

Endocrine disrupting biocides













Why highly hazardous biocides must be phased out

According to the European Union's (EU) new biocide regulation, the marketing and use of biocides with highly hazardous properties will be prohibited in future. This approach is a new and important step towards improving protection of
human health and the environment. However, implementation of the new regulation has been delayed, because the
EU has suspended the obligatory deadline for defining criteria to identify the highly hazardous property of "endocrine
disruption". The new political debate initiated by the EU Commission about how to deal with endocrine disrupting
chemicals is now threating to delay implementation of — or even reduce — the protective standards set out in European biocide regulations.

The use of biocidal products

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.

In order for biocidal chemicals to fulfil their intended function, they must be bioavailable. Biocidal products are generally only rarely applied in closed systems. As a result, the substances enter the environment, leading to exposure of humans, wildlife, and ecosystems1. Consumers come into contact with biocides in daily life in numerous ways – in private households, during leisure activities, or at work. Biocides can be found in antiseptic hygiene products, in antibacterial cleaning products, in insect sprays, or in chemicals used as wood preservatives or to protect products against insects, fungi or algae (see box 1). By July 2011, some 35 000 biocide products were registered as being available on the market in Germany alone2; there are an estimated 50 000 such products on the market in the entire EU. In addition, a very large number of "treated articles" are on the market. This term refers to all mixtures or goods that are produced with the help of biocides or have been treated with biocidal chemicals. Biocidal treatment can be applied to preserve the article itself; some examples are in-can preservatives for paints or insecticides applied to moth-proof wool carpets. Goods can also be treated with biocides to achieve a special function such as reducing bacterial growth for hygienic reasons in the case of performance clothing or articles used in offices and kitchens3.

Ending the use of highly hazardous biocides

Since EU Directive 98/8/EC entered into force in 1998, all biocidal products must undergo an authorisation process prior to becoming available on the market in the EU. This Directive was replaced by EU Regulation 528/2012/EC in September 2013⁴. According to the new regulation, active biocidal substances with special, highly hazardous properties are to be excluded from further use.

If a specific substance fulfils one of the criteria defined in the regulation (see box 2), then it can no longer be used in biocidal products or in goods treated with biocides that are placed on the market in the EU. If no chemical or non-chemical alternatives are available, then an exception to this prohibition can be granted, under certain conditions, for five years. Multiple extensions of this period are possible. Applicants are not required to present substitution plans for these substances.

To date, however, uniform criteria for identifying endocrine disrupting biocides (EDs¹) are lacking. The EU Commission was to have defined such criteria for both biocides and pesticides by December 2013. Despite four years of discussion about proposed criteria, the EU Commission failed to meet this deadline, which is spelled out in the relevant regulations. Instead, it spent considerable time addressing another question, namely, how a "horizontal" concept could be realized that would then apply to all relevant areas of EU law, including the industrial chemicals regulated by REACH, as well as cosmetics, pharmaceuticals, etc. The Commission published a roadmap that encompasses public consultations followed by assessment of the socio-economic impacts of various options that not only involve the ED criteria but also include regulatory procedures⁵. Environmental organisations from all over Europe criticise this delay and the fact that the discussion about how highly hazardous biocide and pesticide substances are to be regulated and banned in some cases has in effect been reopened⁶.

Exposure to endocrine disruptors in early and sensitive stages of development can lead to irreversible damage in later life.



Box 1 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 for plastic, leather, or textiles; substances for preserving masonry or wood; antifouling products for ships, etc.

I ED is the abbreviation for endocrine disruptor; EDCs stands for endocrine disruptor chemicals.

Hazard approach - learning from experience

The hazard approach aims to ensure that highly hazardous biocides and pesticides are banned from future use. In contrast to the classic risk approach, regulatory decisions that are based on this perspective do not take the potential for exposure to a specific substance and the probability of occurrence of negative effects into account. The hazard approach was supported by all EU bodies involved as a solution to various problems associated with the classic risk approach. Numerous examples from the past demonstrate that the usual risk assessment processes for regulating the use of chemicals are often inadequate in protecting human health and the environment and fail to meet the precautionary principle set out in EU law. Risks are frequently underestimated and decisions about threshold values or rules for use are often corrected only in part or after long delays. Just two examples are the endocrine-disrupting insecticide DDT or the antifouling agent TBT, which causes imposex (male sexual organs on female snails).

