Biocide Information 1

Introduction into the authorisation procedure

baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

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Preface

On 8 March 1998, the "Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 regarding the placing of biocidal products on the market" took effect. By this directive, uniform regulations were created for many products regarding the control of harmful organisms e.g. rodents, insects or microorganisms.

In order to guarantee protection for consumers, employees and the environment on the one hand and sufficient efficacy on the other, biocidal products are only allowed to be placed on the market and used when authorisation or registration were issued by the competent national authority. In analogy to medicinal products or pesticides, biocidal products are thus subject to a pre-commercialization check.

This brochure shall give general information about requirements that your company may need to comply with, according to the biocides legislation. As manufacturer and/or importer you will find information such as decision criteria according to which you can evaluate which legal regulation applies to your product or – if you manufacture a biocidal product – how you can prepare for the required authorisation procedure.

Dortmund (Germany), May, 2011
Authorisation Unit for Biocides

98/8/EC

1 What is a biocidal product?

In order to decide whether and which products are subject to the biocidal legislation, the definition of a biocidal product shall be consulted. The German Chemicals Act (ChemG) defines biocidal products pursuant to section 3 b paragraph 1 as:

"... 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 by chemical or biological means ...."

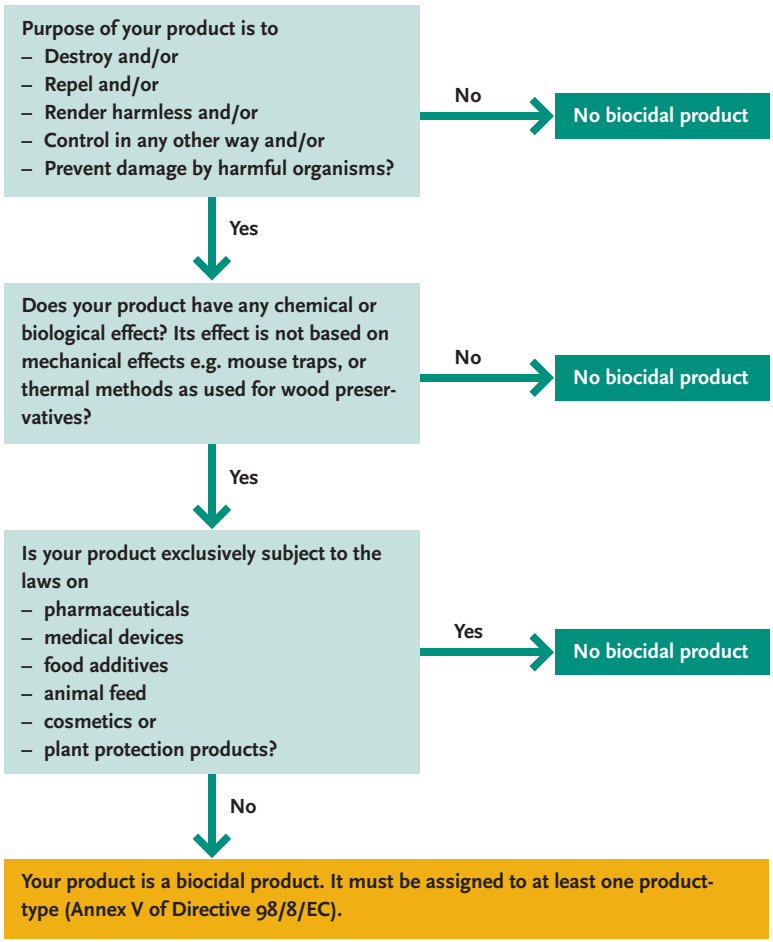
This definition is extensive. Among biocidal products like insecticides or rodenticides (chemicals to control rodents) are also products which hinder damage caused by harmful organisms. Therefore, attractants and repellents (e.g. substances to repel mosquitoes to land on your skin) also fall within the scope of the definition. Thus, as manufacturer of these kind of substances or, for example, pheromones your products may be subject to the biocidal law in the case of respective use and description.

In total, 23 different product-types are identified, which are regarded as biocides (please see the chart). If you produce or import a biocidal product, you must assign the product to at least one of the product-types.

	Product type
1	Human hygiene biocidal products
2	Private area and public health area disinfectants and other biocidal products
3	Veterinary hygiene biocidal products
4	Food and feed area disinfectants
5	Drinking water disinfectants
6	In-can preservatives
7	Film preservatives
8	Wood preservatives
9	Fiber, leather, rubber and polymerised materials preservatives
10	Masonry preservatives
11	Preservatives for liquid-cooling and processing systems
12	Slimicides
13	Metalworking-fluid preservatives
14	Rodenticides
15	Avicides
16	Molluscicides
17	Piscicides
18	Insecticides, acaricides and products to control other arthropods
19	Repellents and attractants
20	Preservatives for food or feedstocks
21	Antifouling products
22	Embalming and taxidermist fluids
23	Control of other vertebrates

Product-types for biocidal products (pursuant to Annex V of Directive 98/8/EC)

Is my product a biocidal product?



Delimitation to other areas of law

According to ChemG § 3 b paragraph 1 No 1 products, which are e.g. regarded as veterinary medicines, as plant protection or as cosmetic products, are not subject to the biocides legislation. These products are subject to other provisions; e.g. a pharmaceutical must be approved pursuant to the drug legislation, and plant protection products pursuant to the plant protection products legislation.

