

## The Biocidal Products Directive 98/8/EC ("BPD")

An Information Sheet Compiled by the LANXESS Material Protection Products Business Unit

The Biocidal Products Directive 98/8/EC which entered into force in May 1998 has been implemented by all the EU member states in their specific national legislation. It covers products which are sold on the European market for biocidal purposes and the active ingredients incorporated.

Active substances that were already available on the market before May 2000 and any preparation made from these are subject to a transitional period of max. 10 years before the provisions of the Directive are applied in full. As far as these existing actives and products are concerned, the respective previous national legislation may continue to apply for the time being.

Lanxess' MPP Business Unit would like to update you on the current situation as regards the Biocidal Products Directive 98/8/EC, its subsequent review regulations, and the main aspects of relevance to customers and suppliers. Sections 1 to 4 of the following summary detail the general features and basic principles of the Biocidal Products Directive, whilst Sections 5 and 6 give practical advice and deal specifically with strategic considerations for our customers.

### 1. AIMS OF THE BPD

The aims of the Directive can be summed up as follows:

- ◆ To guarantee a high degree of protection of human health when handling biocides,
- ◆ To minimise the environmental risks associated with biocides,
- ◆ To harmonise national authorisation requirements for biocides within the EU,
- ◆ To achieve mutual recognition of product authorisations,
- ◆ To establish an EU positive list of authorised biocidal active substances.

### 2. DEFINITION OF ACTIVE SUBSTANCES AND PRODUCTS

The Directive and its subsequent review regulations distinguish between:

**Active substances:** chemical substances and microorganisms with a controlling effect on harmful organisms

- "New" active substances:  
are those that were *not* used in biocidal products prior to May 14, 2000, or which were not identified to the Commission; such substances may only be placed on the market for the use in biocidal products *after they have been fully authorized and incorporated into Annex I* of the Directive.

- "Existing and identified only" active substances: *were used in biocidal products prior to May 14, 2000*; these substances were identified to the Commission under the 1<sup>st</sup> Review Regulation 1896/2000 and are listed in Annex III of the 2<sup>nd</sup> Review Regulation 2032/2003 (updated by Annex III of EC Regulation 1048/2005). Biocidal products containing these active ingredients are allowed to be marketed only by September 1, 2006.
- "Existing and notified" active substances: *were used in biocidal products prior to May 14, 2000*; these substances had to be notified to the Commission under the 1<sup>st</sup> Review Regulation and are listed in Annex II of the 2<sup>nd</sup> Review Regulation 2032/2003 (updated by Annex II of EC Regulation 1048/2005). The actives will be assessed in a 10-year work programme (review programme); they may, subject to certain conditions, remain on the market until the assessment procedure has been concluded/they have been entered into Annex I of the Directive.

**Biocidal products:** active substances and preparations containing one or more active substances in the form in which they are placed on the market and are intended to combat harmful organisms.

A concluding classification of the regulated biocidal products (**product types**) is included as Annex V of the Directive (see also the annex to this information sheet). To qualify as a biocidal product as defined in the Directive the product must generally perform one of the listed functions, e.g. disinfectant, microbicide, wood preservative, insecticide, etc.

Upon the expiry of the 10-year transitional period stipulated in the Directive, i. e. with effect from mid 2010, all biocidal products on the European market may only contain authorised active substances that are included in the EU positive list of substances (i. e. in Annex I of the Directive).

### 3. MAIN ASPECTS OF THE BPD

- ◆ The Directive does **not affect** substances and preparations that are already covered in other EC directives, such as those covering medicinal products, veterinary medicinal products, cosmetic products, crop protection products, food additives, etc.
- ◆ For a **product authorisation** an application must be made separately in each EU member state in which the product is to be placed on the market. To gain authorisation, a product must meet the safety requirements with regard to humans and the environment and must have proven effectiveness. Temporary authorisations may be awarded in special cases.
- ◆ **Mutual recognition** of national product authorisations in the member states simplifies the authorisation procedure: if a given biocidal product is already authorised and registered in one country it shall also be authorised/registered in another state upon application and following the submission of a summary dossier within 120 or 60 days, provided that the state to which the application is made does not raise any particular objections.

**Data protection:** Authorisation data submitted to the authorities may *not* be used by subsequent applicants for their active substance or product authorisations without special permission. However, data protection is granted only for a limited time period.

