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Pestizid Aktions-Netzwerk e.V.




Biocides – risks and alternatives

Challenges and perspectives
regarding the handling of biocides in the EU

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Executive Summary

The EU biocide policy is currently under revision. The European Parliament and the Council are considering the Commission's draft biocide regulation, which is intended to replace the current EU Biocidal Products Directive from 1998. Why should we draw attention to these activities? Biocides are widely and sometimes casually applied in everyday life, such as disinfection or the elimination of household-insects. They can have toxic, carcinogenic or endocrine disrupting properties. So far, there is a huge gap in the relevant data. Preliminary investigations indicate a large and expanding market for all kinds of biocides, although their necessity is often unproven. Serious incidents for health and the environment (e.g. poisoning, pollution) have also come to light (Photo 1). The current EU biocide legislation has failed in its purpose of establishing effective risk management also due to shortcomings in the enforcement phase. Highly hazardous substances which are banned for other purposes can still be sold as biocides-for-everyone. When analysing the Commission's draft for a biocide regulation we have even identified noticeable roll-backs from achieving current environmental and health standards. Hence, one of the key demands of PAN Germany and other NGOs is the establishment of an innovative biocide legislation that ensures the consistent phase-out of hazardous substances, as well as providing an effective framework for the development and use of sound alternatives.

(Photo 1) Between 2003 and 2005, almost 15,600 consumers, workers and professional users suffered acute poisoning or were affected by the application of biocides in the EU. Though, as a consequence of significant data gaps the real situation remains unclear.
Data Source: European Commission, 2006[1]; Photo: Michael Bührke, pixelio.de

Biocides – profile and challenges

Biocides are intended to combat harmful and unwanted organisms outside the agricultural context. In many cases, they are not necessary for our safety. However, they are widely used and can pose adverse effects to human health and biodiversity.

According to Article 2 (1) of the Directive 98/8/EC (Biocidal Products Directive – BPD) biocidal products are defined 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.«*[2] One can differentiate between 23 product types (Figure 1) which are subsumed under four main categories of usage (disinfectants, preservatives, pest control and other biocidal products). Biocides have become part of our everyday life: Almost 400,000 tons of active substances are estimated to be sold in the EU each year. These are used in a variety of applications in households, public buildings and industrial plants (e.g. in the cooling systems of energy power plants). They can even be found in textiles like odourless anti-sweat socks or carpets treated with biocides.

An accurate insight into this battle against unwanted or harmful organisms, as well as the necessity of biocides and their impact is still impossible. So far, there has been a huge gap in market and use data, in information on the effects of exposure or environmental and health impacts, as well as regarding sound or better alternatives.[3] For this reason, it is essential to generate significant data and to ensure transparency. As many biocides can easily be bought in stores and supermarkets (e.g. household pesticides, wood preservatives or disinfectants which are not subject to strict sales controls) one should draw more attention to the fact that such man-made products can have an impact on our health and the environment. Biocidal products can often contain substances of concern with allergic, ecotoxic, carcinogenic, developmental neurotoxic or endocrine disrupting properties (Table 1). We generally become aware of this (again) when we hear about scandalous cases in the media. One well-known incident involved the widescale sale of wood preservatives for indoor use which included pentachlorophenol (PCP), an active substance with carcinogenic and endocrine disrupting properties. Although its application has been strongly restricted since 1989, it is still present in our environment today. PCP can also be released from treated goods imported from non-EU-countries.[4] Another problematic incident is associated with the application of dimethylfumarate (DMF) which is used to kill moulds that may cause furniture or shoe leather to deteriorate during storage and transportation.[5] Hundreds of consumers in countries including France, Poland and the UK suffered severe allergic reactions from contact with DMF-treated products before DMF has been banned in products which are sold in the EU. However, this seems to be just the tip of the iceberg. The application of numerous biocides can be problematic or harmful for professional users or con-

sumers. They pose a particular risk to pregnant women, unborn life, small children or citizens with serious chronic illness (e.g. linkages between childhood cancer and the use of household pesticides have been already detected).[6] However, cumulative exposures or combination effects are still not taken into account when evaluating biocides. Active substances and their metabolites can endanger our biodiversity and vulnerable ecosystems. For example, it has been demonstrated that the use of the antifouling agent tributyltin (TBT) has a serious impact on the marine environment (e.g. masculinisation of female common whelks, accumulation in pot whales).[7, 8] Furthermore, the application of brodifacoum which is very toxic for rodents and freely available on the market, has resulted in the secondary poisoning of non-targeted birds of prey like barn owls.[9] A Scottish study has demonstrated the vulnerability of red kites and foxes to similar rodenticides: Traces of rodenticides were found in more than 50% of the tested individuals, while almost 30% of them showed concentrations that would be regarded as being at the level of causing a health risk.[10]

In addition, 50% of active substances applied in biocidal products have already been prohibited or strongly restricted for agricultural or horticultural purposes in accordance with the plant protection products legislation (Directive 91/414/ EEC)[11, 12] or identified as priority substances pursuant to the provisions of the Directive 2008/105/ EC on environmental quality standards in the field of water policy.[13] This is, for example, the case with the herbicide diuron which is a relevant water contaminant.[14, 15] It can still be used as a biocide like for in-can and masonry preservation.