Risk mitigation measures are not always effective in reducing exposure to an acceptable level. Some measures, for example, prove to be impossible to implement, leading to inappropriate use, poisonings, or accidents. As a result, the United Nation's (UN) Food and Agricultural Organisation (FAO) has recommended, since 2006, a step-wise end to the use of highly hazardous pesticides⁸. A further issue is in some cases the possibility that no threshold value exists for some substances, since even the smallest concentration can have negative effects. These aspects apply especially to biocides and to endocrine disruptors.

Biocide impacts - inadequate data

A further argument that supports the phase-out of highly hazardous biocides are the considerable gaps in existing data that make it difficult to assess the actual exposure of humans and the environment to these chemicals and the resulting impacts. Overall, the data on marketing, application, and exposure of the environment and humans to biocides is inadequate. EU legal provisions on biocides do not require that such data be collected regularly and systematically. Rather, member states are only required to report to the EU Commission on the status of implementation of the biocide regulation every five years. Numerous biocides have to date not been subjected to an assessment of the validity of their approval within the context of the review programme for biocides that have been on the market before May 2000. As a result, the state of knowledge about the potential hazards and exposure levels differs considerably for various substances. It is expected that the review programme will not be completed until 2024¹⁰.

Exposure assessment for biocidal substances is highly complex. The EU Regulation on biocides lists 22 different types of uses of biocides, and an active substance can be approved for one or more of these types of products. Consequently, people and the environment can be exposed to a specific substance from various sources. In the course of the approval procedure, only one formulated product is examined as an example, and exposure scenarios are assessed on this basis. As a rule, the product that is assessed in this way is suggested by the applicant. With respect to use of these products, it must be taken into account that many are used by laypeople; moreover, there is a lack of harmonised standards for best practices in professional areas of use.

Box 2 Exclusion criteria for higly hazardous biocides

(according to Art. 5(1), (EC) 528/2012

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

PBT substances: persistent and bioaccumulative and toxic**

vPvB substances: very persistent and very bio-accumulative**

Endocrine disruptors: According to the EU Commission's Regulation on biocidal products and pesticides, criteria pertaining to EDs were to have been defined by 14 December 2013

Interim criteria are: a) the combination of criteria C and R (carcinogenic and toxic for reproduction, Cat. 2*); b) the combination of toxic for reproduction (R, Cat. 2*) and evidence of having toxic effects on endocrine organs (e.g., the thyroid)

- * Substances that have been classified according to Regulation 1272/2008/EC (CLP) or are equivalent to such a classification
- ** According to Regulation 1907/2006/EC, annex XIII

Six out of twenty-four biocides that are potentially relevant with respect to the drinking water supply²⁴ contain active substances that are possibly endocrine disruptive: 2-Phenylphenol, Diuron, Carbendazim, Cyproconazole, Tebuconazole and Thiacloprid.



Especially problematic is the lack of risk analysis of biocide-treated goods. Applicants are also only required to supply information on whether an active substance or a biocidal product is intended be used to produce or treat other articles. The numerous actual treated goods are not assessed with respect to the effectiveness of the biocide treatment and its potential risks. This is a key weakness in current biocide law. As a result, data is not available on how quickly and to what extent biocides are, for example, washed out of textiles following specific kinds of antibacterial fabric treatment, or are released from treated furniture or carpets, released from building facades with protective coatings by precipitation, or are released into the environment in the process of disposing of treated products. A few studies of such processes have been conducted by governmental authorities or independent institutes; the results offer evidence of in part significant levels of released active substances from treated articles.^{11,12} Also lacking is data on what treated goods are available on European markets and in what amounts.

Moreover, even when use of a highly hazardous biocide (e.g. a wood preservative) has been prohibited in principle, if an exception to this ban has been granted in one EU member state, wood or furniture treated with the biocide can be imported into other member states. Whether and when this gap in EU law will be addressed is unclear.

To sum up: considerable gaps with respect to both data and the legal provisions are evident, which make it difficult to assess the actual extent of exposure risks for humans and the environment for specific substances.

Endocrine disruptors (EDs) - a global threat

In European regulations on biocides and pesticides, endocrine distruptiveness is considered one of chemicals' highly hazardous properties. The UN's World Health Organisation (WHO) and its Environmental Programme (UNEP) have called the impacts of endocrine disruptors a "global threat" Scientific evidence links exposure to endocrine disrupting chemicals to spiralling rates of hormone-related cancers such as breast or testicular cancer, fertility problems, diabetes and obesity as well as learning and behavioural problems in children. Exposure also disrupts the hormonal systems of wildlife.