- ◆ **Research and development:** Special conditions apply. In general, trial products (active substances or preparations) may generally only be placed on the market in a member state following an assessment by the responsible national body.
- ◆ **Costs and charges:** The applicant must bear all the costs incurred in testing and dossier preparation for his active substances and products. These are approximately € 2.5 to 5 million for a complete active substance dossier for an application for its inclusion in Annex I of the Directive. In addition and with regard to active substances, the authorities charge relatively high *processing fees* for their assessment of the application documents.  
Furthermore, at a subsequent stage each biocidal product will be subject to testing and preparation costs for the biocidal product dossier (costs estimated at € 50 - 100 thousand per biocidal product dossier) and to *processing fees* charged by the national authorities in each memberstate. As well, some states are discussing levying sales-based *taxes* on biocidal products.
- ◆ **Cancellation of an authorisation / comparative assessment:** Authorisations may be cancelled or modified if the relevant conditions are no longer fulfilled, if the conditions need to be tightened up in line with the latest findings or if another low-risk active substance is tested and authorised for the same area of application (comparative assessment).
- ◆ **Advertising:** Advertising of biocidal products has to be done in accordance with Article 22. One of the requirements is that it contains the instruction to use biocides safely. The word "biocides" may be replaced by the product type, e.g. wood preservative, disinfectant, etc.
- ◆ **Labelling:** Labelling of biocidal products is harmonised in accordance with Article 20. One of the requirements is that the label contains detailed use instructions and the recommended dose rates. Furthermore, direct or indirect side effects and first aid directions must be given.

The technical details and data requirements for the authorisation of active substances and biocidal products are covered in various annexes to the Directive:

Annex I *):	Positive list of authorised <b>active substances</b> for use in biocidal products
Annex IA *):	Positive list of authorised <b>active substances</b> for use in low-risk biocidal products
Annex IB *):	List of authorised biocidal <b>basic substances</b>
Annex IIA :	<b>Core data set</b> for <b>active substances</b>
Annex IIB :	<b>Core data set</b> for <b>biocidal products</b>
Annex IIIA :	<b>Additional data set</b> for <b>active substances</b>
Annex IIIB :	<b>Additional data set</b> for <b>biocidal products</b>
Annex IVA :	<b>Data set</b> for biological <b>active substances</b> – fungi, micro-organisms and viruses
Annex IVB :	<b>Data set</b> for biological <b>biocidal products</b> – fungi, micro-organisms and viruses
Annex V :	<b>Biocidal product types</b> and more precise description thereof
Annex VI :	<b>Common principles for the evaluation</b> of dossiers for <b>biocidal products</b>

\*) not yet completed

## 4. AUTHORISATION PROCEDURE

### *Active substances*

- "New" active substances that were not used in biocidal products before May 14, 2000 may only be placed on the market in the EU for biocidal purposes if an application (including submission of a dossier) has been made and the active substance has been incorporated into Annex I of the Biocidal Products Directive.
- "Existing" active substances are those active substances that were nominated to the Commission during the review programme and that were already in use in biocidal products prior to May 14, 2000. These actives are subject to the review programme.

"Existing and identified only" active substances were nominated to the Commission under the 1<sup>st</sup> Review Regulation 1896/2000. They are listed in Annex III of the 2<sup>nd</sup> Review Regulation 2032/2003 (updated by Annex III of EC Regulation 1048/2005). Biocidal products containing these active ingredients are only allowed to be marketed by September 1, 2006.

"Existing and notified" active substances were nominated to the Commission under the 1<sup>st</sup> EC Review Regulation 1896/2000, i. e. they had to be supported already with the submission of a certain amount of data as a first step for dossier preparation. They are listed in Annex II of the 2<sup>nd</sup> Review Regulation 2032/2003 (updated by Annex II of EC Regulation 1048/2005). The actives will be assessed as part of a 10-year work programme (review programme); they may, subject to certain conditions, remain on the market until the assessment procedure has been concluded/they have been entered into Annex I of the Directive.

