substance In The Environment

1. Fate And Behaviour In Soil

1.1 Rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least 3 soil types under appropriate conditions.

1.2 Adsorption and desorption in at least 3 soil types and where relevant adsorption and desorption of metabolites and degradation products.

1.3 Mobility in at least 3 soil types and where relevant mobility of metabolites and degradation products.

1.4 Extent and nature of bound residues.

2. Fate And Behaviour In Water

2.1 Rate and route of degradation in aquatic systems (as far as is not covered by Annex II, point 7.6) including identification of metabolites and degradation products.

2.2 Adsorption and desorption in water (soil sediment systems) and where relevant adsorption and desorption of metabolites and degradation products.

3. Fate And Behaviour In Air

If the active substance is to be used in preparations for fumigants, if it is to be applied by a spray method, if it is volatile, or if any other information indicates that this is relevant, then the rate and route of degradation in air shall be determined as far as is not covered by Annex II, point 7.6.2.3

4. Summary And Evaluation Of Parts 1,2 and 3

ANNEX IV
PART C

Further Ecotoxicological Studies On The Active Substance

1. Effects On Birds

1.1 Acute oral toxicity - this need not be done if an avian species was selected for study in Annex II, point 7.4.

1.2 Short term toxicity - 8 day dietary study in at least one species (other than chicken).

1.3 Effects on reproduction.

2. Effects On Aquatic Organisms

2.1 Prolonged toxicity to an appropriate species of fish

2.2 Effects on reproduction and growth rate on an appropriate species of fish

2.3 Bioaccumulation in an appropriate species of fish

2.4 Daphnia magna reproduction and growth rate

3. Effects On Other Non Target Organisms

3.1 Acute toxicity to honeybees and other beneficial arthropods eg predators. A different test organism shall be chosen from that used in Annex II, point 7.4.

3.2 Toxicity to earthworms and to other soil non-target macro organisms.

3.3 Effects on soil non-target microorganisms

3.4 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk.

4. Other Effects

4.1 Activated sludge respiration inhibition test

5. Summary And Evaluation of 1, 2 and 3.

ANNEX IV
PART D

Further Studies On The Fate And Behaviour Of The Environmentally Relevant Components Of The Biocidal Product In The Environment

1. Where relevant all the information required in Annex IV, Part B

2. Testing for distribution and dissipation in the following:

   a) Soil

   b) Water

   c) Air

Test requirements 1 and 2 are applicable only to ecotoxicologically relevant components of the preparation.

ANNEX IV
PART E

Further Ecotoxicological Studies On The Biocidal Products

1. **Effects On Birds**

1.1 Acute oral toxicity, if not already done in accordance with Annex III, point 7.

2. **Effects On Aquatic Organisms**

2.1 In case of application on, in or near to surface waters:

2.1.1 Particular studies with fish and other aquatic organisms

2.1.2 Residue data in fish concerning the active substance and including toxicologically relevant metabolites

2.1.3 The studies referred to in Annex IV, Part C points 2.1, 2.2, 2.3 and 2.4 may be required for relevant components of the preparation

2.2 If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions

3. **Effects On Other Non-Target Organisms**

3.1 Toxicity to terrestrial vertebrates other than birds

3.2 Acute toxicity to honeybees

3.3 Effects on beneficial arthropods other than bees

3.4 Effects on earthworms and other soil non-target macroorganisms, believed to be at risk

3.5 Effects on soil non-target microorganisms

3.6 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

3.7 If the biocidal product is in the form of bait or granules, the following will be required

3.7.1 Supervised trials to assess risks to non-target organisms under field conditions

3.7.2 Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk; in so far as not covered by Annex III, Point 6.6

4. **Summary And Evaluation Of 1, 2 and 3.**

ANNEX V

Biocidal products shall include those product types set out below which can be used for the purposes described :

Product type	Description of use
Disinfectant	Disinfection of skin (human or animal) and articles intended to come into contact with skin.
Swimming pool disinfectant	Disinfection of water used for public bathing.
Food industry disinfectant	Disinfection of containers surfaces and pipework associated with the production of food and drink for humans and animals.
General biocide	Control of harmful micro-organisms in premises vehicles and areas used by humans and animals.
Sanitary biocide	Control of harmful micro- organisms in sanitary convenancies and equipment
Air conditioning biocide	Control of harmful organisms in air conditioning systems.
Wood preservative	Protection of sawn timber and timber products from harmful organisms.
Textile preservatives	Protection of textiles from harmful organisms.
Masonry preservatives	Protection of masonry and other construction materials (except wood) from harmful organisms.