Special characteristics of many EDs make it difficult or even impossible to determine the no-effect level of exposure or supply evidence of monocausal relationships between exposure and damage. In studies conducted to date, low-dosage effects, non-monotonic dose-response relations, development-related susceptibilities, delayed effects and effects that transcend generations as well as combination effects due to exposure to several substances have been observed. Moreover, current test procedures yield information on only some of the possible endocrine disrupting effects^{14,15,16}.

The costs that emerge as a result of these negative impacts, such as the loss of biodiversity, are difficult to calculate. The Nordic Council of Minister has calculated that the health-related costs for damage to male reproductive organs alone (e.g. testicular cancer, infertility) amount to several hundred million euros per year in the EU¹⁷. According to another study, if only a small portion of endocrine-related cancers, diabetes, obesity, and infertility could be avoided by reducing human exposure to endocrine-disrupting chemicals, then health-care costs in Germany alone could be reduced by about five billion euros¹⁸. Besides the personal suffering of those people affected, such socio-economic costs are a further weighty argument in favour of avoiding the impacts of those endocrine-disrupting substances that have been identified by implementing effective bans and substitution measures.

Box 3 WHO/IPCS definition

"An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and <u>consequently causes adverse health effects</u> in an intact organism, or its progeny, or (sub)populations.

A potential endocrine disruptor is an exogenous substance or mixture that possesses properties that <u>might be expected</u> <u>to lead to endocrine disruption</u> in an intact organism, or its progeny, or (sub)populations." (WHO/IPCS, 2002)



Wood preservatives are released into the environment during application and washout. Tests show that when people who have not been trained in appropriate procedures paint a fence, as much as 6 % of the active substance propiconazol is released into the environment due to drippage (see note 1).

Identifying endocrine-disrupting biocides

In principle, the aim of establishing a harmonised, uniform procedure for identifying endocrine disruptors, independent of whether they are used as biocides, pesticides, industrial chemicals, or for other purposes is a positive development. However, we must clearly distinguish between identification, on the one hand, and regulation after identification has occurred, on the other. Provisions for regulating biocides and pesticides have already been passed by the respective legislative bodies and must be implemented as agreed. According to these rules, biocides with endocrine-disrupting properties are subject to the exclusion process if they "are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties" (see 528/2012/EC, Art. 5 (1)(d)). Reference to REACH means that not only the protection of human health is considered but also probable environmental damage, since according to REACH EDs are substances "for which there is scientific evidence of probable serious effects to human health or the environment". Biocide and pesticide regulations differ with respect to this part of the text.

The text of the regulation also emphasizes (see underlined text) that the exclusion process applies to both substances for which the negative impacts have been proven and those for which the impacts are considered possible or probable. The biocide regulation thus establishes an unequivocal framework, that is, a legally-binding definition of which ED biocide must be subject to regulation. This definition is comparable to the complete WHO/IPCS definition established in 2002 (see box 3)¹⁹.

In general, categorisation should follow various levels of the strength of evidence. Due to the very diverging levels of eco-toxicological data on biocides, a third class of ED candidate substances must be established, for which there are indications of endocrine-disruptive properties, but where the evidence does not as yet suffice to justify classification in categories 1 and 2. For those who are granted authorisation, this third category would have to be linked to the requirement that further data be generated that verify or disprove endocrine hazards. Compared to the suggestions presented by the EU Commission (see ref. 5), this is equivalent to option 3, in which a distinction is made between confirmed, suspected, and potential EDs (based on the hazard approach, which means without risk-related criteria such as potency). The current interim rules on identifying endocrine-disrupting biocides (see box 2) must be replaced by a three-tiered classification system as soon as possible. The interim criteria are inadequate and should have been replaced by December 2013 at the latest. They only take into account chemicals that are potentially carcinogenic or toxic for reproduction. Other possible endocrine-disrupting effects on the brain or metabolism that may promote behavioural disorders, diabetes, or obesity are not included (see position of the public consultation of the EDC-free Europe campaign at www.no2hormonedisruptingchemicals.org/en).