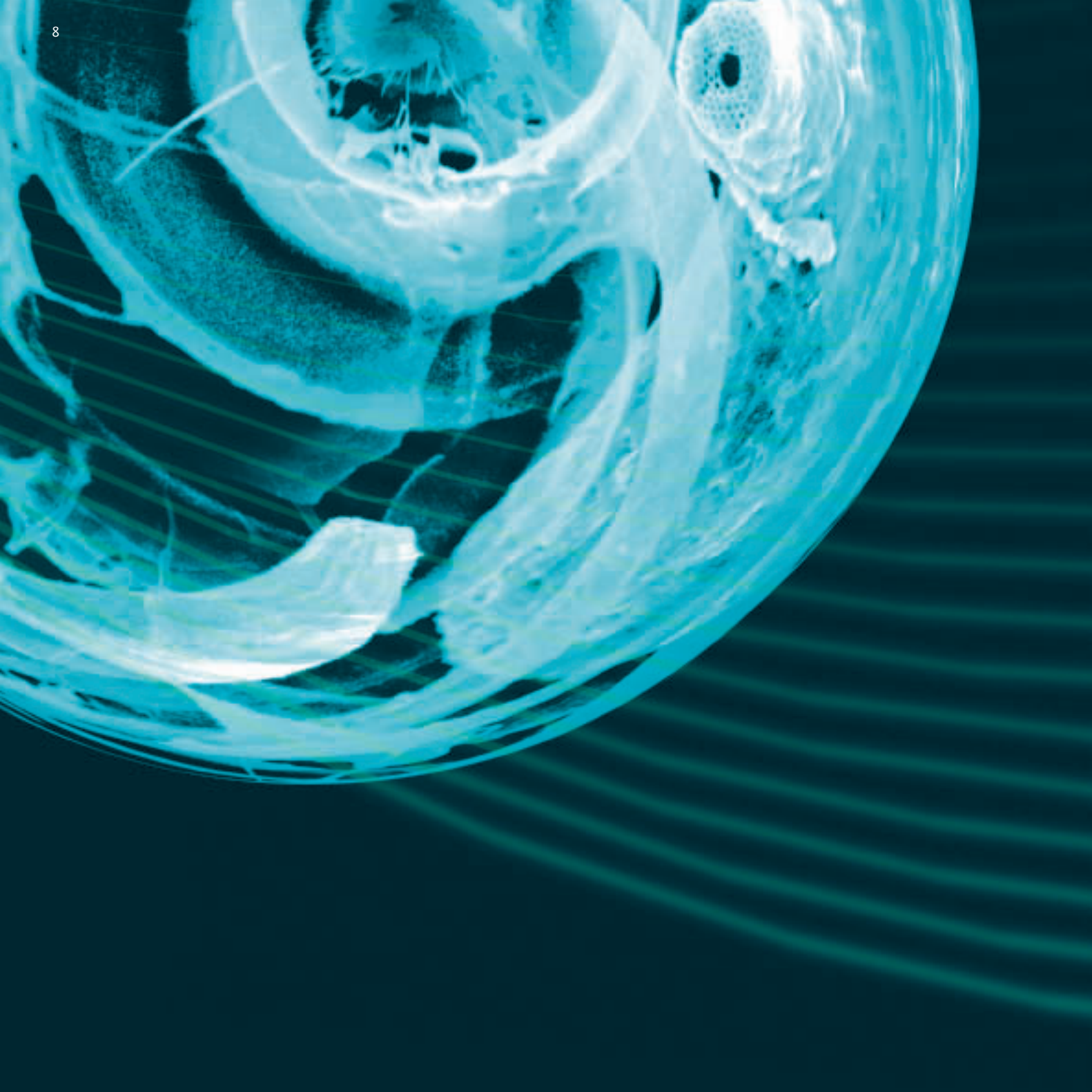
The differentiation whether a product is a biocide or e.g. a pharmaceutical is often difficult. Whether a commercial product against fleas is to be regarded as repellent (i.e. a biocide) or as a pharmaceutical cannot be decided at first glance. The EU published a collection with individual cases – Manual of Decisions (please see the Links list) – for orientation purposes. It lists examples of various decisions of assignment in different Member States. These decisions are, however, not legally binding. Therefore, it is conceivable that national authorities may give dissenting decisions. If you are not certain whether your product must be regarded as a biocide or is subject to any other regulation, you should contact the competent authorities.

In many cases it is also a question of product claim and/or customer expectation whether a product is regarded as a biocide. If, for example, the packaging material of a detergent contains the information that it has a disinfectant effect this detergent must be regarded as a disinfectant and as a biocidal product in consequence. A detergent without effect on microorganisms, however, is not subject to biocides legislation. The customer's expectations may be relevant in cases where a product has been advertised as having a disinfectant effect for a long time and this advertisement is removed without a change of the product composition.

Examples of biocidal products

You are a manufacturer of sanitary cleaners for private consumers. In addition to tensides and scents the cleaner also contains a substance that has a disinfectant effect. Accordingly, the cleaner is advertised as “antimicrobial”.	This product is a biocidal product of product-type 2 on the basis of its antimicrobial effect.
You are a manufacturer of wall paint for private consumers. In addition to solvents and colorants the paint contains also small quantities of a biocidal substance, which protects the colorants during storage from decomposition by microorganisms.	This product is not a biocidal product because the substance used only protects the product itself, however, shall not have any biocidal effect after painting. However, the manufacturer or importer of the substance (and the product which contains the substance), which is added to the wall paint during the manufacturing process, must have a respective authorisation as biocide.
You are a manufacturer of wood varnish, which in addition to oils and colorants contains an active biocidal substance that both protects against decomposition during storage and against blue stain fungi.	This product is a wood preservative, i.e. a biocidal product of product-type 8 because the timber is protected against blue stain fungi.
You are a manufacturer of candles which contain a certain scent. This scent shall repel mosquitoes. The candles are offered as anti-mosquitoes candles, accordingly.	This product is a biocidal product of product-type 19 because of its repellent effect against mosquitoes.
You are a manufacturer of adhesive fly traps, which contain adhesives but no attractants.	This product is no biocidal product because the adhesive traps have neither a chemical nor a biological but a physical effect.

