

# Key Issues

To effectuate the anticipated high level of protection, in 2000 the EU set up the Biocides Review Programme which is intended to extend over a period of ten years.

Approved existing active biocidal substances, the notifications of which have been accepted, are evaluated in four priority lists during different stages of the programme. The active substances have been assigned to the EU Member States according to their percentage of votes in the European Council. The first list includes wood preservatives and rodenticides. The next active substances, up for review from

2006, are those used in molluscicides, insecticides, repellents and attractants as well as active substances contained in antifouling products. In 2007 dossiers have to be submitted for disinfectants, in-can preservatives and metalworking-fluid preservatives. The remaining product types will be reviewed starting in 2008.

Pursuant to given legal provisions, data on new active substances for use in the different product types may at any time be submitted to the competent authority, which in Austria is the Federal Ministry of Agriculture, Forestry, Environment and Water Management.

**Mould:** fungicidal substances in biocidal products can destroy mycelium and mould spores.

## Improved Labelling

From June 2005, companies will have to comply with new labelling requirements for biocidal products which, for example, imply information on the common or chemical name of the active substance and its concentration in the product. Any person who wants to place a new biocidal product on the Austrian market furthermore has to follow a compulsory declaration procedure. In cases where suspected poisoning arises, this obligation will facilitate immediate and more efficient first aid treatment. For more information, please refer to [www.biozide.at](http://www.biozide.at)



Umweltbundesamt GmbH  
Spittelauer Lände 5  
1090 Vienna/Austria

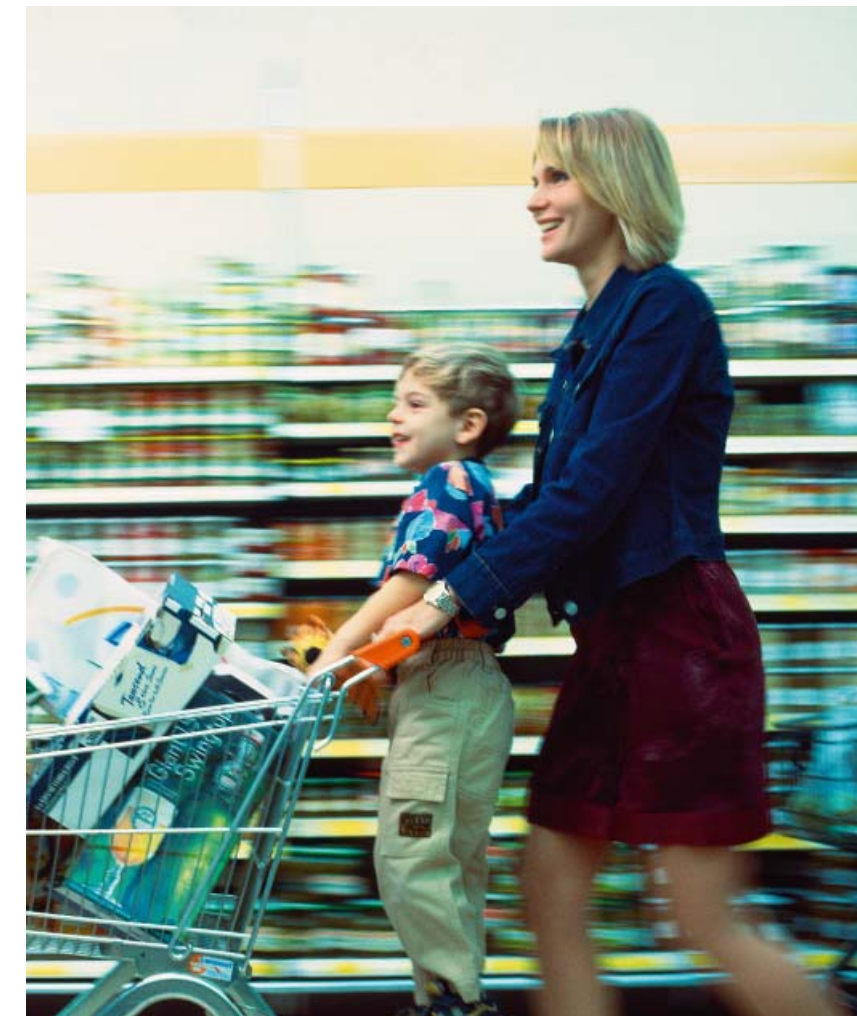
Dr. Elisabeth Fassold  
Tel.: +43-(0)1-313 04/3750  
Fax: +43-(0)1-313 04/3700

biozide@umweltbundesamt.at  
[www.umweltbundesamt.at/biozide](http://www.umweltbundesamt.at/biozide)



## [www.umweltbundesamt.at/umwelt/biozide/](http://www.umweltbundesamt.at/umwelt/biozide/)

- Risk assessment of biocides
- Preparation of product authorisation and registration
- Professional consulting, expert advice and information



## Benefits, Risks & Facts

Biocidal Products in Austria

# New Regulations for Biocidal Products

Consumers are exposed to biocidal products in their daily lives in many different ways. Besides the anticipated beneficial effects, the application of biocides may also pose risks to human health and the environment.