A new challenge is the growing use and sale of nano-biocides (e.g. nano-silver). Such products can have different properties and impacts from „normal biocides". So far, there have been no sufficient test methods to identify the real risks of nano-biocides. Some studies indicate health and environmental risks (e.g. toxic for water fleas).[16] Others demonstrate that nano-biocides leach out from treated façades or textiles into water ecosystems.[17] For this reason, the German Federal Environment Agency recommends avoiding use of such products as long as there is no clarity about their (potential) environmental and health impacts.[18] As with the (advanced) discussion about pesticides there is also the question of whether the

(Figure 1) **Biocidal Product-Types**

MAIN GROUP 1 **– Disinfectants and general biocidal products**
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

MAIN GROUP 2 **– Preservatives**
6 ► In-can preservatives
7 ► Film preservatives
8 ► Wood preservatives
9 ► Fibre, leather, rubber and polymerised materials preservatives
10 ► Masonry preservatives
11 ► Preservatives for liquid-cooling and processing systems
12 ► Slimicides
13 ► Metalworking-fluid preservatives

MAIN GROUP 3 **– Pest control**
14 ► Rodenticides
15 ► Avicides
16 ► Molluscicides
17 ► Piscicides
18 ► Insecticides, acaricides and products to control other arthropods
19 ► Repellents and attractants

MAIN GROUP 4 **– Other biocidal products**
20 ► Preservatives for food or feedstocks
21 ► Antifouling products
22 ► Embalming and taxidermist fluids
23 ► Control of other vertebrates

use of biocides is always necessary or even the best approach. For example, it is demonstrated that biocide-treated socks are not as effective as normal cotton socks.[19] Experts from authorities recommend not using household disinfectants in principle as there are enough appropriate and sound alternatives capable of achieving a sufficient level of sanitation.[20] They also advise against the use in everyday situations of biocides treated articles, such as treated bin liners, bathmats or refrigerators because they are redundant. Considering essential areas of application (e.g. intensive care unit) one should also be aware of the risks associated with the widely and improper use of biocides. The European Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) expresses the following concerns: The frequency of antimicrobial resistance in bacteria has increased in conjunction with the advancing usage of antimicrobial compounds.[21] One recently published study has demonstrated that relevant bacteria can develop resistance to antibiotics if they are exposed to widely used disinfectants (e.g. benzalkonium chloride).[22]

Besides, one can challenge the potential benefits of biocides in tackling direct or indirect impacts of climate change. For instance, WHO Europe recommends (non-chemical) precautionary measures for the management of tick-borne encephalitis.[23] At the same time, scientists indicate that some biocides can contribute to the climate change (e.g. the insecticide sulfuryl fluoride which is 4000 times more efficient than carbon dioxid).[24] Finally, regarding the handling of the risks of biocides throughout their whole life-cycle (i.e. in view of their production, marketing, usage and disposure), the European biocide industry, including downstream users, have yet to propose appropriate measures.

(Table 1) Examples of hazardous substances used in common biocidal products

Biocide	**Application**	**EC-Classification[25]**
permethrin	insecticide	very toxic for aquatic organisms, may cause long-term adverse effects in the aquatic environment, harmful by inhalation, harmful if swallowed,may cause sensitisation by skin contact *known to have endocrine disrupting, neurotoxic, developmental and reproductive toxic effects*[26]
propiconazole	wood preservative	very toxic for aquatic organisms, may cause long-term adverse effects in the aquatic environment, harmful by inhalation, harmful if swallowed,may cause sensitisation by skin contact
triclosan	in-can preservative (e.g.cosmetics), disinfectant, treatment of textiles	very toxic for aquatic organisms, may cause long-term adverse effects in the aquatic environ ment, irritating to eyes, irritating to respiratory systems
benzalkonium chloride	e.g. disinfectant for personal hygiene, preparation of surfaces	highly toxic to water organisms, harmful in contact with skin, (increase in resistance of bacteria)

Current legal framework

A common biocide-policy was introduced in 1998. The Biocidal Products Directive 98/8/EC (BPD) was an important step towards tackling the risks of biocides through the systematic identification of biocides marketed in the EU and the establishment of a harmonised framework for authorisation. However, several shortcomings and delays have resulted in a failure so far to protect human health and the environment.

The introduction of an EU biocide policy was necessary as most countries within the EU did not have specific provisions for the authorisation (of all kinds) of biocides (particularly Austria, France, Germany and Luxembourg).[27] In order to achieve this, the BPD requires a harmonised mechanism for the authorisation of biocides (Figure 2): Before a newly developed active substance be sold in the EU (e.g. in a biocidal product) it must be approved for inclusion into a Community list (= Annex I of the BPD). In this framework the competent authorities evaluate the relevant ingredient based on a specific risk assessment scheme. Besides, requirements have been established so as to harmonise national product authorisation and inspection systems. To check old active substances which were already on sale before May 2000 a programme has been introduced which systematically registers and reviews those biocides (through a ten-year review programme). Subordinated regulations and guidelines have been adopted for clarifying and adapting this programme.[28, 29] Furthermore, the BPD introduced the substitution principle (the replacement of hazardous substances with less problematic ones), the promotion of low-risk substances (establishment of a positive list) and provisions for reducing animal testing and tackling poisonings. In addition, the requirements for accurate advertising and labelling biocidal products can be regarded as a further positive outcome as well as the binding establishing and publishing of implementation reports. However, much remains undone or the Community has changed the law since 1998.

From the environmental and health point of view the whole architecture of the BPD is inadequate as it neither provides efficient requirements for the protection of biodiversity or vulnerable people at a high level nor to apply the precautionary principle. There is no cut-off regime in order to ban hazardous biocides. The low-risk approach is not safe enough as it allows the use of substances with endocrine disrupting, developmental neurotoxic, corrosive or bioaccumulative properties. The legal definition of harmful organisms does not exclude the use of toxic biocides against unwanted and possibly endangered species. Besides, an appropriate mechanism for the coordination and compliance with the standards and relevant instruments of the modern environmental EU legislation like the Water Framework Directive (WFD) is not guaranteed. Furthermore, the current biocide legislation does not sufficiently regulate articles that are treated with biocides (e.g. imported biocidally treated carpets). It also fails to make provisions for the use phase, nor does it include sufficient requirements regarding public information and reporting (e.g. no explicit requirements for gathering and documenting market data or environmental impact data). From the authority's and industry's point of view the provisions are regarded as too complicated to easily apply or indeed comply with them.[31, 32]

(Figure 2) Timetable of the implementation of the Biocidal Products Directive 98/8/EC (BPD) & current derogations[30]

14.05.2000
► transposition of the Directive in national laws,
► Start of the new authorisation system (= new active substances need approval at Community level)
► Start of a 10 years-programme to register and review old active ingredients (on the market before 14.05.2000)
► Ban of harmless product advertisement

30.05.2003
► First national implementation report to be compiled (incl. data on market surveilance and poisonings)

14.12.2003
► Ban on the placing of the market of old active ingredients which are not identified and notified (comply with first requirements for inclusion into Annex I)

01.09.2006
► Ban on the placing of the market of old active ingredients which are identified but not notified

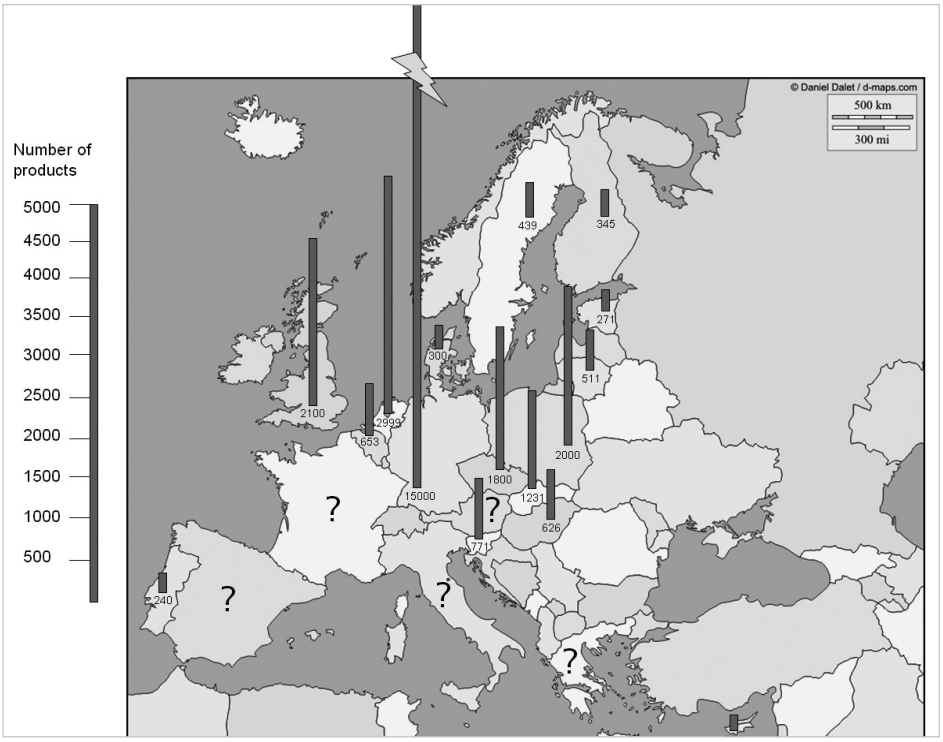
13.05.2010 – postponed until 14.05.2014
(Mini Revision of BPD in 2009)
► Phase – out of national authorisation systems applied for products with old active ingredients,
► Finalisation of review-programme, ban on the placing of the market of old active substances which are notified.

Implementation – well done?

The implementation of the Biocidal Products Directive (BPD) has not been sufficient. As regards the marketing or the application of biocides, many violations and open questions have emerged. While the public is faced with the consequences of inappropriate pest management, the number of authorised and probably harmful biocides is still increasing. Encouraging approaches to tackle this problem are few and far between.

Many obligations await implementation or their implementation has been delayed. According to the available information more than 400 old and possibly problematic active substances in about 50,000 products can continue to enter the EU-market because the review of most of these biocides has so far not been carried out (Figure 3).[33] Only one active ingredient has so far been listed in Annex IA for low-risk substances.[34] At the present rate, it will take significantly more than 10 years to assess all relevant substances and their possible risks and hazards in view of their specific application, and to approve or reject an inclusion in the Community Annexes. The objective of the Directive was to finish this work in 2010. The delay is not solely due to the fact that several new countries joined the EU over the previous years. Many 'old' member states complain that insufficient human resources have impeded consistent implementation of the Directive.[35] As a consequence, the Community has adopted a Mini-Revision[36] of the Directive for the extension of the review programme and current national authorisation systems until 2014. Moreover, the implementation reports of the Commission have disclosed several significant shortcomings at national level:[37] The data provided for the reporting

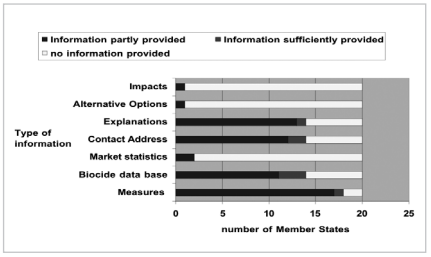
(Figure 3) Number of biocidal products authorised in the EU member states
Data source: European Commission 2006[45], Design: Sarah Kullmann



requirements is mostly insufficient to get a clear, comprehensive and differentiated overview of the situation (e.g. as regards the design and results of controls). Almost 15,600 cases of poisoning or relevant incidents were recorded in the EU for the period between 2003 and 2005. Consumers as well as professional users were affected. It is not clear whether this situation might be even worse (several member states like Denmark, Germany, Greece, Italy, Portugal or United Kingdom did not provide any or only insufficient data)[38], and which specific products were the causes of each incident. However, in the majority of the cases the poisonings are related to the use of insecticides, rodenticides, disinfectants, repellents and wood preservatives.[39] Bromadiolone and permethrin were amongst the main active substances which were involved in these incidents.[40] Only two member states have provided any data on (domestic) animal poisoning and no systematic information has been reported on wildlife poisoning. The generation of sufficient market statistics and appropriate data concerning the application of biocides – as it is obliged for pesticides – is outstanding.[41] Few positive approaches are documented like market-related reporting in Sweden.[42]

Besides, there is hardly any information about relevant, specific or coordinated measures to ensure the proper use of biocides (e.g. coordinated schemes for training professional users).[43] PAN Germany's investigations demonstrate that there is generally no transparent and consistent biocide policy at national level which could promote the use of sound alternatives. For instance, when examining biocide-related official web pages (Figure 4),[44] a comprehensive platform is largely unavailable. In many cases, information is not easily accessible, remains too technical or is not up-to-date. In principle, the authorities do not provide sufficient information about authorised or registered biocides at national level, nor do they explain their risks. They do not refer to possible alternatives like non-chemical approaches. It is nearly impossible to find volume data on sales and application, results of environmental or health-related assessments, or information about implementation, including control reports or relevant contact persons.

(Figure 4) Type of information available on official biocide-related web pages in 20 EU member states[47]



According to the results of PAN Germany's survey, several incidents, ranging from problematic to scandalous, have been reported from different member states in the EU, indicating a need for urgent improvements to current risk management efforts.[46] These include:

- easy access to products with highly hazardous substances
- ongoing indoor pollution/exposure to contaminated products
- improvidently application of biocides & biocidally treated products in schools and kindergartens
- use of biocides near the aquatic environment with hardly any official control
- marketing of illegal products
- aerial spraying of biocides

Spain

(Photo 2) Biocides are also used in the workplace. In Spain several chronic diseases have resulted from biocide use in offices.
Photo: Paul Georg Meister, pixelio.de

Spain established its national law on the manufacture, marketing and use of non-agricultural pesticides in 1983, much earlier than many other EU member states.[48] So far the government has not introduced a systematic approach for reducing the application of biocides and promoting sound alternatives. Official attempts to enhance transparency can be partly documented. For instance, a public data base provides both information on all biocidal products registered in Spain and information on the type of application for which the relevant products can be used.[49] Additionally, product-related risk phrases (e.g. information about their risks for health and environment) are available. Based on one official source, almost 2,600 poisoning incidents or accidents with biocidal products were recorded in 2005, of which more than 50% can be associated to the use of pyrethroid insecticides and rodenticides.[50] Current data or relating to the long-term effects of exposure to biocidal products is not available at the official source.

Some related problems were highlighted in the Spanish media:[51] One of the first well-known cases was the poisoning of 15 workers in a hospital in Barcelona in the 1990s. The people affected developed the Multiple Chemical Sensitivity (MCS) Syndrome after the regular exposure to low doses of biocides. The affected persons suffered from shortness of breath, a heightened sense of smell, altered memory, frequent fatigue, headaches, etc. They experience attacks when they are in surroundings where any of the relevant substances appear (e.g. in public buildings with biocidally treated materials or surfaces). This has resulted in a serious limitation to their social life. According to initial estimates, 5% of the Spanish population suffers from Multiple Chemical Sensitivity. Over the last few years, a minimum of 40 additional cases have been documented in working areas like hotels and administration offices (Photo 2). A large number of these cases usually involve exposure to pesticides including biocides, solvents and products like formaldehyde or chloride. They have resulted from fumigations carried out without respecting the necessary safety conditions, the use of prohibited products, and non-compliance with safety distances. For example, a female worker used to work in an office which was fumigated with organophosphorus biocides every three months, although bugs had never been detected in the office. A (subcontracted) company applied such products during the office time. As the air conditioning system was not efficient enough to clean the contaminated air she was slowly poisoned. Over the course of the following years more and more people became ill in the office. Relevant official measures to tackle this problem sufficiently are still outstanding.

Hungary

In Hungary a system for authorising biocidal products has been established and according to the official data 600 – 700 biocidal products have been granted for authorisation.[52] Public information about the Hungarian approach is very restricted. Based on the information of the environmental NGO Levego Munkacsoport (LM) serious cases have been identified and documented as regards the marketing, control and application of biocides.[53, 54] The sale of biocides, especially insect busting chemicals is steadily on the rise. In the mass media they are advertised as harmless, and the scenting of insect sprays encourages their wider use. A variety of insecticides can be found in almost all households, targeting ants and mosquitoes separately. The common user casually discharges these toxics into the air without any precautions. Not only the public, but also the authorities use problematic substances or allow them to be sprayed in public areas. Even dichlorvos[55] were recently used for mosquito control, although it is carcinogenic and genome damaging. Thanks to the pressure of Levego Munkacsopport its application for mosquito control was banned in 2007. More and more scientific information about the danger to human health posed by biocides found in Hungary becomes available: they cause cancer, damage the DNA, as well as the hormone and nervous system. On a number of occassions Levego Munkacsoport has suggested to ban such products. Though the proposed restrictions were rejected by the authorities, the majority of the substances that LM complained about were „banned on European Union level" in August 2008**,** so hopefully they will disappear from the shelves of Hungarian shops. Unfortunately, there are still too many worrying active agents in circulation. After the investigation into the sale of biocides in stores and supermarkets (Photo 3) LM concluded the following:

- 92 biocidal products were found. Altogether they include 45 different active substances
- 11 active ingredients were identified as problematic as they have possible carcinogenic, immune modulating, ecotoxic, endocrine disrupting, highly toxic or other effects (e.g. cypermethrin, d-penothrin, chlorpyrifos, permethrin, deltamethrin)
- several of these substances have been banned as pesticides (withdrawn from Annex I of Directive 91/414/EEC)
- several substances were already banned for wholesale in accordance with the biocide legislation (e.g. the possible human carcinogen and hormone-damaging bioallethrin)

Mosquito repellents are always on the agenda. Out of the approximately 50 species of mosquitoes occurring in Hungary, many bite, making life for people living or holidaying near lakes and rivers unbearable. Naturally, they have a negative impact on tourism. Malaria disappeared in Hungary before the middle of the 20th century, and no other diseases spread by mosquitoes really need to be reckoned with. Unfortunately, aerial spraying against mosquitoes is still in practice and everyone has access to deltametrin, which is „especially hazardous to aquatic environments and is a possible genome-damaging substance".

(Photo 3) In Hungary aerial spraying against mosquitoes is still in practice.
Photo: Georg Schemainsky, pixelio.de

Bulgaria

(Photo 4) 30 children were severely poisoned by application of cypermethrin in the grounds of a kindergarten in Dolna Mitropolia.
Photo: Lubka, picasa.com

National Movement Friends of the Earth (NM FoE) Bulgaria have identified several problematic cases relating to the authorisation, marketing, application and management of biocides in Bulgaria:[56] One crucial problem is the current pest management on the grounds of kindergartens. One high profile case illustrates that the application of biocides on such places poses a real risk of adverse effects on children: On 30th May 2007 the yard of the kindergarten in Dolna Mitropolia was treated against ticks with the product „Bandy 10“, which contains the active substance cypermetrin. This biocide is very persistent and has acute toxic, developmental neurotoxic, mutagenic, carcinogenic and endocrine disrupting properties. Although the children were not allowed to play outside the next day it is assumed that open windows and the hot weather resulted in a mass poisoning with the biocide concerned. 30 children aged between 5 and 7 from the kindergarten were so heavily poisoned that they had to be taken to the toxicology department of the local hospital (Photo 4). Following the incident, a company which applies biocides made a request for information to the responsible authorities. Their questions concerned the application conditions and unclear dosage recommendations for the use of the same product, but the request was left unanswered. NM FoE Bulgaria presented the case to the public, but, unfortunately there has been no reaction from the competent authority so far.

When evaluating biocidal products sold in central markets in Sofia in 2007, NM FoE Bulgaria detected several violations of product and labelling standards. For instance, the products included illegal active ingredients like deltametrin (an insecticide that is acutely toxic, carcinogenic, developmentally toxic and neurotoxic) or they were not officially labelled with the certificate of the Ministry of Health. It can be concluded that such products are illegally imported. These challenges on the market are also currently present. The prior notification of a biocide application in public areas is not common. NM FoE Bulgaria has achieved a situation where professional users are obliged to post some notification after the application of biocides. However, this obligation is not compulsory, and in the observed cases it was insufficient. Sometimes, an A4-size notice is posted on some trees in some parks indicating that a biocide has been applied. In one big park these notices were affixed to only a few trees, and they were not clearly visible. Moreover, the notices in question provided neither information on the applicator, nor data concerning the product and possible impacts. There is a lack of awareness among the public and users of the risks associated with the use of biocidal products and, as a consequence, an absence of proper application in the case of such products. Biocides are, for example, applied in restaurants without protecting the food from being contaminated. In hospitals there is no evacuation of patients at the time of the application of biocides. On the other hand, the public is very interested in information on biocide related-issues in case it is available.[57]

United Kingdom

In 1986 the UK established legislation and a system to control the placing of biocidal products on the market.[57] 2,100 products have been authorised, a figure which is relatively high in comparison to other countries.[59] The competent authorities deliver only a limited insight into biocide-related measures. The official web page does not provide information on the authorised products, nor is there any advise on issues like the proper use of biocides, or information on alternatives.[60]
Data on cases of poisoning only give an initial overview of the situation. There is no differentiation between incidents with biocidal products and pesticides. In total, almost 700 cases have been recorded. Most of them (44%) are associated with insecticides. In the context of its pesticide campaign, Health and Environmental Alliance (HEAL) found some striking problems regarding pesticide (including biocides) use in British schools (Photo 5):[61]

- in most cases it remains unclear if or how pesticides are applied at school and which precautionary measures are carried out by the responsible authorities (only 15% of the 206 local authority education departments which were asked in this survey responded to the questionnaire)
- none of the responding departments has established an integrated pest management policy for its school until now
- in only 36% of the cases pesticides are applied in or nearby the school when nobody is in the school
- in only 27% of cases are the school council or pupils warned before or during application of pesticides
- in some cases, extremely toxic biocides were used (e.g. the rodenticides aluminium phosphide and bromadioline)

(Photo 5) A survey in 206 British schools reveals that pupils are insufficiently protected from exposure to biocides
Photo: Carmen, picasa.com

Germany

Germany is the country with the most intensive production and largest biocide market in the EU. Almost 25,000 products can enter the market.* [62] Despite of the associated risks and impacts which have been documented since the 1970s (e.g. problems with wood preservatives),[63] the legislator did not introduce specific legislation for the authorisation and use of biocides until 1998. But along with transposition of the BPD in 2002, an innovative requirement in the German Chemical Act has been adopted which intends to ensure that the public is appropriately informed on the use of alternatives.[64] Actually, the Federal Environment Agency is preparing a comprehensive web portal with biocide-related information which is expected to be launched in April 2010.**

This effort is necessary as the reporting, monitoring and control system has to be improved on national and on regional level in order to ensure transparency and a high protection level for consumers. For example, the available web data base on active substances and biocidal products provides only limited information (e.g. no information concerning properties of biocides and related risks).[65] There are some improvements at regional level (e.g. publication of the results of the market surveillance in the Federal State of Brandenburg)[66] and on national level (an initial federal report on the affect of several biocides on water bodies).[67] A report of this kind represents a marked effort compared with the outcome in many other EU countries. Many producers and distributors are still failing to provide customers with safe products or correct information about biocides. In market surveillance carried out by German authorities in 2006/2007 infringements were found in the case of up to 50% of the products checked.

It is also striking that there have been no improvements over the previous situation. Current inventories of PAN Germany and other sources demonstrate that:

- products do not always feature adequate labelling (e.g. labelling on a popular toilet disinfectant does not disclose its active substances)
- risky products or substances rarely indicate risks (e.g. no or not all required warnings are indicated)
- products breach advertising laws (e.g. insect sprays with pyrethroids are labelled as harmless (Photo 6)
- products have been illegally sold in stores or on the internet (e.g. 4 products with wood preservatives like permethrin or cyfluthrin, and which have not been registered and thus banned for sale since 2003)[69]
- many biocide-treated products on sale are non-essential (e.g. biocide-treated bin-liners)

Finally, a strategy for ensuring a proper use of biocides and for the promotion of sound alternatives is not established so far.

As a result, there are always incidents, even in 2010 (e.g. 28 people have been affected due to the improper use of a rodenticide in a building in Gummersbach, Northrhine-Westphalia).[70]

(Photo 6) Label on moth spray with pyrethroids sold in Germany inaccurately claiming it is harmless. This is illegal.
Photo: PAN Germany, Sarah Kullmann

* personal information by Federal Institute of Occupational Safety and Health (BAUA), 12.12.2009
** personal information by Federal Environment Agency, 27.1.2010

In Belgium a national authorisation system controlling the marketing of biocides was established in 1975.[71]

In the European context, the number of authorised biocides is relatively limited (= 653 products and 114 different active substance of which 42 are also used as pesticides).[72]

The government introduced a federal programme for the reduction of pesticides and biocides in 2005 which is subject to review every two years.[73] Such a programme is unique within the EU and aims to reduce the impact of the use of hazardous biocides, particularly wood preservatives, rodenticides, insecticides, acaricides and other biocides. The initial objective of the programme was to reduce the negative impacts of relevant biocides by 50% by 2010. Apart from generating market data (tonnage of sales of each type), an appropriate indicator system is supposed to be developed in order to get information on the impact of the biocidal products released. In developing such indicators the authorities will consider the hazards and exposure scenarios regarding all active substances which are used for the relevant products. On this occasion, an ad-hoc working group has been established which represents relevant stakeholders. The first review report demonstrates that initial measures have been introduced (e.g. development of a first risk indicator, generating market data and public information).[74] Further activities are planned (e.g. communication plan for rising citizens´s awareness). Public information is provided, in particular, by a web page[75] which both explains measures of the government, and gives advise for cititizens how to prevent or minimise the use of biocides and pesticides in their own household and garden (Figure 5).[76] In addition, there is also an accessible database that includes data on both authorised biocidal products and active substances.[77] These sources also provide information on the risk-phases associated with the specific biocide.

Despite the fact, that such efforts can be regarded as an important step in the right direction and are welcome, it should also be taken into consideration that the Belgian government still has to cope with the following challenges: In several cases, available information is neither easily accessible, nor comprehensive and sufficient enough (e.g. database on biocides). Public information concerning the use phase remains too limited (e.g. as regards instructions for all product types and recommended alternatives). Besides, an appropriate framework for the active involvement of environmental NGOs is not ensured. One can identify further shortcomings: The government's reduction programme doesn't focus on the minimisation of the dependency on biocides, but only on the reduction of the impact of biocides. Until now, risk indicators are only available for product types 18 (insecticides, acaricides, other arthropods) and 14 (rodenticides). No actions are initiated in order to reduce the impact of pesticides and biocides on bees. Moreover, in the last review (2009), the deadline for achieving the objectives by 2010 was postponed by two years. Finally, data on poisoning incidents are not comprehensive as there is no obligation to communicate relevant cases to the poisoning centre.[78] According to the available data the exposure incidents remain on a high level and small children, in particular, are affected (in 73% of almost 900 cases reported).[79]

(Figure 5) The Belgian authorities have published a brochure supporting environmentally-friendly alternatives for biocides (here: an alternative to applying rodenticides)
Source: Federale Overheidsdienst Volksgezondheit, 2007[80]

Experiences from abroad: Canada's approach

By considering approaches outside the EU we can learn about innovative measures on how to enhance the use of alternatives. In Canada, for instance.
The Canadian Pest Management Regulatory Agency (PMRA) has established a strategy to promote proper use of pesticides, also encompassing non-agricultural application types.[81] In this framework, a comprehensive web information guide was introduced to raise awareness amongst consumers and professional users for sustainable approaches to pest management.
For example, regarding 26 common household pests (e.g. rats, wasps, mosquitoes), structured „pest notes" were published (Photo 7), providing a better understanding of the organisms concerned and referring to relevant precautionary measures and approaches to control.[82] When it comes to controlling them, the competent authority recommends the use of physical measures over (chemical) pesticides. Furthermore, useful advice on understanding product labels is provided.[83]

(Photo 7) Detail of a „pest note" published by the Canadian authorities recommending sound prevention measures (here: measures to avoid silverfish infestation) Source: Health Canada


Vacuum regularly.

How can I manage them?

Sanitation to control silverfish and firebrats

Sanitation is the first and foremost element of any effective silverfish and firebrat control program and is most suitable for the control of all crawling insects.

- Vacuum regularly to help remove food particles and insect egg masses.
- Regularly clean around and behind appliances and machinery, inside cupboards, drawers and pantries and keep countertops clean. Also clean beneath sinks and other dark or humid locations.
- Wrap or insulate pipes that have excessive condensation, repair leaky faucets and pipes, ventilate bathrooms and dehumidify areas of excess moisture.

The draft biocide regulation – a critical comment

Although a revision of the Biocidal Products Directive 98/8/EC (BPD) is crucial, the proposed biocide regulation is a counter-productive answer to the challenges associated with the marketing and use of biocides in the EU. It will simplify the marketing of any kind of biocides at the expense of protecting human health and the environment.

Positive aspects of the draft regulation Pursuant to BPD Article 18 (5) the Commission revised the biocide law resulting in a proposal for a new biocide regulation, published on 12 June 2009.[85] This law is planned to come into direct effect in member states in 2013. PAN Germany acknowledges some improvements resulting from the Commission's draft. Particularly, the newly proposed provisions for biocide-treated articles and materials and the requirements for the specific labelling of such goods, which have long been recommended by PAN, can be regarded as a significant step forward. There are also some positive aspects associated with the introduction of a cut-off regime based on a „property approach" (exclusion of substances on the base of inherent hazardous properties), the promotion of non-chemical alternatives and amendments for the welfare of animals (e.g. obliged exchange of data regarding previous animal tests and promotion of alternative test methods). Another positive aspect is the reference to the protection of biodiversity for the first time.

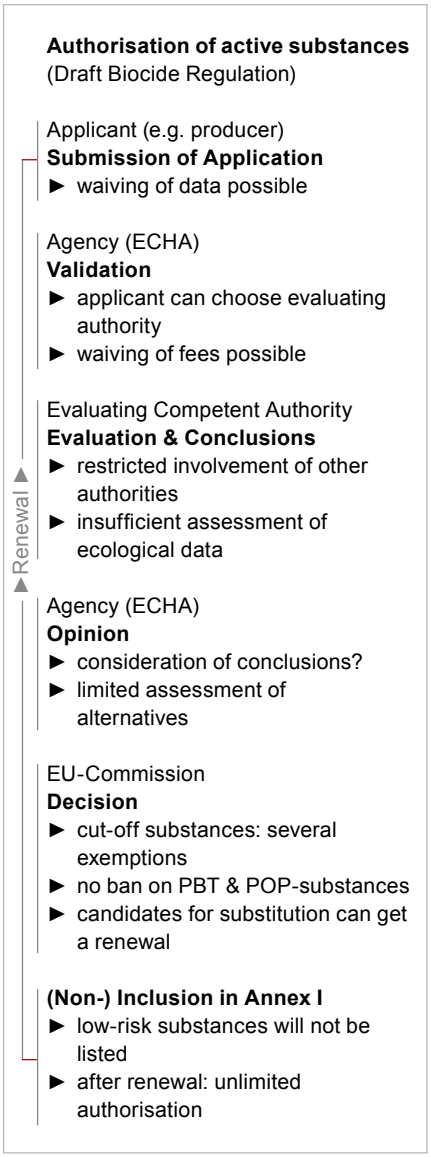
Issues of concern The main purpose of the intended biocide regulation is not to protect the environment and human health but to simplify the authorisation procedure in order to increase the free marketing of biocides (e.g. established in recital 3 of the draft biocide regulation). In contrast to REACH[86] and the newly adopted Regulation on Plant Protection Products[87], the precautionary principle and Community standards for the protection of water ecosystems and humam health (e.g. the objectives of the Water Framework Directive) *from the adverse affects of chemicals* are not embedded. (Figure 6).

The draft regulation also includes several other problematic modifications and deteriorations (Table 2):

► The substitution principle is poorly defined: In comparison to the current BPD, the competent authorities are not (automatically) required to oblige applicants to gather all relevant data (e.g. for the protection of groundwater). Besides, when evaluating biocides, the authorities do not, in principle, have to consider and prefer sound alternatives. Hazardous substances with mutagenic, carcinogenic or reproductive toxic properties can receive approval. The draft regulation also allows for the bypassing of the substitution principle (in case of gathering experiences) and the approval of hazardous substances for a further 10 years.

► Highly hazardous substances can get further approval: At first glance, there seems to be criteria for refusing to authorise certain substances due to their hazardous properties. Although such an approach is very positive, the concrete arrangement is insufficient: The provision does not address substances with hazardous effects on the environment or biodiversity. It also includes several vague exemptions (e.g. exemptions for substances with „negligible" effects) which allow the authorisation of even the most problematic biocides.

(Figure 6) The commission has proposed an authorisation scheme for active substances that has several loop holes.



► The criteria for the so-called „low-risk" products are too weak to prevent an EU-wide authorisation and use of harmful active ingredients. Contrary to the BPD, a product that includes substances with bioaccumulative and highly toxic properties can be authorised as low-risk product. Besides, active ingredients included in low-risk biocidal products will be no longer subject to a comprehensive risk assessment because they don't have to be approved for inclusion into Annex I. Vague exemptions and criteria will be introduced so that it is not guaranteed if sufficient precautionary measures are carried out after a product is granted for authorisation.

► The draft regulation provides the opportunity for an unlimited approval of active substances once their authorisation has been renewed. According to the BPD, the authorisation is limited to 10 years.

► The Commission suggests a one-zone approach for the authorisation of certain biocidal products. That means: The authorisation of biocidal products (low-risk ones & with new active ingredients) will be directly effective in all member states once they get the permission at EU level. This is problematic as the regional conditions could be very different in Europe (e.g. with respect to the climate, the environment, vulnerability of ecosystems or demographic patterns such as the requirements or distribution of vulnerable groups. Only in a few cases, is a national competent authority allowed to effectively restrict or refuse the authorisation of hazardous biocides on its territory (specifically biocides to combat birds, fishes and other vertebrates).

► While the authorisation procedure has been simplified and comprehensively harmonised, nothing significant has been done to tighten regulations for the use phase of biocides. Although the title and purpose of the draft regulation refers to the initial application of biocides, there are no additions to existing provisions introduced with the BPD. This is remarkable as there are many unanswered questions to this issue and infringements are often seen.[88]

► No consistent efforts for transparency: It is required that relevant data collected or generated by the ECHA be freely accessible on the agency's webpage. This is welcome. On the other hand, the Commission is no longer required to summarise and publish national implementation reports although current national efforts remain insufficient and intransparent.

(Table 2) Identified gaps in the draft biocide regulation (Commission's proposal) in comparison with current chemical laws

REACH, Regulation (EC) 1107/2009 and Directive 98/8/EC

Issue	Result
purpose	Art. 1 of REACH and Reg. (EC) 1107/2009 requires a high level of human health and environmental protection & it ensures the precautionary principle: substances & products shouldn't have adverse affects; Art. 4 of Reg. (EC) 1107/2009: special protection of vulnerable groups
envi- laws	Art. 2 of REACH: compliance with provisions of Directives 2000/60/EC and 96/61/EC
cut-off	Annex II of Reg. (EC) 1107/2009: ban on POP-, PBT- and vBvP-substances
low-risk approach	Art. 2,8,10 of Directive 98/8/EC: relevant active substances must be listed in Annex I (A), no substances of concern, no bioaccumulative & persistent active ingridients
substitution approach	Art. 10 of Directive 98/8/EC: no approval of active ingredients of concern, if there are appropriate alternatives, old active substances have to be phased-out within 4 years
use-phase	Art. 55 Reg. (EC) 1107/2009: introduction of a Directive for the sustainable use of pesticides (Directive 2009/128/EC), integrated pest management shall be applied at 1/2014 latest
reporting	Art. 24 of Directive 98/8/EC: implementation reports to be published, every 3 years
safeguard clause	Art. 4,7,32 of Directive 98/8/EC: Member State can restrict, adjust or prohibit the use of an biocidal product for the protection of human health and the environment
data	Art. 8 of Directive 98/8/EC: relevant data should be gathered, data waiving restricted
renewal	Art. 10 of Directive 98/8/EC: an active substance can only be approved for 10 years

Conclusions – five key demands

Revision of the Biocidal Products Directive 98/8/EC (BPD) is now at a crucial stage. A key recommendation by PAN Germany is to consistently apply the precautionary principle for the new biocide regulation and establish a coordinated framework for promoting sound alternatives.

Revision of EU biocide law provides the opportunity to re-define EU-level biocide policy and tackle its shortcomings. The Commission introduced a draft biocide regulation in June 2009. The European Parliament and Environment Council must decide about this initiative and are currently dealing with the proposal. The available time to complete their negotiations is brief. Several interest groups have made known their expectations but most do not care about necessary efforts for the protection of human health and the environment. That is why PAN Germany is committed to a sustainable revision of the Biocidal Products Directive. Detailed positions and recommendations have been published to coincide with preliminary official consultations, negotiations and meetings.[89] PAN Germany and thirteen supporting European NGOs have also brought forward key demands in view of the proposed biocide regulation.[90] In particular, the NGOs urge the European Parliament and the European Council to significantly improve the Commission's draft in five areas, which are crucial for the benefit of our future:

- The regulation should strengthen the precautionary and substitution principles in order to protect human and animal health and the environment from the adverse affects of biocides.
- New regulations must ensure an effective control of both materials treated with biocides and nano-biocides including the clear labelling of such products.
- Sufficient rooms to manoeuvre have to be maintained on national level, particularly for ensuring more strict national protection levels.
- Transparency and participation of the professional public is crucial and must be guaranteed: Requirements are necessary for a sufficient reporting on market data, alternatives, impact assessment, qualification, research and enforcement.
- A binding provision is essential for introducing a Community Framework Directive by 2013 regarding the use of biocides within the EU for risk reduction and the promotion of sound chemical and non-chemical alternatives.

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