Consumer product preservatives	Protection of products marketed to the consumer, other than food and feed, from harmful organisms.
Industrial biocides	Control of harmful organisms affecting industrial processes
Specialist biocides	Control of harmful organisms in connection with specific products, substances, materials, articles on areas not covered by other product types.
Rodenticide	Control of rats, mice or other rodents for purposes of public health and wellbeing.
Avicide	Control of birds for purposes of public health and wellbeing.
Molluscicide	Control of snails and other molluscs, both terrestrial and aquatic for purposes of public health and wellbeing.
Insecticide/Acaricide	Control of insects, mites and other arthropods for purposes of public health and wellbeing.
Anti fouling biocide	Control of fouling organisms on ships, boats, aquatic structures and articles.

FINANCIAL STATEMENT

SECTION 1

1. **Title of operation:** Proposal for a Council Directive concerning the placing of biocidal products on the market.

2. **Budget headings involved:** B4-3040, A1178, A1520, A2510, A260 and A5010.

-	B4-3040	Environment legislation
-	A1178	Technical and administrative assistance in support of different activities
-	A1520	National experts on secondment
-	A2510	Expenditure on meetings of committees whose consultation is compulsory in the procedure for drafting Community legislation
-	A260	Studies and consultations
-	A5010	Departmental data processing.

3. **Legal basis:** Article 100a of the EEC Treaty.

4. **Description of operation**

4.1 Specific objective of operation: To harmonize the rules relating to the placing of biocidal products on the market. This objective fits into the more general framework of the legislation on pollution by toxic and dangerous chemicals, on evaluation of the risks posed to man and the environment by chemicals, on industrial installations and on biotechnology.

4.2 Duration: Unlimited.

4.3 Target population: Chemical industry (producers, importers, distributors and formulators), general public (consumers) and professional users (potentially all branches of industry).

5. Classification of expenditure or revenue

5.1 Non-compulsory expenditure.

5.2 B4-3040: Differentiated appropriations.

5.3 No revenue is expected.

6. Type of expenditure

Part A of the Budget

The Directive provides for the establishment of a network for exchanges of information on biocidal products and the active substances which they contain. This will require funds for services, consultations and purchases of computer hardware in order to set up a central unit for the network within the Commission.

Part B of the Budget

Technical advice will be needed on scientific and/or specific technical questions. This will be financed by means of study contracts and in the form of financial contributions.

Expenditure on this specific operation (biocidal products) comes under the general heading of expenditure in connection with environment legislation (Article B4-304 of the preliminary draft budget for 1993). More specifically, it comes under the heading "Products, industrial installations and biotechnology", which has been allocated a total of ECU 1.620 million in the preliminary draft budget for 1993 (Article B4-304, point 7.2).

7. Financial impact on appropriations for operations (part B of the Budget)

The studies, consultations with experts and various financial contributions will cost an estimated ECU 300 000 per year from 1993 on.

This expenditure will take the form of contracts of limited duration with third parties. These services will be provided extra muros. These contracts could serve such objectives as development of criteria for evaluating the risks posed by biocidal products, feasibility studies on a step-by-step approach to the data to be supplied by applicants or, finally, evaluation of the impact of selected active substances on man and the environment. Financial contributions to conferences and international workshops organized by, for example, the OECD or NGOs are also envisaged.

The total expenditure is expected to break down as follows: financial contributions: 80% or approximately ECU 240 000; studies and consultations: 10%, i.e. approximately ECU 30 000, each.

SECTION 2: ADMINISTRATIVE EXPENDITURE

(Part A of the Budget)

1. Human resources

(a) In-house staff

The operation will require extra in-house staff to administer the Directive. Category A, B and C staff will be needed for the decision-making procedures to implement the Directive (review of existing active substances, examination of applications for inclusion of new active substances in Annex I, establishment of the common principles for the evaluation of dossiers, administration, etc.). It will be possible to cover these requirements by interdepartmental redeployment or by allocating vacant posts.

In 1993 and 1994 a team of one A grade and one C grade could perform the necessary tasks.
From 1995 on, the total number of in-house staff required will be: one A grade, two B grades and one C grade.

The estimated annual costs incurred will be:

1993 and 1994:	ECU 180 000/year
1995 on:	ECU 360 000/year

Method of calculation: ECU 90 000 per official per year.