Tip: **Contact the competent authorities if you are not sure regarding the assignation of your product!**



2 What is the procedure for biocides?

In order to guarantee protection for consumers, employees and the environment on the one hand and a sufficient effect on the other, biocidal products are subject to an authorisation. Within the framework of such an authorisation in Germany you as the applicant submit an application to the authorisation unit. The Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) in Dortmund is the competent authorisation unit in Germany: **www.baua.de**

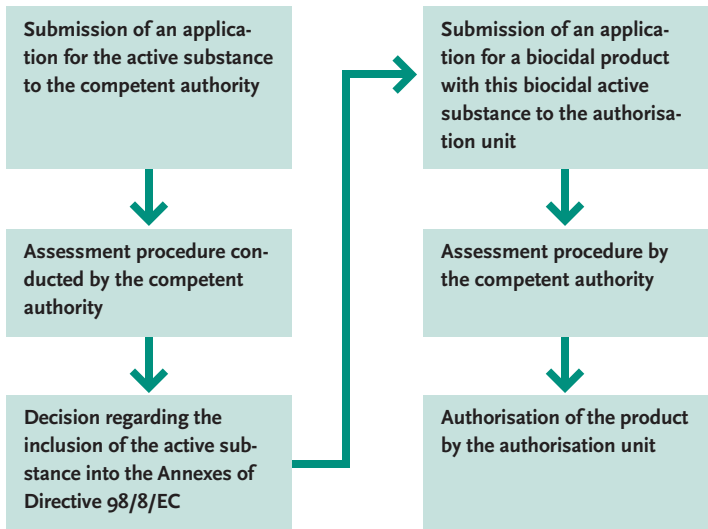
As a precondition for the authorisation or registration the active substances of the biocidal product must be listed in Annex I or IA of Directive 98/8/EC and the requirements listed therein must be met.

In practice, the procedure regarding biocides consists of an active substance procedure and a product procedure – please see chart.

Legal basis for authorisation:
§ 12a et seq. ChemG

legal basis for authorisation unit:
§ 12j paragraph 1 ChemG

Schematic flow chart of the biocides procedure



The active substance procedure

Biocidal products may contain active substances that are listed in a "list of permitted active substances" only. You will find this list in the Annexes I and IA of Directive 98/8/EC. For the purpose of the inclusion of an active substance into these annexes, you as the applicant fill in the respective application form so that all information necessary for a comprehensive risk assessment is available. Inter alia, extensive studies on the effect of the substance on human health and the environment, on the exposure situation and on measures for the protection of man and the environment must be submitted.

This information is thoroughly assessed by the competent authorities, and after the assessment there will be a decision about the inclusion of the active substance into one of the annexes in a voting procedure on EU level.

There are transitional rules for existing active substances. As long as no decision is taken whether these existing active substances are included in the annexes of Directive 98/8/EC, biocidal products containing these active substances may be placed on the market in Germany without authorisation.

Regarding new active substances the following applies: products with such new active substances must be authorised prior to any first placing on the market.

Examples for marketability of active substances (as of May 2011)

You wish to use propionic acid as an active substance for a disinfectant.	**This active substance can be found in Commission Regulation (EC) No 1451/2007 in Annex I "active substances identified as existing", however, not in the list of the notified active substances. Biocidal products with this active substance are for this reason no longer permitted to be placed on the market since September 2006. Thus, the active substance must be included in the annexes and the respective product must be authorised prior to any new placing on the market.**
You wish to use octanoic acid as an active substance for an insecticide (= product-type 18).	**The active substance is included in Annex II of Commission Regulation (EC) No 1451/2007 "active substances to be examined under the review programme", inter alia for product-type 18. Until a decision is taken regarding the inclusion of the active substance in the annexes of the Directive, the active substance may be contained in insecticides and placed on the market without an authorisation.**
You wish to use cyanamide as an active substance for a rodenticide (= product-type 14).	**The active substance is included in Annex II of Commission Regulation (EC) No 1451/2007, however, not for product-type 14. The active substance can no longer be placed on the market for rodenticides since September 2006.**
You wish to use benzyl benzoate as an active substance for an insecticide (= product-type 18).	**The active substance is included in Annex II of Commission Regulation (EC) No 1451/2007 "active substances to be examined under the review programme", however, it is in the list of active substances which will not be included into the Annex of the Biocides Directive and has the phase-out date of 21 August 2009. The active substance can no longer to be placed on the market for insecticides.**

Legal basis regarding transitional rules:

§ 28 paragraph 8 ChemG in conjunction with Article 16 paragraph 2 Directive 98/8/EC and Commission Regulation (EC) No 1451/2007

In Commission Regulation (EC) No 1451/2007 you can find out what is considered an existing active substance. In Annex I of that Regulation all active substances are listed that were available on the market prior to the year 2000 and thus meet the requirement of the definition of existing active substances.

For some of these substances the European Commission already took the decision together with the Member States that they shall not be included in the annexes of Directive 98/8/EC: i.e. those substances for which no application was submitted by any company.

Therefore, this Regulation has a second Annex. It lists all active substances, for which a company has declared to provide the required documentation. The so-called notified substances are allocated to the product-types to which this notification is applicable. An existing active substance in biocidal products must be listed in this Annex II of the Commission Regulation (EC) No 1451/2007 in order to be marketable in biocidal products.

Since the publication of the Commission Regulation (EC) No 1451/2007 some time has passed, however. During this time decisions were taken against the inclusion of active substances, partly because despite notification no application was submitted or partly because the competent authorities decided that the use of an active substance entails non acceptable risks. Thus, the Commission Regulation (EC) No 1451/2007 does not offer most updated information. What does this mean to you?

In order to ensure that your biocidal product together with the active substances contained will be marketable in the future you should also check the list of not included active substances, which the European Commission publishes on its homepage and updates regularly (please see Links). From this list you may learn whether your product must be taken off the market, although all contained active substances are notified, and until what date this has to be carried out.

Since the year 2004 the data regarding the notified active substances are submitted to the authorities sorted by priority. At present (May 2011) this submission phase is almost completed. The applications are assessed by the authorities, and subsequently, in the Commission procedure, the Commission and the Member States decide on the inclusion. For some active substances decisions have already been provided (please see Links). In the event of a "positive" decision, a "Commission Directive amending Directive 98/8/EC to include an active substance in Annex I, IA or IB" (inclusion directive) for this active substance will be published. The directive determines the required purity of the active substance and the application of specific provisions. For existing active substances it also sets a date for the submission of an application for authorisation of products with this active substance in order to ensure marketability for the time of the application procedure.