- Dossier submission: The 2<sup>nd</sup> Review Regulation 2032/2003 and the 3<sup>rd</sup> Review Regulation 1048/2005 specify deadlines for the submission of complete dossiers to support the active ingredients within their notified product types. Additionally, a rapporteur member state is appointed who shall carry out the evaluation of the dossier. The following table provides an overview:

Submission Dates of the Dossiers	Product Types
28.03.2004	wood preservatives (PT08) rodenticides (PT14)
01.11.2005 - 30.04.2006	Molluscicides (PT 16) Insecticides (PT 18) Repellents (PT 19) Antifouling products (PT 21)
01.02.2007 - 31.07.2007	Disinfectant product group (PT 1, 2, 3, 4, 5) In-can preservatives (PT 6) Metalworking fluid preservatives (PT 13)
01.05.2008 - 31.10.2008	Film preservatives (PT 7) Fibre, leather, rubber, polym. materials preserv. (PT 9) Masonry preservatives (PT 10) Liquid-cooling and processing systems preserv. (PT 11) Slimicides (PT 12) Remaining product types (PT 15, 17, 20, 22, 23)

***Biocidal products:***

- Biocidal products containing "new" active substances, i. e. active substances that were *not* used prior to May 14, 2000 or which have not been identified under the 1<sup>st</sup> Review Regulation, may not be placed on the market without official permission. In other words, an application must be made first (including submission of dossiers on both the active substance and the biocidal product), followed by inclusion of the active substance in Annex I of the Directive before any sales in the EU can start. Temporary authorisations may be awarded in special cases.
- Biocidal products containing "existing and identified only" active substances, i. e. active substances that were already used in biocidal products prior to May 14, 2000 and that have been "identified only" to the Commission under the 1<sup>st</sup> Review Regulation are not allowed to be marketed after September 1, 2006.
- The placing on the market of biocidal products containing "existing and notified" active substances, i. e. active substances that were already used in biocidal products prior to May 14, 2000 and that have been notified to the Commission for a certain product type, may continue on the market for that specific product type and for the time being (for a period of max. 10 years) in line with the respective national legislations. During this time, the "existing and notified" active substances are subject to the review programme. *Final authorisation* for a biocidal product will be requested by the national authorities once an active substance has been entered into Annex I of the Directive; then the submission of a *biocidal product dossier* will become necessary.

National regulations and ordinances shall apply during the transitional phase. Products registered in accordance with national provisions shall remain confirmed for the time being, whilst new local registrations may need some adapted procedures compared to the previous standards.

The consequences of the review regulations for active substances and biocidal products made from these substances can be summarised as follows:

<b>Active substance</b>	<b>Effects on the placing on the market of the active substance and biocidal products made from the substance</b>	<b>Time limit on sale of existing stocks</b>	<b>Active substance in assessment programme under Directive</b>
Not identified and Not notified	No further selling after Nov. 2003, i. e. entry into force of 2 <sup>nd</sup> review regulation 2032/2003	None	No
Identified, but Not notified	No further selling after Sept. 1, 2006	None	No
Identified and Notified	Placing on the market until decision on inclusion (or non-inclusion) of the active substance in Annex I in accordance with national legislations; subsequent submission of product dossiers for final national product authorisations	On a case-by-case basis	Yes

## 5. WHAT SHOULD LANXESS CUSTOMERS DO

We recommend that our customers ascertain whether their products fall under the *definition of biocidal products* as detailed in the body text of the Biocidal Products Directive. This means checking whether the products fit the definition of biocidal products and do not fall under any exception clauses and borderline issues. Areas that require special checking include the claims on the customer's product label or product description in the relevant information sheets. Similarly, the specific definitions contained in Annex V of the Directive must be considered.

If the customer has confirmed that his product is a biocidal product, in a second step, the biocidal *product type* as classified in Annex V of the Directive must be ascertained for his product.

The next clarification necessary is related to all active ingredients incorporated in the customer's biocidal product whether they have been *notified* for his specific product type (see Annex II of EC Regulations 2032/2003 and 1048/2005) and thus are candidates for final evaluation and inclusion in Annex I of the Directive. The customer may check directly by his own the annexes of the Review Regulations or ask his supplier for support. Furthermore, he may encourage his supplier to initiate the preparation of a complete dossier for the relevant active ingredient and his specific product type and/or mode of application; in certain special cases the supplier may need the customer's close co-operation to cover specific efficacy and exposure questions related to the use of the biocidal product, or to define specific frame formulations for submission with the dossier.