(b) Outside staff

(1) Preparation and scientific monitoring of implementation of the Directive (Item A1520 and/or Article A260)

For lack of vacant posts, the support of outside scientific experts will be required for the preparatory work for implementation of the Directive and for implementation itself.

In 1993 and 1994 an estimated one man-year will be needed.

From 1995 on an estimated two man-years will be needed.

The appropriations needed for these outside staff have been requested in the preliminary draft budget for 1993. However, these functions could be performed by officials appointed to posts authorized under the procedure for converting appropriations into posts. In this case, the funds needed to pay the salaries would be taken from these budget headings.

The estimated annual costs incurred will be:

1993 and 1994:	ECU 40 000/year
1995 on:	ECU 80 000/year

Method of calculation: ECU 40 000 per expert per year.

(ii) Establishment of an information exchange network (item A1178)

To ensure correct implementation of the Directive, the assistance of service-providers and consultants will be needed to set up the information exchange network and the central unit within the Commission. Based on experience with the establishment of a similar network on dangerous chemicals, to implement Directive 67/548/EEC, the total expenditure is estimated at ECU 350 000 or four man-years.

From 1996 on, provision must also be made for the costs of adapting the system to any changes and for maintenance.

The indicative schedule of appropriations could be as follows (item A1178):

	ECU
1993	150 000
1994	100 000
1995	100 000
1996 et seq.	30 000 (maintenance)

The ECU 150 000 earmarked for 1993 have been entered in the preliminary draft budget for 1993 under the heading "Flanking policies".

2. Equipment (item A5010)

Establishment of the information exchange network and, in particular, of the central unit within the Commission will entail purchases of equipment and computer hardware. Based on experience with establishment of a similar network for chemicals, the total cost is estimated at ECU 500 000.

From 1996 on, provision must also be made for the cost of maintenance of the equipment acquired (10% of the initial cost).

The indicative schedule of appropriations could be as follows (item A5010):

	ECU
1993	50 000
1994	250 000
1995	200 000
1996 et seq.	50 000 (maintenance)

3. Meetings (item A2510)

The Directive provides for the establishment of a committee to manage the Directive and, in particular, to adapt it to technical and scientific progress. The meetings of this committee and of its working parties will cost an estimated ECU 77 000 per year from 1994 on.

Method of calculation:

- 2 plenary meetings (24 experts):
  482 x 24 x 2 = ECU 23 000/year

  6 meetings of working parties (12 experts):
  482 x 12 x 6 = ECU 35 000/year

- 4 restricted meetings (5 Member States):
  482 x 10 x 4 = ECU 19 000/year

4. Overview of expenditure from Part A of the Budget (in thousand ECU/year)

YEAR	IN-HOUSE STAFF	OUTSIDE STAFF		EQUIPMENT	MEETINGS	TOTAL (Part A)
		A1520 and/or A2600	A1178	A5010	A2510	
1993	180	40	150	50	-	420
1994	180	40	100	250	77	647
1995	360	80	100	200	77	817
1996 et seq.	360	80	30	50	77	597

SECTION 3: ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

1. Objectives and coherence with financial programming

This Directive forms part of the programme to complete the internal market and is designed to supplement the Community's policy to control chemicals in general and pesticides (biocidal products) in particular. It is included in the Fifth Action Programme on the Environment, as adopted by the Commission in March 1992 (Doc. COM(92)23 final).

The operation is provided for in DG XI's financial programming and comes under the heading "Products, industrial installations and biotechnology" (ECU 1.620 million in the preliminary draft budget for 1993).

2. Grounds for the operation

The diverging national authorization systems for biocidal products cause an enormous waste of human and financial resources, at the expense of the Member States and manufacturers, due to repetition of the tests, procedures and evaluations of the active substances used in the biocides. The Community procedure for evaluation of the active substances will enable the industry to obtain approval (in practice, inclusion in Annex I to the Directive) for each active substance in a single Community-wide evaluation procedure.

At the same time, the national authorizations for products on the market will be based on criteria defined at Community level and the requirements concerning the dossier to be submitted will also be harmonized. In addition, virtually automatic mutual recognition of the authorizations is proposed. The Directive will, therefore, allow free movement of biocidal products and of the active substances which they contain, with the objective of completing the internal market. These measures will also cut the financial and staff costs for the industry and the national authorities.