Tip: **Make sure that the active substance in your biocidal product is marketable in the future!**

The inclusion directive using an example of an existing active substance

In contrast to the REACH regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals) applicable to industrial chemicals, in biocidal legislation there are no general deadlines for the submission of the applications for authorisation. There are individual deadlines and these depend on the active substances that a product contains. The respective dates can be found in the inclusion directives for each active substance. The inclusion directives are published on the internet (please see Links).

One part of the inclusion directive is a chart containing different details on the active substance (please see chart). There are 9 columns with serial numbers and details regarding the general and scientific name (including identification codes like the CAS- or the EC-No). In the fourth column, you will find the "minimum purity of the active substance in the biocidal product as placed on the market". It indicates the required purity of the active substance. In case the purity is below the degree as indicated in the inclusion directive, the active substance must not be used for a biocidal product.

The "date of inclusion" indicates the date of inclusion of the active substance in Annex I or IA of Directive 98/8/EC. This date is about 2 years from the publication of the inclusion directive. Upon inclusion into one of the annexes, an application for authorisation must be submitted for biocidal products containing the respective existing active substance if it is intended to leave the biocidal product on the market for the period of the authorisation procedure. Thus, right after publication of the inclusion directive you should begin to collect the documentation for the application.

Legal basis for the transition regulation: § 28 paragraph 8 ChemG

"Deadline for compliance" is the date when the requirement of Directive 98/8/EC must be met: the granted authorisation for a biocidal product. For you this means: when the active substance is included in the Annex of Directive 98/8/EC, you are not yet obliged to prove authorisation for your product but you need to submit a complete application for authorisation to the authorisation unit in due time. In this case you may continue to market your product without authorisation until a decision is taken regarding your application for authorisation.

The authorisation unit assesses your application during this time and decides on authorisation or refusal. In order to be able to make use of the transition rules you have to submit your dossier within 24 months after the publication of the inclusion directive to the authorisation unit. A small hint: you will find the publication date at the beginning of the inclusion directive. However, we recommend submitting the dossier as soon as possible in order to ensure that the procedure is completed by the end of the deadline for compliance (column 6).

It should be noted that the date at which your application must be submitted to the competent authority may differ slightly in the various EU Member States. Often, the documents must be submitted by the indicated date of inclusion, in some Member States however, the deadline may expire some days earlier. If you wish to submit your dossier timely in a certain Member State you should inform yourself about the applicable deadline in that respective State. The Commission provides a list of the competent authorities in the single Member States on its website (please see Links).

Set-up of a chart from the Inclusion Directive

Columns in the inclusion directive								
No	Common Name	IUPAC-name, Identification numbers	Minimum purity of the active substance in the biocidal product ...	Date of inclusion	Deadline for compliance with Article 16 paragraph 3 ...	Expiry date of inclusion	Product type	Specific provisions
Entered contents								
Serial number	Common name of substance	IUPAC-name, CAS-number of the substance	Degree of purity that the active substance must reach in order to be permitted for use in a biocidal product	As of this date the active substance is considered as included in the annex	As of this date an application for authorisation must be decided positively for further marketing	As of this date the active substance is deleted from the annex (possibly application for extension necessary)	Product type for which the acceptance into the annex applies	Special conditions of use that must be considered upon product authorisation

Examples for the date regarding the application for authorisation (in Germany)

A biocidal product of product-type 8 contains the active substance propiconazole. According to the inclusion directive the deadline for compliance of propiconazole is 31 March 2012, the inclusion directive was published on 25 July 2008.	The complete dossiers concerning the application for authorisation must be received by the authorisation unit by 25 July 2010.
A biocidal product of product-type 8 contains the substances clothianidin and thiamethoxam. The inclusion directive for clothianidin was published on 15 February 2008, and for thiamethoxam on 25 July 2008.	The complete dossiers concerning the application for authorisation must be received by the authorisation unit by 25 July 2010.
A biocidal product of product-type 8 contains the substances IPBC and fenoxycarb. The inclusion directive for IPBC was published on 29 July 2008, for fenoxycarb no inclusion directive has so far been published.	As long as no inclusion directive has been published for fenoxycarb, no application for authorisation can be submitted. After publication, the complete dossier for the application for authorisation must be received by the authorisation unit at the latest 24 months after the inclusion directive is published.
A biocidal product of product-type 18 contains the active substances clothianidin and benzyl benzoate. For clothianidin PT 18 no inclusion directive has so far been published. For benzyl benzoate a decision for non-inclusion was taken with the effective date of 21 August 2009.	For this biocidal product no application for authorisation can be submitted.

In case a biocidal product contains several active substances you must submit the dossier for your product by the date which is 24 months after the publication of the inclusion directive for the **last** active substance of the product.

In case you do not submit an application for authorisation to the authorisation unit in time, i.e. within 24 months, after publication of the inclusion directive, you will not be able to benefit from the transition period for your biocidal product until the deadline for compliance. In this case you are not permitted to place your product on the market.

The inclusion of the active substance into the Annex of Directive 98/8/EC is limited in time, usually for 10 years. The date of the expiry of the inclusion can be found in column 7 of the inclusion directive. If you are interested in the continuous placing on the market of your active substance and products you should, within due time, submit an application for re-inclusion into the Annexes of Directive 98/8/EC; please note that a new evaluation might be necessary!

The penultimate column – product-type – indicates the product-type of the inclusion to the Annex of Directive 98/8/EC. You are permitted to use the active substance only for a biocidal product of this product-type, the use of the active substance for any other but the indicated product-types is not permitted.

Legal basis:

section 12 d of Chemistry law (German ChemG) authorisation procedure

Legal basis:

§ 12 g ChemG recognition of foreign authorisations and registrations

The last column in the chart of the inclusion directive – special conditions – describes potential conditions that must be considered during the product authorisation procedure. This column may provide, for example, that a product containing this active substance may only be authorised for professional use, that these products must not be authorised for outdoor use or that upon usage certain measures must be taken to minimise the risk for man or environment.