Biocides that are potentially endocrine disrupting

According to an investigation conducted by PAN Germany in October 2014, about 10% of the biocides which have been submitted for notification or already authorised within the framework of the review programme are found in selected priority lists or survey studies as possible EDs (see table). Because of the limited number of references and existing gaps in data on many biocides, this proportion is presumably higher.

| Table PAN Germany list of potentially | | | |
|---------------------------------------|--|--|--|
| endocrine-disrupting biocides | | | |
| (October 2014) | | | |

| Biocid substance (incl. CLP classification) | Product type (PT) (Annex V, 528/2012/EC) | |
|---|---|-----------------------------------|
| | authorised | notified |
| Abamectin (R2) | 18 | |
| Bendiocarb | 18 | |
| Bifenthrin (C2) | 8 | |
| Boric acid (M1b) | 8 | |
| Carbendazim (C1B, M1B) | | 7, 9, 10 |
| Chlorocresol | | 1, 2, 3, 6, 9, 13 |
| Cypermethrin | 8 | 18 |
| Cyproconazole (R2) | 8 | |
| Deltamethrin | 18 | |
| Diazinon | | 18 |
| Diuron (C2) | | 7, 10 |
| Fenoxycarb (C2) | 8 | |
| Fipronil | 18 | |
| lambda- Cyhalothrin | 18 | |
| Metam-Sodium | | 9, 11 |
| Permethrin | 8, 18 | 9 |
| 2-Phenylphenol | | 1, 2, 3, 4, 6, 7, 9, 10, 13 |
| Piperonylbutoxid | | 18 |
| Propiconazol | 8, 9 | 7 |
| Pyriproxyfen | 18 | |
| Tebuconazol (R2) | 7, 8, 10 | 9 |
| Terbutryn | | 7, 9, 10 |
| Tetramethrin | | 18 |
| Thiacloprid* (C2) | 8 | |
| Thiram | | 9 |
| Triclosan | | 1 |
| Zineb | 21 | |
| | | |

The list takes into account substances already approved or notified (pending) for authorisation within the review programme and one new substance* which are listed in at least one of the following references: EU priorities list (ED categories 1 and 2)²⁰, Mckinlay et al. 2008²¹, WHO/UNEP 2013⁹, Kortenkamp et al. 2012¹¹, Swedish Chemicals Agency (KEMI) 2008²², WRC PLC 2013²³

No biocide under review has been classified as a C2+R2 substance and fulfils the first interim criterion for EDs. However, fenoxycarb and thiacloprid (both C2 substances) can be considered toxic for reproduction. Carbendazim und boric acid fulfil the CMR exclusion criterion, but nevertheless boric acid has already been approved for ten years and carbendazim has actually been evaluated as a potential candidate for substitution with possible approval of seven years. The insecticide abamectin and the wood preservatives cyproconazole and tebuconazole are classified as toxic for reproduction (R2). This would fulfil the second interim criterion, if in addition evidence of an endocrine-disrupting effect has been found during the assessment. Though the assessment reports indicate that insufficient data was provided to assess possible endocrine-disrupting effects, the substances have been authorized.

The urgent need for ED criteria set down by the EU Commission is underscored by various dossiers for biocides that have already been authorised. Rapporteur Ireland, for example, writes about zineb, an antifouling agent: "...the anti-fouling should be further assessed with regards to its potential endocrine disruptor properties once further guidance is available and preferably before the product authorisation stage" (Assessment Report, December 2013). Referring to the insecticide deltamethrin, rapporteur Sweden writes: "...due to limitations in the test guidelines available at the time, the potential for endocrine effects may not have been fully investigated. ...the potential for endocrine disruption of deltamethrin is reconsidered when EU harmonised guidance is established based on the work and final conclusions of the EC work on defining criteria to identify endocrine disrupting substances" (Assessment Report, Mai 2011).

While the EU Commission continues to delay implementation of the ED criteria, a growing number of biocides suspected of having ED properties are being authorised without at least being labelled as candidates for exclusion or substitution. When the EDC criteria are defined by the EU Commission, at the latest, the ED potential and thus the basis for deciding on authorisation of such critical substances should be reassessed.

Assessment of alternatives and exceptions for highly hazardous biocides

The exclusion process is not similar to any classic ban on specific substances. Rather, the biocide regulation includes provisions according to which, under certain conditions, an exclusion candidate can be granted authorisation for a period of five years (see box 4). Biocide products that contain such a highly hazardous substance can only be authorised on a national level and only if the member state establishes additional measures to minimize risks, "to ensure that exposure of humans and the environment to that biocidal product is minimised". Such products may not be made available on the market for use by the general public (see Art. 19(4)). This is especially important because biocide products, in contrast to pesticide products, are freely available on the market and there are no requirements stipulating that qualified sales representatives must advise consumers.

The decisive factor in permitting exemptions is proof that no appropriate alternative substances or (non-chemical) methods are available (see Art. 5(2) of the biocide regulation). In other words, besides the three criteria for exemptions, two further decisive prerequisites must be fulfilled, in order for use of an identified exclusion candidate to be permitted for a limited time period and a limited geographical area: the confirmed non-substitutability of an active substance and the reduction of exposure to a minimum.



Sustainable use of antifouling surface-treatment products is not feasible, because the active substances they include are washed out. However, various biocide-free alternatives are available. Mechanical cleaning methods are especially effect as alternative in fresh water environments. A number of European countries have already enacted a general ban on use of antifouling products that contain biocides in inland bodies of water, among them Denmark, Sweden, and Great Britain (Umweltbundesamt, press release No. 47/2014).

In the EU Commission's roadmap on options for regulating endocrine disruptors, these decisive factors are not mentioned (see ref. 5); only the exemption criteria are referred to. The risk-based and socio-economic elements included in the criteria are presented by the EU Commission as options for other legislative bodies. PAN's position is that this view distorts the intention and the spirit of the biocide regulation.

While establishment of uniform identification criteria for endocrine disruptors is a worthwhile aim, the debate that has been initiated about standardising regulatory decision making across all areas of EU law is relevant for neither biocide regulations, nor for the rules on pesticides. Moreover, weakening or even abandoning the exclusion process and the hazard approach to EDs would have negative impacts on the regulation of all highly hazardous active substances. This would run counter to the goals of both regulations, which were agreed upon in a democratic policy-making process.

It would be useful if first experience could be gained with exemptions for biocides before extending this option to other regulatory spheres is considered. Such experience is lacking to date, in particular with respect to the controversial derogation C, which is very open to interpretation (see box 4). Here, weighing the effects of use or non-use of a substance with respect to the health impacts for humans and animals and the environmental effects in relation to the applications of biocides may be sensible if, for example, lack of protection against a specific pest that poses a threat to human health would affect an entire society. According to the biocide regulation, in order to protect a member state's cultural heritage, that state can be permitted the use of a specific substance without authorisation, as long as no alternatives exist (Art. 55(3)). But a ban on a cosmetic or pesticide product due to its endocrine-disrupting properties would threaten neither the health nor the cultural heritage of a society.

The availability of appropriate alternatives will contribute to systemical phasing out highly hazardous biocides. More important is the question of how comparative assessments are undertaken. Since several active substances have been notified for each kind of product type (see ref. 10), it is probable that alternative substances will be available. The availability of non-chemical processes must be included in the comparative assessment; moreover, savings with respect to external costs (e.g. for water suppliers) are to be included in the evaluation. Positive examples of the availability of non-chemical alternatives are product types 7 and 21 (see illustrations). Wherever necessary, special programmes can create incentives for further product innovation. Where alternatives are lacking, substitution plans should be developed that ensure that products containing highly hazardous biocides are phased out.

PAN Germany advocates implementing the provisions of the biocide regulation, which entered into force in September 2013, without further delay, and also calls for introduction of criteria for identifying endocrine-disrupting biocides with a three-tiered classification system on the basis of the hazard approach. Decisions concerning special derogations should be based on plausible criteria within a transparent decision-making process and should be complemented by substitution plans. Innovative non-chemical alternatives to biocide use must be promoted. Exposure of human beings and the environment to highly hazardous biocides such as endocrine disruptors must be ended.

Box 4 Derogations for approval of highly hazardous biocides (Art. 5(2), 528/2012/EC)

"(a) the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment;

(b) it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or

(c) not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance."



Thermal insulation composite systems without biocide coatings to prevent the growth of algae and fungi (PT 7) can be awarded the German environmental label "Blauer Engel". Within a short period, the number of products certified with this label rose from one to eighteen and the number of companies selling such products increased from one to eleven (RAL-UZ-140, / www.blauer-engel.de).

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