

The European Union's new Regulation on biocides



European Union law on biocidal products has been revised. The changes apply to products such as disinfectants, household pesticides, or wood preservatives and to articles treated with biocidal products.

From the perspective of environmental and consumer protection, the new regulation brings positive reforms with respect to authorising products and making them available on the market but a harmonised EU framework for the sustainable use of biocides that reduces risks is still lacking.

A healthy world for all.

Protect humanity and the environment from pesticides. Promote alternatives.

Current European legislation on biocides

Biocidal products...

... **are intended to** destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by any means other than mere physical or mechanical action.

... **consist of, contain, or generate** one or more active substances. A treated article with a primary biocidal function is also considered a biocidal product.

... **are** pest control products such as rodenticides or insecticides, disinfectants, preservatives, substances for preserving masonry or wood, antifouling products for ships, etc.

Biocidal products combat harmful or unwanted organisms, and because of their properties and uses may pose a threat to human health, animals, and the environment.

Since 1998, making biocidal products such as household pesticides or disinfectants available on the market has been subject to a European Union (EU) Directive (98/8/EC). Work on revising this legislation has been ongoing since 2009. The current Directive established for the first time an approval procedure for biocides and national product authorisation processes that make mutual recognition of authorisation possible. However, the Directive did not establish a harmonized framework for use of biocidal products that set, for example, standards for professional users or for integrated pest management. Reviewing the approximately 350 active biocidal substances notified so far will take at least until May 2014, presumably longer. Most of the biocidal products currently on the market have not been authorised according to procedures as defined in the current Directive. In Germany alone, more than 35 000 biocidal products fall under the Directive;¹ the total number in the EU is estimated to be about 50 000.

Improvements and shortcomings in the Regulation from the perspective of environmental and consumer protection

Hazard approach bans active substances of high concern

The new biocide Regulation prohibits the use of active biocidal substances with extremely hazardous profiles in biocidal products (see the box on the right for exclusion criteria).

This approach is in agreement with the revision of the Pesticide Regulation enacted in 2009 and strengthens considerably the precautionary principle of preventing adverse effects from hazardous substances. Especially the fact that environmental properties are now taken into account (PBT, vPvB) is an important improvement; these elements were missing in the EU Commission's first draft.

... and has been watered down by derogations

Extensive derogations limit the effect of the exclusion procedure. Member states can authorise active substances if the exposure to humans or the environment is negligible, or if evidence is provided showing that the biocide is essential to prevent or to control a serious danger, or it is shown that non-approval of the active substance would have disproportionate negative impacts for society. Approval is for a five-year period at most but can be renewed. These derogations by far exceed those that otherwise apply to hazardous pesticides and are also not tied to the development of mandatory substitution plans.

It is therefore questionable whether serious efforts to develop alternatives to these highly

hazardous substances will be promoted or such products as anticoagulants in rodenticides that are toxic for reproduction or carcinogenic wood preservatives such as creosote will remain in use on the basis of these derogations. The Regulation stipulates that the derogations outlined above will only be applicable to member states that implement risk mitigation measures. However, products that are treated with exclusion candidates (e.g., wood treated with creosote) and used in one member state on the basis of a derogation are not explicitly banned from being sold throughout the EU market, according to the provisions of the Regulation.



Step-wise substitution should be the goal

Other active substances that have been recognized as problematic should be labelled »substitution candidates« and gradually replaced, based on comparative assessment, with less hazardous alternative substances or with non-chemical methods of combating

or preventing the occurrence of harmful organisms. New additions to the criteria catalogue for substitution include, for example, substances classified as respiratory sensitizers, but other adverse health aspects such as developmental neurotoxic properties are missing. Whereas less hazardous substances must be assessed in order to renew approval every fifteen years, the Regulation specifies that substitution candidates are subject to reassessment every seven years.