The authorisation procedure

In order to obtain an authorisation for a biocidal product a company must compile a dossier pursuant to Article 8 paragraph 2 and Annex IIB /IIIB of Directive 98/8/EC. It shall include data regarding the biocidal product and data regarding the active substances contained in the product. The required data includes information that can be used as a basis for the assessment of risks for man and environment arising during the use of the biocidal product. Upon receipt of the application the authorities involved in the procedure assess the submitted information and take a decision on the authorisation of the product on the basis of this assessment.

Since the inclusion of the active substance into the Annex of Directive 98/8/EC is limited in time, the authorisation for a biocidal product is also limited in time. The authorisation expires on the date of expiry of the inclusion for the first contained active substance in the Annex of Directive 98/8/EC. Thus, at the latest one year prior to the expiration of the authorisation, you should apply for the extension of the authorisation.

Authorisations have national validity. In case you intend to place a product on the market in other EU states that has already been authorised on a national level, you should submit an application for “mutual recognition”

considering the respective data requirements. The application must include a certified copy of the authorisation notice.

Registration and mutual recognition

In case all active substances of your biocidal product are included in Annex IA of Directive 98/8/EC and your product contains no further substances of concern (and the product entails only a low risk for man, animals and the environment), you can apply for registration of your biocidal product. The term "registration" must not be confused with what is considered as registration under REACH.

Annex IA lists active substances with a low risk potential. Therefore, a markedly smaller set of information must be submitted for the application for registration than for an application for authorisation.

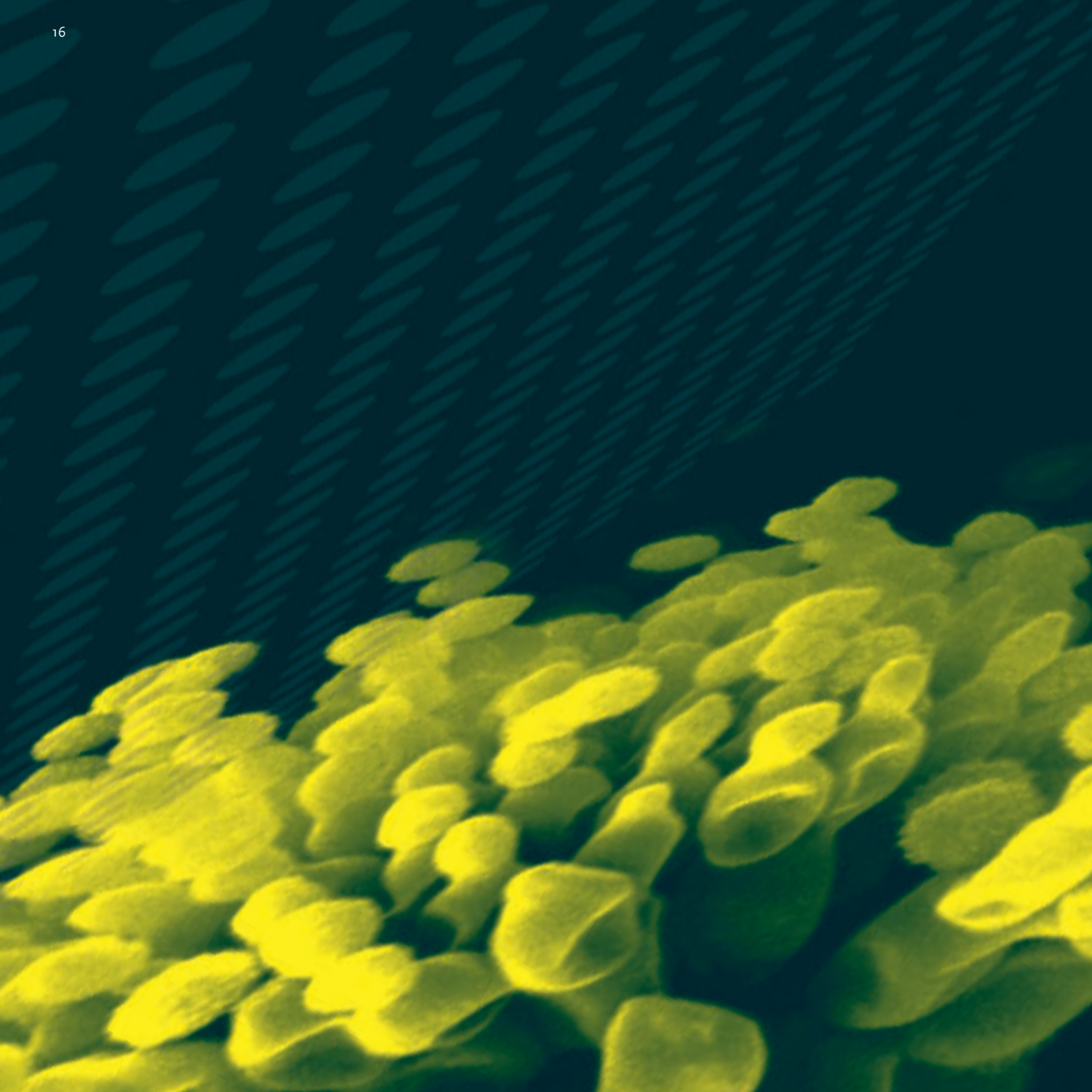
In case a product is already authorised in another EU Member State, an application for recognition of this foreign authorisation can be submitted in Germany under consideration of the respective data requirements. Naturally, a certified copy of the foreign authorisation notice must be included.

It should be noted that for biocidal products with existing active substances the application for mutual recognition or registration must also be submitted to the authorisation unit 24 months after publication of the inclusion directive for the respective active substance at the latest. In case the application is not submitted in due time, the biocidal product loses its marketability until authorisation or registration is accepted. Please note that in general the certified copy of the authorisation in the first Member States is not available at this date and has to be submitted after authorisation in the first Member State is granted.

The costs ...

Authorisation of a biocidal product (per product-type)	**10.000 – 45.000 €**
Extension of authorisation (per product-type)	**1.500 – 17.500 €**
Registration of a biocidal product (per product-type)	**750 €**
Mutual recognition of an authorisation (per product-type)	**2.500 €**
Mutual recognition of a registration (per product-type)	**500 €**

Fees according to the Chemicals–Cost Ordinance (ChemKostV). For an authorisation further cost arise for the preparation of the necessary studies and for the elaboration of dossiers.