At the same time the operation will ensure a high level of protection for man and the environment by applying strict, harmonized evaluation criteria. The proposal will provide a means of keeping dangerous products off the market and will encourage the placing of cleaner, healthier products on the market. In this context, although it is hard to quantify the benefits of this operation, they are sure to be considerable (lower health care costs, less pollution, etc.).

Burden-sharing

The Member States will be responsible for most of the work generated by this Directive. The Commission's role will be limited to the coordination necessary, to settling disputes and to laying down common guidelines for granting authorizations for products, which will continue to be done at national level.

All in all, the resources to be mobilized at Community level by the Member States and the parties concerned should reflect this share of responsibilities.

3. Monitoring and evaluation of the operation

The Directive requires each Member State to report every three years on the measures taken to implement the Directive. The Commission will compile a summary of these national reports.

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS

with special reference to small and medium sized enterprises (SMEs)

Title of proposal :

Proposal for a Council Directive concerning the placing of biocidal products on the market.

Reference Number (Repertoire) : 392.1TI (1991)

The proposal

1. Why is Community legislation necessary in this area ?

During discussions in Council of Directive 91/414/EEC concerning the placing of plant protection products on the market and following the adoption of the 8th Amendment to Directive 76/769/EEC concerning the restriction on the marketing and use of certain dangerous substances and preparations, the Council requested that a Community strategy on the marketing and use of biocidal products be developed.

Accordingly, the Commission services have assessed the possibilities for introducing regulatory measures at Community level for biocidal products.

This assessment has shown that biocidal products currently have a widely different regulatory status in the Member States. This ranges from very comprehensive in a few Member States to little or no legislation in others. Such disparities in regulation can lead to barriers to trade between Member States and may create unequal conditions of competition, thereby directly affecting the establishment and functioning of the EEC internal market for chemicals.

The assessment also showed that biocidal products themselves are an extremely varied group of chemicals in terms of their nature and their current uses. Such products have widely varying exposure scenarios and can present potential hazards for the environment, risks at the workplace and possible hazards for the consumer. Given that existing Community legislation and initiatives involving biocidal products have up to now been aimed at quite specific problems involving individual active substances, there is now an urgent need to effectively regulate this wide range of chemicals to provide a high level of protection for man and the environment throughout the Communities.

There are several thousand biocidal product formulations and several hundred active substances which are used in them currently on the Community market. This group of chemicals therefore represents a significant sector of the EEC chemicals market (some 400 MECU) and as such should urgently be given attention with regard to regulation.

The main aims of the current proposal are therefore :

- harmonisation of the internal market for biocidal products and their active substances;

- to provide a high level of protection for health, safety, the environment and consumers.

The Impact on Business

2. Who will be affected by the proposal ?

The Directive will be applicable to any named person on business including manufacturers and importers with a permanent office within the Community and who wishes to place on the EEC market a biocidal product. It will also affect those who provide active substances to be used in a biocidal product. It is expected that manufacturers and importers of such chemicals will be both from large multinational businesses and also from SMEs.

Given the enormous diversity of the chemicals involved and their uneven regulatory status throughout the EEC, it has been difficult to accurately assess to which sectors of business this Directive will be most applicable to and the geographic areas in which they will be concentrated. It is clear however, that generally larger businesses of the EEC chemical industry are primarily concerned with the research, development and manufacture of active substances for use in finished products. Conversely, the SME sector of the chemical industry is particularly concerned with the formulation of preparations using existing active substances together with appropriate co-formulants, stabilisers, anti-oxidants and wetting agents etc.

3. What will business have to do to comply with the proposal ?

Under the terms of this proposal any manufacturer or importer of a new biocidal product or active substance who wishes to place this onto the market will first require authorisation to do this. For an active substance, authorisation will be at Community level whereas for biocidal products, authorisation will be by the Competent Authority of the Member State where the preparation is to be marketed.

In anticipation of any risks for man and the environment that marketing may entail, the application for an authorisation of a biocidal product will require an applicant to submit technical dossiers. However, the information to be provided in the dossiers will be dependant upon the uses of the product and the risks it is likely to pose for man and the environment. It may include data on physico-chemical properties, efficacy data for preparations, information relating to safety precautions during use and information on the necessary action in case of an accident. Where appropriate it will also include relevant toxicological and ecotoxicological data on the active substance.

Given the diversity of chemicals being considered under the proposal, the Commission has sought to develop a flexible approach as to which data are required for each product type. Therefore, certain pieces of information which are not necessary owing to the nature of the chemical or its proposed or existing uses need not be supplied. Such flexibility is particularly necessary for existing substances and products which have a long history of safe use as biocides.

In the event of any new information becoming available concerning either an authorised active substance or biocidal product, the current proposal also lays down an obligation on the authorisation holder to make such information available immediately to the Member State where the authorisation was granted.

Furthermore, before authorisation can be granted for a biocidal product, the Member State concerned will also check that the applicant has a permanent office in the Community and that any advertisement for the product is accompanied by a warning notice.

4. What economic effects is the proposal likely to have ?

The harmonisation of the EEC market in this area will lead to clear advantages for the chemical industry. A Community-wide authorisation scheme will mean that an authorisation holder will essentially be free

to market his product in any of the 12 Member States and depending on the products, reach a potential consumer base of 340 million. Additionally, the authorised product will have been assessed for a risk to health and the environment. In the EEC this will mean that the authorization holder could potentially enjoy a competitive advantage when exporting his product outside of the Community to countries in which similar levels of protection are afforded for man and the environment and to those NON-EC countries which demand evidence of registration in the supplying state (e.g. Middle Eastern countries).

Currently, the basic data set required for a new substance under Directive 67/548/EEC costs approximately 150,000 ECU. The implementation of this Directive may, for some industries, also lead to additional costs compared to the current situation in the EEC. These additional costs will be most apparent to the industry in those Member States which presently have less stringent regulatory provisions than are proposed here and to those whose regulatory regimes do not embrace all the proposed biocidal products. Levels of cost recovery for registration work undertaken by Competent Authorities will be a matter for Member States. In some Member States it is expected that a more thorough assessment will need to be undertaken of chemicals currently marketed than is presently required. It may be speculated that for such industries the incentive to market new products may be slightly reduced as a result of the additional cost involved in supplying information for the authorisation of their products. However the existence of clear rules for authorisation in all member states together with provision for mutual authorisation of products offers clear benefits to these marketing biocidal products in the Community.

In order to allow the chemical industry to adjust to the new regulatory provisions, a ten year transitional period is provided for in the proposed Directive. In this period biocidal products and active substances already being marketed before the Directive is implemented will be permitted to continue to be marketed with the provision that the Commission will initiate a programme for the gradual review of these chemicals.

5. Does the proposal contain measures to take account of the specific situation of SMEs ?

In order to avoid suffocating the development of new products by an overly bureaucratic procedure, the proposal foresees that new products may be afforded provisional national authorizations for a limited period. Such national procedures can be more flexible and allow product and market development at a national level before going Community wide. This option should be a distinct advantage to SME's.

6. CONSULTATIONS

Industry Consultations

International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP)
European Confederation of Woodworking Industries (CEI-Bois)
Confederation of European Pest Control Associations (CEPA)
European Chemical Industry Council (CEFIC)

Other organisations

European Environmental Bureau (EEB)
Worldwide Fund for Nature (WWF)
EEC Union of Water Suppliers (EUREAU)

Consultations with the above listed groups indicated a generally favourable response to the proposed Directive, particularly with respect to the harmonization of the EEC market for biocidal products. This was seen as advantageous both for industry and to groups which are primarily concerned with the protection of man and the environment.

Nevertheless, in a series of discussions with industry which have taken place over the last 18 months, concern has been expressed about certain aspects of the proposal. These have principally been concerned with exactly which products will fall within the scope of the directive, the need to ensure a common approach by Competent Authorities to evaluation of data, the issue of confidentiality, and the extent to which data provided by applicants will be subject to data protection.

The revised text of the Commission proposal addresses all these points. In order to indicate which products are within the scope of the proposal, a series of indicative "product types" has been drawn up, broadly along the lines already followed by industry. So far as a common approach to evaluation of data is concerned, the proposal included a commitment for the Commission to develop "Common Principles for the Evaluation of Dossiers". It is anticipated that studies currently being undertaken in this field will be useful in helping the Commission develop these "Common Principles". With regard to the issue of confidentiality, the proposal draws heavily on the approaches already agreed under Directive 91/414/EEC on plant protection products and on the 7th Amendment to directive 67/548/EEC concerning the classification, packaging and labelling of dangerous substances. Finally, on the matter of data protection, the Commission has responded to industry's concern that a realistic period of data protection must be provided, not only in respect of data on new active substances but also for new data generated for existing active substances. In developing the proposal the Commission has been conscious of the need to balance the interests of those who generate such data with the interests of those who wish to draw upon it in support of applications for authorizations.

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