During the EU evaluation process of the active ingredient the customer may stay in contact with his active ingredient supplier so that he is well informed when the active ingredient will be listed in Annex I of the Directive. Then it is his turn to start the preparatory work for his own *biocidal product dossier* in order to meet the submission deadlines of the competent national EU authorities who will carry out the final product dossier evaluation and grant the requested national biocidal product registrations. For more comprehensive and detailed information about the whole EU evaluation process and its legal background the customer may also check the biocides website of the European Chemicals Bureau on a regular basis: <http://ecb.jrc.it/biocides/>.

As in most EU member states *national biocidal product lists* have already been established, we generally recommend that all biocidal product manufacturers should keep up to date on the **national biocidal product legislation** in their own countries (e.g. through the national chemical associations). In most cases small product dossiers are already required now; in some cases further requirements have to be observed, *inter alia* regarding lot numbers, expiry dates, or registration numbers to be placed on the packagings, or even special biocidal product labels to be attached to the products.

## 6. WHAT WILL LANXESS DO?

With its Biochek®/Metasol®/Preventol®/Tektamer® brands, Lanxess offers a range of active substances and active substance concentrates for various different industrial applications, e.g. for the formulation of wood preservatives, in-can preservatives, disinfectants etc. However, Lanxess is not only affected by the forthcoming EU biocidal product legislation in its capacity as a supplier of active substances, but also as a manufacturer of biocidal products, with its comprehensive range of preservatives, for example. Through its membership in CEFIC (European Chemicals Association) and its active co-operation with numerous national chemical associations Lanxess

has always been and remains fully informed about the latest developments in European legislation on biocidal products. Where required, Lanxess' expert field staff have also been on hand to brief our customers in this area. This is something we obviously want to continue.

Although there are still some minor unclear areas in terms of the final EU registration process and the detailed data requirements and waiving options of the Biocidal Products Directive, we can provide our clients with the following assurances as regards our range of products and active substances:

1. The MPP Business Unit of Lanxess Deutschland GmbH is willing –as far as economically reasonable– to support its own active substances and preparations by providing appropriate data during the transitional programme with an ultimate aim of seeing these active substances included in the positive list (Annex I) of the Directive.
2. Lanxess' MPP Business Unit will brief its customers where necessary on its registration strategy (submission of an identification/notification/final dossier) and on the state of the registration process (dossier submitted for a certain product type/successful inclusion of a substance in Annex I) with regard to its active substances and preparations. Provisional internal lists of active substances to be 'identified'/'notified'/'dossier submitted' within the context of the registration process have been drawn up and are available to our employees who will consult with our customers.
3. Upon request Lanxess can provide confirmation of the registration status of our Lanxess' active substances at any time, also stipulating the relevant product types.
4. The MPP Business Unit will continue to co-operate actively with our customers giving advice and supporting national customer registrations by providing access to submitted data and/or frame formulations ("Letter of Access") where appropriate.

Leverkusen, August 2005

*This information and these recommendations are given in good faith but without warranty. Our advice does not release you from the obligation to verify the information provided. The application, use and processing of our products and the products manufactured by you on the basis of our technical advice and your products' legal authorisation and registration are beyond our control and, therefore, entirely your own responsibility.*

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## Annex

### PRODUCT TYPES as defined in Annex V of the Biocidal Products Directive

(please refer to the text of Directive 98/8/EC for a more detailed definition)

Main group 1:	Disinfectants	<ol style="list-style-type: none"> <li>1. Human hygiene</li> <li>2. Private area and public health</li> <li>3. Veterinary hygiene</li> <li>4. Food and feed area</li> <li>5. Drinking water</li> </ol>
Main group 2:	Preservatives	<ol style="list-style-type: none"> <li>6. In-can applications</li> <li>7. Films</li> <li>8. Wood</li> <li>9. Fibre, leather, rubber and polymerised materials</li> <li>10. Masonry</li> <li>11. Liquid-cooling and processing systems</li> <li>12. Slimicides</li> <li>13. Metalworking fluids</li> </ol>
Main group 3:	Pest control	<ol style="list-style-type: none"> <li>14. Rodenticides</li> <li>15. Avicides</li> <li>16. Molluscicides</li> <li>17. Piscicides</li> <li>18. Insecticides, acaricides and products to control other arthropods</li> <li>19. Repellents and attractants</li> </ol>
Main group 4:	Other biocidal products	<ol style="list-style-type: none"> <li>20. Products for food or feedstocks</li> <li>21. Anti-fouling products</li> <li>22. Embalming and taxidermist fluids</li> <li>23. Products for the control of other vertebrates</li> </ol>