3 What to do and when to do?

Currently (May 2011), there are just a few authorised biocidal products in Germany. The reason: since the authorisation procedure for biocides commences only after the respective active substances are included in the annexes of Directive 98/8/EC, and the first active substances were however included in the year 2009, it will still take time until authorised biocidal products will be on the market. Presently, we are processing the first applications.

How to obtain an authorisation?

If you wish to submit an application for authorisation of your biocidal product you must compile a comprehensive dossier. This dossier must include a detailed description of the composition of your product as well as information regarding the product as a basis for the evaluation of the product and its impact on man and the environment. Studies must be attached to the dossier as such (this is the so-called doc. IV-level) and in form of standardised study summaries (doc. III-level). Hereinafter, it is your responsibility to summarise the data regarding the product and provide a risk evaluation that also refers to the exposure during use (doc. II-level). The required studies are studies examining the physico-chemical properties, toxicological and eco-toxicological properties, the efficacy and the analysis techniques. You will find exact details regarding formats, data requirements, reasons for the non-provision of data and required testing conditions in the Technischer Leitfaden für die Zulassung/Registrierung eines Biozid-Produktes (Technical Guidance regarding the authorisation/registration of a biocidal product) (available in German language only, please see Links).

You are obliged to use the format of the biocidal register ("R4BP") for the application. Please consider the so called "R4BP user guide", which was created by the European Commission (please see Links).

In addition to the data regarding the biocidal product you must also submit the data regarding the active substance. Usually, these include the data that was submitted during the active-substance procedure for risk assessment of the active substance. In general, you will be able to refer to this data. To this end, you must contact the owner of the data and negotiate the conditions for a reference. You may identify the owner of the data through the "assessment report" that is published together with the inclusion directive. The owner of the data provides you with a "letter of access" which includes the studies and data to which you may take reference. Please attach this letter of access to your application for authorisation.

In case you have your own valid studies or receive these from your supplier you may also submit those. However, you need to prove that the active substance used in your studies is chemically identical to, and toxicologically and eco-toxicologically equivalent with, the active substance that was included in the Annex of Directive 98/8/EC.

If you wish to carry out new studies you should be aware that for reasons of animal welfare tests on vertebrate animals must not be repeated. In case valid tests on vertebrates are available you must refer to those. Thus, before you commence such a study you have to contact the authorisation unit in order to find out whether respective data are available.

Tip: **Before you carry out tests on vertebrates contact the authorities whether there are already available data!**

Legal basis:

§ 20a ChemG – use of test results of third parties, obligation of preliminary inquiry

Legal basis:

§ 16 f ChemG – reporting regarding biocidal products and active substances

Authorisation is specific to the product. If, for example, the manufacturer of one of the ingredients of the product changes, the authorisation unit must to be informed and a new application for authorisation must be submitted if necessary.

Since the inclusion of the active substances in the annexes of Directive 98/8/EC is subject to a time limit the granting of an authorisation is also limited in time. The limitation depends on the active substances contained in your biocidal product and the expiry date of the inclusion of this active substance into the annexes of Directive 98/8/EC.

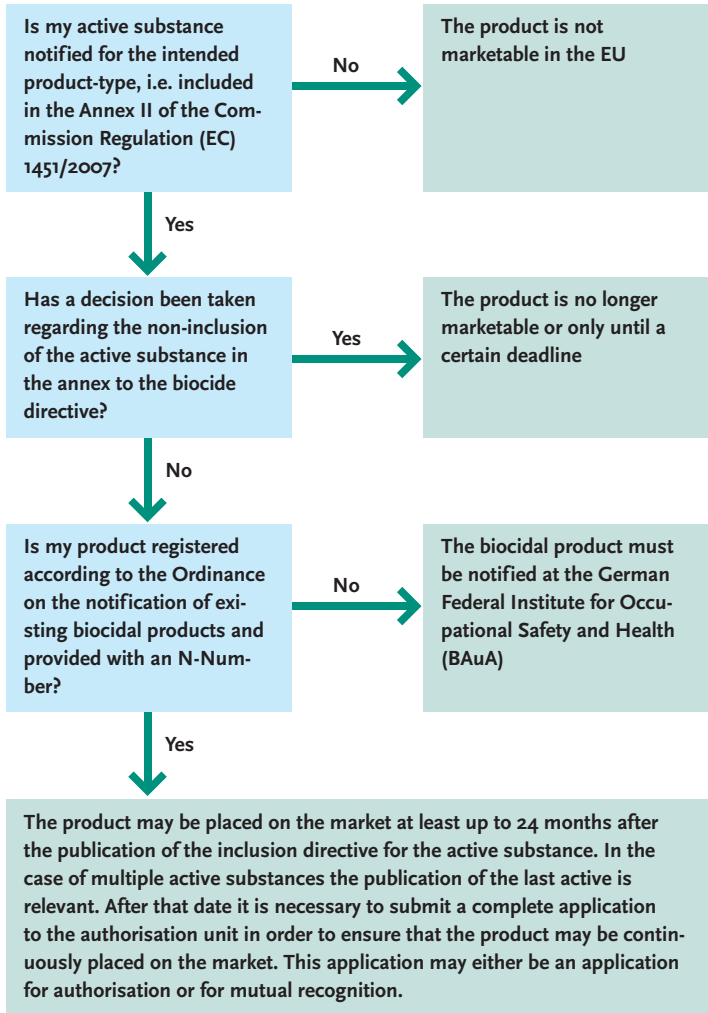
The authorisations for your biocidal products are national authorisations, i.e. they are valid in the Member State in which you submitted your application only. If you wish to place your biocidal product on the market in another Member State, you also need to obtain an authorisation in this Member State. In this case you submit an application for mutual recognition to the competent authority of the other Member State. This means: you inform e.g. the British authority in your application that your product was or will be authorised by the German authority (or vice versa), and the British authority will grant an authorisation if they understand the German arguments regarding the decision to grant the authorisation and if there are no conflicting national provision.