With the adoption of general principles for authorisation of biocidal products the EU aimed at raising the level of protection within the Community. In Austria these Regulations were transferred into national law through the implementation of the Biocidal Products Act in 2000.

**Biocides:** four main groups with 23 product types: Disinfectants and general biocidal products, Preservatives (e.g. wood preservatives), Pest control (e.g. insecticides), Other biocidal products (e.g. antifouling paints for vessels)



In the future, biocides will be subject to risk assessment procedures as well as improved and extended labelling which will provide consumers with more detailed product information.

Biocidal products are intended to destroy, deter, or otherwise exert a controlling effect on harmful organisms by chemical or biological means. They are also applied to protect materials or to extend their service life. Compared to pesticides, biocidal products are primarily used for non-agricultural purposes.

## Risk Assessment

Any use of a biocidal product by professionals or non-professional consumers may pose a risk. Risk assessment aims at determining the extent of the dangers involved, at quantifying the detrimental impacts and at calculating the probability of these adverse effects to occur. All evaluations rely on scientific methods and are based on detailed use and effects analyses. In a first step, the physico-chemical, toxic and ecologically harmful properties of the product in question,



**EU Biocides Policy:** Protection of man and the environment

as well as indirect impacts, such as accumulation in breast milk or contamination of groundwater, are examined to define the hazard potential. In the second step, exposure of users, affected population groups and the environment is assessed. The ratio of the hazard potential to the expected exposure level is taken to identify the risk of the product under review. Depending on the results, the use of some products may be restricted to the professional level. These procedures will first be applied to wood preservatives and rodenticides.

A cost-benefit analysis, which takes into account the efficacy and indispensability of a product, provides additional indication as to whether a risk is acceptable or not. The less effective the product is, the less risky its use must be. As a result, some applications may not be approved any more or with restrictions, e.g. the use of disinfectants in private house-

holds. For more information, please refer to [www.umweltbundesamt.at/biozide](http://www.umweltbundesamt.at/biozide).

## General Basis and Milestones

The Biocidal Products Directive agreed upon in 1998 lays the foundations for risk assessment of biocides. In Austria this EU Regulation was put into national legislation through the Biocidal Products Act in 2000. In 2003, the Second Review Regulation brought along a remarkable milestone with the publication of an inventory list containing 953 active biocidal substances currently marketed in the EU. Only active substances listed in the Annexes of the latter regulation may be contained in biocidal products anymore. Simultaneously, the next stage of market clearance was launched, which will ban identified active substances by 1st

September 2006. Moreover, the evaluation programme for a total of 353 existing active substances was started (EU Review Programme). The target of the programme is to elaborate a final list of positively rated active substances which are consequently accepted for use in biocidal products within the whole European Union. Moreover, biocidal products containing active substances listed in Annexes I or IA of the directive, have to be authorised or registered, respectively, at national level. Registration is restricted to low risk biocidal products, which only contain substances listed in Annex IA. Authorisation and registration of wood

**EU review:** active substances for control of rodents will be evaluated from 2004.



preservatives as well as rodenticides will start in 2006.

## Timetable

- 7.9.2000 First Review Regulation: Call to identify and notify existing active substances marketed within the European Union.
- 24.11.2003 Second Review Regulation: Publication of the lists containing all identified and notified substances.
- 14.12.2003 Ban of active substances that have neither been identified nor notified
- 28.3.2004 Deadline for submission of application dossiers for substances on the first priority list.
- 1.9.2006 Ban of identified active substances

## Regulations

Biocidal Products Directive (Directive 98/8/EC)  
First Review Regulation (Commission Regulation 1896/2000/EC)  
Second Review Regulation (Commission Regulation 2032/2003/EC)  
Biocidal Products Act BiozidG, Federal Legal Gazette I No 105/2000  
BiozidG-Gebührentarif-V I [BiozidG-Ordinance on the Legal Charges I (Federal Legal Gazette II No 251/2002)]  
BiozidG-Gebührentarif-V II [BiozidG-Ordinance on the Legal Charges II (Federal Legal Gazette II No 331/2003)]