Introduction of a new Union authorisation

Biocide manufacturers, in particular, have called for simplified and expedited authorisation procedures for their products for the entire European market. The new Regulation includes the stepwise introduction of Union authorisation by 2020. EU authorisation is not possible for products containing exclusion candidates. Whether Union authorisation will be introduced for rodenticides, products used to combat birds, fish or other vertebrates, or for antifouling products will be decided based on a report that the EU Commission must present by 31 December 2017. In Germany, toxins for use against fish, birds and higher mammals are already prohibited in the interests of animal welfare. Union authorisation procedures will now become the jurisdiction of the European Chemicals Agency (ECHA). Member states can bring an appeal against authorisation

Reasons for the revision

When the current EU Directive went into force in 1998, it was already being criticized as too complicated and inadequate in some respects. Demands for simpler and quicker authorisation procedures and, EU-wide authorisation came especially from industry. Authorities from the member states called for uniform testing and evaluation during authorisation and consumer and environmental non-governmental organisations (NGOs) criticized, among other things, the lack of rules on articles treated with biocides and on biocide use phases. The EU Commission presented a draft revision in June 2009.

PAN Germany has participated with other stakeholders in negotiating revisions to the legislation and together with other NGOs recommended changes that enhance protection of the environment and consumers. The final proposal was passed by the EU Parliament in a second reading on 19 January 2012. The Directive has now become a Regulation »concerning the placing on the market and use of biocidal products«. ² The Regulation will replace the current Directive and thus be directly applicable in the EU member states, probably as of September 2013.

Exclusion criteria for hazardous, active biocidal substances

CMR substances: carcinogenic, mutagenic, or toxic for reproduction (Cat.1a and 1b*)

PBT substances: persistent, bio-accumulative, and toxic*

vPvB substances: very persistent and very bio-accumulative*

Endocrine-disruptive substances: Criteria are to be proposed by the EU Commission by 13 December 2013; in the interim: carcinogenic and toxic for reproduction (both Cat. 2*) or toxic for reproduction (Cat. 2*) and with toxic effects on the endocrine organs

* Substances that have been classified according to Regulation 1272/2008/EG or are equivalent to such a classification

decisions and apply for changes; the final decision remains with the EU Commission. Union authorisation is only allowed if »similar conditions of use [exist] in all Member States« To date, such harmonised regulations do not exist and regional conditions such as climate differences must be considered. How the phrase »similar conditions of use« will be defined is thus a key issue. The EU Commission has been charged with drawing up such guidance documents before the Regulation goes into effect. PAN's opinion is that a stakeholder consultation should be conducted for drafting these guidance documents.

Simplified product authorisation makes transparency essential

Under the terms of the new Regulation, a biocidal product that contains active substances »with a more favourable environmental or human health profile« can be authorised under a simplified and thus cost-reduced procedure. Authorisation in a single member states will then suffice to allow these products to be placed on the market throughout the EU. Active substances that have been assessed as belonging to the category eligible for the simplified procedure are listed in a new annex, Annex I and include, for example, lactic acid, with its anti-microbial properties, or lavender oil. Not eligible for the simplified procedure are biocidal pro-



ducts whose intended use requires personal protective equipment or those that contain nanomaterials or other substances of concern. The Regulation spells out the adverse properties that will result in exclusion from the simplified authorisation. Generating and assessing all the information needed according to the criteria catalogue represents a challenge. Should hazards of specific substances or mixtures be overlooked, the market advantage of simplified authorization could quickly lead to incalculable negative impacts. The EU Commission and the ECHA, as the competent authorities, should therefore ensure transparency in evaluating and reaching decisions about the inclusion of active substances into Annex I.

Nanomaterials: caution is needed

Because of the unique behaviour, toxic properties, and possible risks of biocidal products that contain nanomaterials (for example, nanoscale silver compounds), spe-

cial risk assessment methods are prescribed for these active ingredients and products. Products treated with nanomaterials must also be clearly labelled and are not eligible for simplified authorisation. Member states must generate information on the use of nano-biocides and on their potential hazards for the reports mentioned above.

Consumer protection has been improved

... with respect to products on the market:

The cases in which biocidal products cannot be made available to the general public have been extended. To date, restrictions on marketing applied only to toxic or very toxic products or those with CMR properties; in future, products with endocrine-disrupting, PBT or vPvB properties and those with developmental neurotoxic or immunotoxic effects will also be banned from sales to non-professional, untrained persons. The challenge here will be implementing effective market controls, for example, for online sales.

... with respect to articles treated with biocides:

In future, goods treated with biocides such as antibacterial agents or fungicides can only be placed on the market in the EU if the biocides employed have been authorised by the EU for the specific use in question. This also applies to all goods imported from third countries. Besides closing a significant gap in EU law, this new provision



is expected to have positive impacts on occupational safety in the countries where the goods are manufactured. Under the new rules, biocide-treated articles must be clearly labelled if biocidal properties are claimed or if contact with humans or the release to the environment is possible. Upon request by a consumer, suppliers of treated articles are required to supply free of charge information on the biocidal treatment of such articles within 45 days.

...with respect to information for consumers: Information on approved active biocidal substances and authorised biocidal products will be provided via data bases that can be accessed on the internet. Member states

must publish reports on implementation of the Regulation every five years that compile information on environmental risks, poisoning incidents, and the hazards associated with the use of nano-materials. Furthermore, member states are obliged to provide the general public with information on the benefits and risks of biocidal products and opportunities for reducing their use. The German government already meets this obligation, for example, through a website maintained by the Federal Environment Agency (Umweltbundesamt, www.biozid.info).

Measures for achieving the sustainable use of biocidal products postponed

PAN Germany and other environmental NGOs called for EU harmonisation of biocide use instructions and for a legislative framework for use phase rules similar to those that apply for pesticide use.³ With respect to these key issues, the biocide Regulation is disappointing. Rules aimed at sustainable, risk-minimizing use of biocide products are still lacking. And there are also significant

gaps in information from the biocide sector, for example, statistics on sales and use. Moreover, a weak compromise lead to provisions in the Regulation stipulating that three years after it has taken effect the EU Commission must present a report on the areas that, in the opinion of environmental NGOs, require a harmonised framework. These include measures to minimize the use of biocides, the development and implementation of integrated pest management, common monitoring strategies, and obligatory reports or the establishment of common standards of expertise for professional biocide users and distributors and for the quality of application techniques.

Furthermore, additional protective measures should be possible for sensitive areas such as schools, kindergartens, public spaces, or in the vicinity of groundwater or nature reserves. The Commission shall, on the basis of that report, present a legislative proposal »if appropriate«. The Regulation does not specify a time frame for this decision.

Reference

- 1 Deutsche Bundesregierung (2011): Vierter Bericht über die Substitution risikoreicher durch risikoärmerer Biozid-Wirkstoffe und Biozid-Produkte, über den aktuellen Sachstand zur Umsetzung der Biozid-Richtlinie und des Überprüfungsprogrammes der Altwirkstoffe sowie der aktuellen Entwicklungen auf EU-Ebene, Drucksache 17/6903 vom 02. 09. 2011: dipbt.bundestag.de/dip21/btd/17/069/1706903.pdf
- 2 European Parliament legislative resolution of 19 January 2012 on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (05032/2/2011 – C7-0251/2011 – 2009/0076(COD)): www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0010+0+DOC+XML+V0//EN
- 3 PAN Germany (2010): Sustainable use of biocides in Europe – urgent need for action: www.pan-germany.org/download/biocides/briefing_sustainable_use_of_biocides.pdf



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PAN Germany is a charitable organisation which provides information on the adverse effects of pesticides and promotes environmentally friendly and socially just alternatives. We are part of the Pesticide Action Network International. Our working areas range from critical-constructive assessments of policy and legislation to practical services for farmers and consumers.

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Hamburg, February 2012

Text: Susanne Smolka; Translation from German: Paula Bradish; Layout: grafik:sommer, Hamburg; Printed on recycled paper with reduced environmental impact, Photos front page: jorisvo/Fotolia.com, we*ge/photocase.com, hoges/Fotolia.com, Dron/Fotolia.com, mangostock/Fotolia.com; Photos Page 2 – 4: we*ge/photocase.com, Andrea Nest/photocase.com, djama/Fotolia.com



This project was implemented with financial support from Federal Environment Agency and Federal Ministry for the Environment, Nature Conservation and Nuclear Safety

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