Ordinance on notification and Poisons Information Centre

Although most of the the biocidal products are currently not subject to authorisation in Germany they must, however, be "notified". This means: according to the Ordinance on the notification of existing biocidal products (ChemBiozidMeldeV) particulars of the products must be given to the authorisation unit regarding the trade name of the biocidal product, the identity of the active substance and the product-type. The notification is free of charge and conducted online per trade name and product-type (please see paragraph Links). In case a product is placed on the market under different trade names several notifications will be necessary. The notified products receive a registration number, which consists of a letter ("N-") and a 5-digit number. It must be applied onto the product.

In addition to the notification at the authorisation unit anyone who places a biocidal product on the market under their trade name is obliged to report it to the German Poisons Information Centre which is allocated to the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR). The reports must be provided without delay and are valid on a national level only.

Can my product containing existing active substances be placed on the market?



Labelling and advertisement

In addition to this notification the biocidal products are subject to specific rules for marking and labelling. The same applies to advertising of biocidal products.

The classification and labelling of biocidal products is subject to the GHS Directive (1272/2008) regarding classification, labelling and packaging of substances and mixtures.

Additionally, biocidal products must comply with further labelling rules. Please refer to the following chart for further information.

Overview regarding information to be attached to a biocidal product (pursuant to Article 20 paragraph 3 of Directive 98/8/EC)

Information to be indicated on the label	Information that may be indicated also elsewhere (e.g. package insert)
Identity of every active substance and its concentration in metric units	The type of preparation (e.g. liquid concentrate, granules, powder)
Authorisation number as given by the competent authority*	Directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorisation.
Use for which the biocidal product is authorised *	Particulars of likely direct or indirect adverse side effects and any directions for first aid
If accompanied by a leaflet insert, the sentence: "read attached instruction before use" must be written on the label	Directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging
If applicable (e.g. wood preservatives): categories of users of a biocidal product *	Formulation batch number or designation and the expiry date relevant to normal conditions of storage
	Information on safe use
	If relevant: information on specific danger to the environment
	For microbiological biocidal products: labelling pursuant to Directive 90/679/EEC

* This information has to be indicated only after effected authorisation of the biocidal product.

There are special regulations regarding the advertisement of biocidal products. Each advertisement must be accompanied by the indication:

„Biozide sicher verwenden. Vor Gebrauch stets Kennzeichnung und Produktinformation lesen.“ (= Use biocides safely. Always read the label and product information before use.)

This indication shall clearly stand out from the rest of the advertisement for the product. The advertisement of a biocidal product shall under no circumstances mention the terms “non-toxic”, “harmless” or any similar indication that trivialises the actual effect of the product. The term biocide, however, may be replaced by respective other terms, for example insecticides, algicides, etc.

However, this applies only to external advertisement for the product; this means that the design of the packaging is not affected by these rules. Beyond that, the provisions have to be interpreted narrowly, in particular they also apply to the marketing of biocidal products on the internet.

Legal basis:
§ 15 a ChemG

How can you prepare yourself?

Ensure that the active substance contained in your biocidal product for your product-type is still in the existing active substance procedure and no decision has been taken regarding a non-inclusion! Check whether an inclusion directive has been published for this active substance and until when your product needs an authorisation regularly!

The formulants (solvents, dyestuffs, etc.) in your biocidal product are subject to the REACH regulation for industrial chemicals. It is possible that due to REACH some substances will be taken off the market in the medium-term. If you have doubts whether this applies to your formulants, please contact your supplier. If you import these formulants from non-EU states you are obliged to have them registered from the amount of one (metric) ton per year pursuant to the REACH regulation.

In case you found out that there is a deadline for the authorisation of your biocidal product, commence to compile a dossier for your product. Some studies are very time-consuming. Contact the owner of the active substance studies if you wish to refer to the data used!

If you plan to carry out tests on vertebrate animals contact the authorisation unit first! If there is data already available you are obliged to use these for reference.

If you wish to market your product in several EU Member States take a decision on where you wish to submit your application for authorisation and in which states you wish to apply for mutual recognition!

4 Links

Legal texts

German Chemical Act (ChemG)

Gesetz zum Schutz vor gefährlichen Stoffen (Chemikaliengesetz – ChemG)
(Law for the protection against dangerous substances (Chemikaliengesetz – ChemG))
"Chemicals Law in the version of 2 July 2008 (federal gazette I p. 1146)" (available in German language only)
www.bundesrecht.juris.de/chemg/

Chemicals–Cost Ordinance (ChemKostV)

(Ordinance where the fees regarding the biocide authorisation procedure are indicated)
Verordnung über Kosten für Amtshandlungen der Bundesbehörden nach dem Chemikaliengesetz (Chemikalien-Kostenverordnung – ChemKostV)
(Ordinance concerning the cost of official act of federal authorities pursuant to the Chemicals Law (Chemicals-Cost Ordinance – ChemKostV))
"Chemicals cost regulation in the version of 1 July 2002 (federal gazette (BGBl.) I p. 2442), last amended by Article 3 of the law dated 20 May 2008 (federal gazette (BGBl.) I p. 922)" (available in German language only)
www.bundesrecht.juris.de/chemkostv_1994/

Ordinance on hazardous substances

Verordnung zum Schutz vor Gefahrstoffen (Gefahrstoffverordnung – GefStoffV)
Ordinance for the protection against hazardous substances (ordinance on hazardous substances – GefStoffV)
"Ordinance on hazardous substances dated 23 December 2004 (federal gazette (BGBl.) I p. 3758, 3759), last amended by Article 2 of the ordinance dated 18 December 2008 (BGBl. I p. 2768)" (available in German language only)
www.bundesrecht.juris.de/gefstoffv_2010/

Ordinance on the notification of existing biocidal products (ChemBiozidMeldeV)

Ordinance concerning the notification of biocidal products pursuant to the German Chemicals Act (Ordinance on the notification of existing biocidal products – ChemBiozidMeldeV) "Biocide reporting regulation dated 14 June 2011 (federal gazette (BGBl.) I p. 1085)" (available in German language only)
www.bundesrecht.juris.de/chembiozidmeldev_2011/

Biocides Directive

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market
EU-Official Journal L 123 dated 24 April 1998 p. 0001–0063
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0008:EN:HTML

Dangerous Substances Directive

Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
EU Official Journal no 196 dated 08/16/1967 p. 0001–0098
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31967L0548:EN:HTML

Dangerous Preparations Directive

Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations
Official Journal no L 200 dated 7/30/1999 p. 0001–0068
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0045:EN:HTML

CLP regulation

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending regulation (EC) No 1907/2006 (Text with EEA relevance)
Official Journal no L 353 dated12/31/2008 p. 0001–1355
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:01:EN:HTML

Commission regulation (EC) No 1451/2007

Commission regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance)
Official Journal no L 325 dated 12/11/2007 p. 0003–0065
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:325:0003:01:EN:HTML

REACH regulation

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
Official Journal no L 396 dated 12/30/2006, p. 1–849
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF

Information on substances

List of substances that were notified but are not included in the Annex of the Directive 98/8/EC:
http://ec.europa.eu/environment/biocides/pdf/list_dates_product_phasing_out.pdf

List of substances that are included in the Annexes of the Directive 98/8/EC:
http://ec.europa.eu/environment/biocides/annexi_and_ia.htm

Community Register for biocidal products (R4BP):
https://webgate.ec.europa.eu/env/r4bp/user.create.cfm

Guidance

Technischer Leitfaden für die Zulassung/Registrierung eines Biozid-Produktes (Technical guidance regarding the authorisation / registration of a biocidal product, available in German language only):
www.baua.de/de/Publikationen/Fachbeitraege/Biozid-Leitfaden.html

Manual of Decisions to find out whether a product is a biocide:
http://ec.europa.eu/environment/biocides/manual.htm

Guidance for identification and naming of substances (RIP 3.10):
http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

R4BP user guide created by the European Commission:
http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/r4bp&vm=detailed&sb=Title

Authorities

Zulassungsstelle für Biozide
Federal Institute for Occupational Safety and Health
(Bundesanstalt für Arbeitsschutz und Arbeitsmedizin)
Fachbereich 5 „Bundesstelle Chemikalien/Zulassung Biozide“
Gruppe „Zulassungsverfahren Biozide“
Friedrich-Henkel-Weg 1–25
D-44149 Dortmund
mailto: **chemg@baua.bund.de**
www.zulassungsstelle-biozide.de

Further authorities involved in the biocides procedure

Federal Environmental Agency (Umweltbundesamt (UBA))
www.umweltbundesamt.de

Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung (BfR))
www.bfr.bund.de

Federal Institute for Materials Research and Testing (Bundesanstalt für Materialforschung und –prüfung (BAM))
www.bam.de

Poison and Product Documentation Centre
giftdok@bfr.bund.de

Further Links

Biocides site of the European Commission
http://ec.europa.eu/environment/biocides/index.htm

Competent authorities in other EU Member States
http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/competent_authorities/_EN_1.0_&a=d

REACH-CLP-Helpdesk
www.reach-clp-helpdesk.de/en/Homepage.html

5 Glossary

Existing active substance	Biocidal active substance that was on the market already prior to 14 May 2000 and is listed in Annex I of the Commission Regulation (EC) 1451/2007.
Biocidal product	Active substances or 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 by chemical or biological means (§ 3 b paragraph 1 No 1 ChemG).
Active substance	Substances or micro-organisms including a virus or a fungi having general or specific action on or against harmful organisms (§ 3 b paragraph 1 No 1 ChemG).
Identified active substance	Active substance that within the framework of the existing active substance program was identified as a biocidal active substance and is listed in Commission Regulation (EC) No 1451/2007. Active substances that are identified but not notified at the same time must no longer be placed on the market.
Placing on the market	Any supply, whether in return for payment or free of charge, or subsequent storage (except: storage for export or disposal). Importation of a biocidal product is also regarded as placing on the market (Article 2 paragraph 1 of Directive 98/8/EC in connection with Article 2 of Commission Regulation (EC) No 1451/2007).
IUCLID	"International uniform chemical information database" database system that includes data collected and reported by the European industry for the evaluation and control of existing chemical substances and their impact on the environment.
Notification	Pursuant to the Ordinance on the notification of existing biocidal products, rendering of information to the authorisation unit regarding a biocidal product.
New active substance	Active substance that was not on the market prior to 14 May 2000 and is not listed in Annex I of Commission Regulation (EC) No 1451/2007.

Notified active substance

Active substance that within the framework of the existing active substance program was identified as biocidal active substance and for which a participant of the existing active substance program declared its intention to submit an application.
A list of the notified active substances can be found in Annex II of the Commission Regulation (EC) No 1451/2007. Since modifications occur from time to time regarding the notified substances one has to be aware of amendments (e.g. decisions taken by the European Commission regarding the non-inclusion of active substances).
A notification is valid for one active substance in connection with one product-type.
Substances regarding which a formal decision was taken that these are not included in Annex I or IA of the Directive 98/8/EC, must not be included in any biocidal product and not be placed on the market after a transition phase.

Product-type

Functions listed in Annex V of Directive 98/8/EC that a biocidal product can fulfil by definition. Each biocidal product must be allocable to one of these 23 categories.

Registration

Authorisation procedure for biocidal products with "low risk potential" (products not containing substances of concern and exclusively containing biocidal active substances that are listed in Annex IA of Directive 98/8/EC).

Harmful organism

Any organism which has an unwanted presence or a detrimental effect for humans, their activities or, the products they use or produce, or for animals or for the environment (§ 3 b paragraph 1 No 6 ChemG).

Imprint

Biocide Information 1
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Publishers:
Federal Institute for Occupational Safety and Health
Friedrich-Henkel-Weg 1–25
44149 Dortmund
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Translation: Carolin Strieder, Solingen
Layout: eckedesign, Berlin
Production: DruckVerlag Kettler, Bönen/Westfalen

1st edition, May 2011

ISBN 978-3-88261-690-3

ISBN 978-3-88261-690-3

baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin