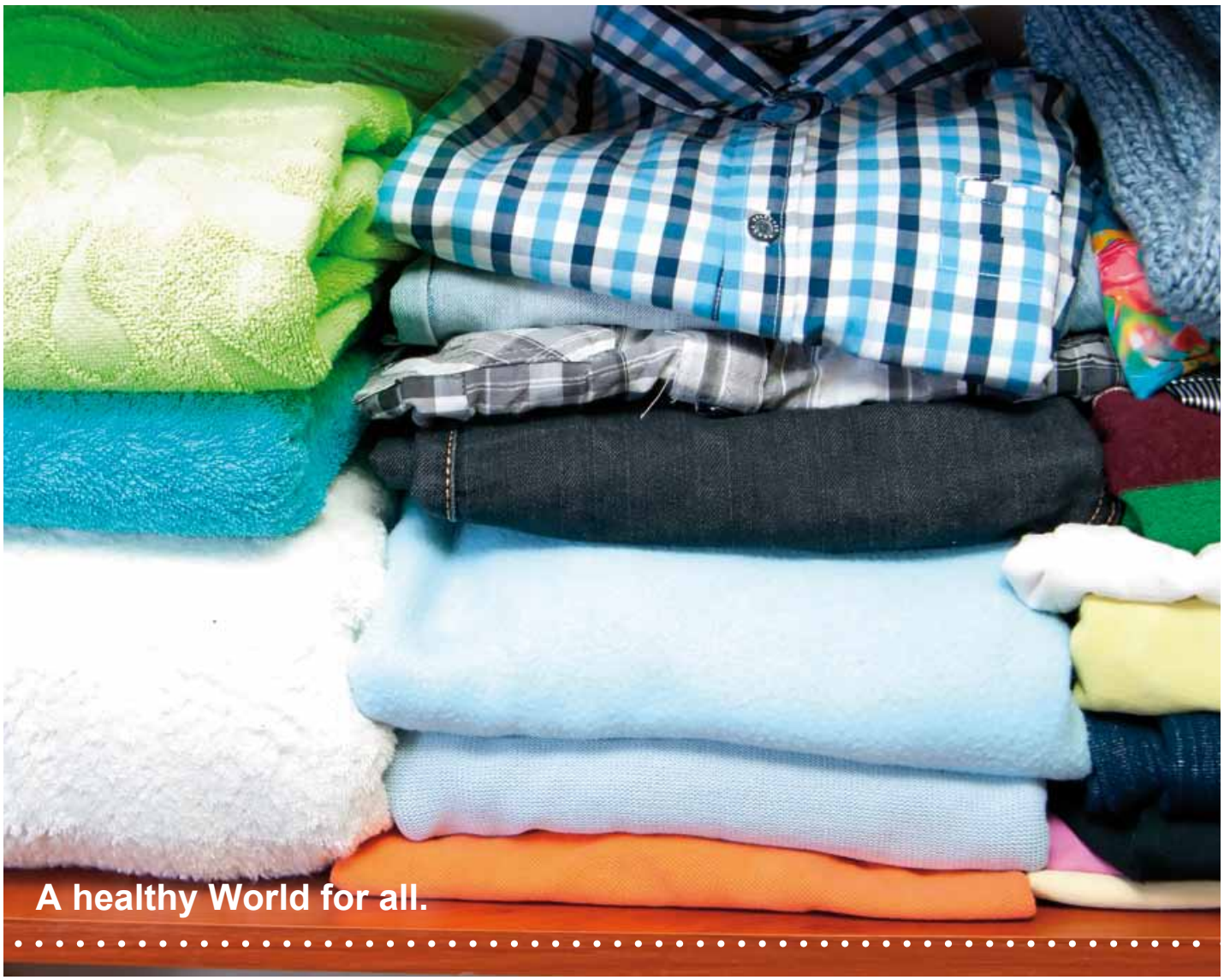
PAN Germany
Pestizid Aktions-Netzwerk e.V.

Biocide-treated Consumer Products

Markets – Policies – Risks



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Abbreviations

Art.	Article
BPD	Directive 98/8/EC or Biocidal Products Directive
BPR	Regulation 528/2012/EC or Biocidal Products Regulation
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Federal Institute for Occupational Safety and Health, Germany
BfR	Bundesinstitut für Risikobewertung, Federal Institute for Risk Assessment, Germany
PT	Product type (as defined in Annex V, BPR)
UBA	Umweltbundesamt, Federal Environment Agency, Germany

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Summary

Numerous consumer products are treated with so-called biocides to preserve the products themselves or produce specific functions. Biocides prevent the growth of bacteria, fungi, algae, or viruses or repel or combat insects. Their uses are diverse and range from repelling moths in wool carpets, to preventing the growth of odour-causing bacteria in textiles, to antibacterial coatings for plastic products used in the kitchen or bathroom. Biocidal properties are generally seen as product enhancements; their positive effects for consumers with respect to hygiene and preventive health care are emphasized. For suppliers, these promotional arguments may also justify higher prices than those charged for competitors' products that have not been treated with biocides. To date, there is no register of treated articles available in the EU, nor are market statistics available. However, this appears to be a rapidly expanding market with an increasingly diverse range of products.

Biocides are not harmless. These are hazardous substances that are designed to damage organisms. Many also have undesired side effects that further harm human health or the environment. Consequently, they are subject to an authorisation process that is intended, first, to determine whether the biocidal active ingredient or product is sufficiently effective and second, to assess risks linked to its use which may affect consumers and the environment and, if necessary, reduce them by permitting use subject to certain restrictions. Due to considerable delays in implementing existing regulations in the past, numerous active substances that play an important role in treating products, such as disinfectants and preservatives, have not been subject to an authorisation process. As a result, consumers have been exposed to biocidal products in treated articles that have not been assessed by the competent authorities.

Nonetheless, there are still numerous gaps in the regulations on marketing treated articles. The recent reform of European biocide legislation will rectify many of these regulatory deficits. A new regulation will take effect in September 2013, but a number of details must be spelled out in guidelines and further legislation.

This publication summarizes the legislative changes for producers, commerce, non-governmental organisations, and interested consumers; identifies important unresolved issues in implementation; and formulates recommendations for further action. With the help of a non-representative e-commerce market check, a survey of the range of consumer products treated with biocides currently available on the market is presented, focusing is on those with antibacterial function. In this investigation, PAN asked how well consumers are informed by suppliers about the purpose of biocidal treatment and the biocides used.

This brochure aims to stimulate a discourse that will address the necessity of using problematic substances in consumer products for households or offices. In most of these use areas, biocide treatment is not essential and can lead to health and environmental problems. Many products treated with biocides are not compatible with the goal of sustainable and environmentally-sound consumption.

Identifying biocide-treated articles

Products that combat pests and are not used as plant protection products or as pharmaceuticals are considered to belong to the group of substances called biocides. Biocide-treated articles are substances, mixtures, or articles that have either been treated with biocides or to which biocides have been added in order to impart them with a biocidal function. Treatment with biocides can serve two goals:

► **Internal biocidal effect:** The article is treated (e.g. coated) with one or more biocidal active substances or biocidal products during the manufacturing process in order to protect the product itself from microbial degradation or from other damage caused by undesirable organisms. (Box 1)

The Biocidal Products Directive 98/8/EC (BPD) does not take into account products that have been treated with biocides in this way; this gap is problematic. For articles produced in the EU, only biocide active substances and formulations are permitted that have been authorised according to the BPD, but this rule does not apply to articles imported from non-EU countries. As a result, suppliers are subject to different rules. Moreover, imported goods can also be treated with biocides that do not comply with EU standards and which may not be accepted for this specific use in the EU for health or environmental reasons. One example is pentachlorophenol (PCP) for treating leather goods. This gap will be closed when the new Biocidal Products Regulation (BPR) enters into force on 1 September 2013, after which all biocide-treated goods available on the EU internal market will be subject to EU law.

► **External biocidal effect:** Here, an article is treated with one or more biocidal active substances or biocidal products to create a biocidal effect when the article is in use that does not (or not exclusively) serve to protect the material. (Box 2)

According to current interpretation, these articles are subject to BPD 98/8/EC when the active substance is inseparably connected to the article and is released on the article's surface or when the targeted organism is not damaging for the article itself. In these cases, the article functions as a vehicle for the biocide active substance and thus itself becomes a biocidal product.

To date, borderline cases were discussed in a consultation group with representatives of member states and the EU Commission. Their non-binding evaluations are published in a "Manual of Decisions" (MoD)[1] on the EU Commission's biocide website, which is constantly updated. Biocidal products that require authorisation include, according to the experts' decisions, toothbrushes, nappies, dummies for babies, or toilet seats that have been treated with biocide substances like silver nanoparticles or triclosan to prevent the growth of microorganisms on their surface. One example involves an antibacterial rubbish bag; here, a biocidal substance was added to the polymer during extrusion in the manufacturing process. (Box 3)

When the provisions of the new BPR take effect on 1 September 2013, these decisions will be subject to review. According to the new regulation, articles treated with biocides are considered biocidal products when they have a "primary biocidal function". But the precise meaning of this definition is not clarified in the text, so that considerable space for interpretation remains.

Box 1: **Products with internal biocidal effect**

Examples of this type of protection of materials are:

- lumber treated with a wood preservative in a pressure or vacuum process (PT 8)*
- carpeting treated with insecticides against moth damage (PT 9)*
- leather goods treated with fungicides to prevent mould and mildew (PT 9)*
- in-can preservatives for water-based paints, varnishes, or adhesives (PT 6)*
- paints, papers, sealants, and adhesives treated with fungicides or algicides against mould, mildew, and algae growth (PT 7)*

Box 2: **Products with external biocidal effect**

Examples of this type of biocide treatment include:

- textiles, plastic articles, or other goods with an antibacterial hygienic function intended, for example, to inhibit the growth of pathogens or prevent disagreeable odours (PT 2)*
- mosquito nets treated with insecticides to kill insects (PT 18)*
- textiles such as sleeping bags treated with repellents to repel insects (PT 19)*
- adhesive flypaper with added attractants (PT 19)*

* PT = Product type of the biocide use as defined in Annex V, BPR 528/2012/EC

New regulations on biocide-treated articles

Since 2000, specific regulations apply to making biocidal products available on the market within the European Union (EU). According to Directive 98/8/EC, biocidal active substances and biocidal products are subject to an authorisation process. Authorisation to be placed on the market is for a defined period for specific uses (e.g. as disinfectants, preservatives, protective substances, or household pesticides).[2] With the introduction of BPR 528/2012/EC[3], the most recent reform of European law on biocides, the EU now also regulates the use phase of biocidal products and articles that have been treated with biocides[4]. These new regulations must be enacted by 1 September 2013, with a transitional period for certain provisions. The following aspects of the new legal provisions are especially relevant with respect to treated articles:

► **Definition of "treated articles":** With the BPR, lawmakers have introduced for the first time a definition of "treated articles". According to Art. 3 (1)(l) of the BPR, this includes any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.

► **Rules for the use of treated articles:** A new provision of the BPR stipulates that all biocidal active substances intended for use in treating goods to be sold on the EU market must be approved for such use before they are introduced. Among the important aspects examined during the evaluation process are whether the treatment is sufficiently effective (i.e., whether the intended effect is lost when the product is washed) and whether unacceptable risks linked to the use and disposal of the product can occur for consumers and the environment.

According to Art. 58 of the BPR, the active substances used must be included in the list compiled by the EU Commission in accordance with Art. 9(2) or in Annex I for the simplified authorisation procedure. Furthermore, they must meet the requirements for use formulated there, that is, be permitted for use in treating products. These requirements do not apply to goods "where the sole treatment undertaken was the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment".

Treated articles that are already on the market can continue to be placed on the market after 1 September 2013 if an application for approval of the active substance(s) for the relevant producttype is submitted by 1 September 2016, at the latest (see Art. 94, BPR). The EU Commission can formulate further details of the procedures that manufacturers or applicants must comply with in order to obtain authorisation for the active substances / biocidal products used.

Box 3: **Evaluation of an antibacterial rubbish bag**

The experts explained their decision as follows: "Although the treated garbage bag is a product where the intended control effect is on the surface of the treated article only and the active substance is not intentionally released for effects outside, it is obvious that the intended effect of the biocidal substance is not to protect the garbage bag, but humans, i.e. outside the treated article. The treated bags are therefore considered to be within the scope of the BPD." (MoD, English version dated 21 December 2011, p. 79).

Definition of a biocidal product

Any substance or mixture with one or more active substances that are intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a effect on any harmful organism by any means other than mere physical or mechanical action. A treated article that has a primary biocidal function shall be considered a biocidal product (see BPR 528/2012/EC, Art. 3 (1)(a)).

Manufacturers who use biocidal active substances to treat a product (for example, a silver compound in a cleaning cloth with designated antibacterial or odour-inhibiting effects) is obliged to observe the supplementary provisions on deadlines for authorisation applications and, where applicable, additional requirements as stipulated in laws on biocides. The approval of every active substance is reviewed in intervals; according to BPR Art. 4, the first review must occur ten years after approval has been granted for the first time and every fifteen years thereafter, in keeping with Art. 12. If the need arises (especially following evidence of significant safety hazards), an immediate review may be required. This process would include scrutiny of the specific uses permitted, conditions for use, and the designated efficacy of the biocidal treatment.

Stricter provisions apply to the use of especially hazardous substances as defined by BPR Art. 5 and Art.10; in principle, these substances are not to be allowed on the market or must be substituted. These so-called candidates for exclusion or substitution exhibit especially dangerous properties, that is, they are carcinogenic, mutagenic, reprotoxic, or hormone-disruptive, or have hazardous environmental properties. If use of candidates for exclusion is permitted in exceptional cases, for example because less hazardous alternatives are not available, all risks must be reduced during the use phase and use of the biocide is restricted with respect to the use area and period (that is, only within the country where use is considered to be imperative). In these cases, the intervals between authorisation reviews are reduced to five and seven years.

Comparable review intervals also apply to the authorisation of biocidal products that can be employed to treat goods. Examples are trademarked products such as Microban® or Sanitized®, which are offered with a variety of active substances and combinations of substances for treating a wide spectrum of materials (Box 4).

The European Chemical Agency in Helsinki (ECHA) and the EU Commission supply information online on the active substances and biocidal products that have been approved and authorised and further information, e.g. on their classification and properties (see Art. 67).

► **Regulations on importing treated articles:** For the first time, there are explicit and binding provisions in EU law that regulate all treated articles available on the internal market. Prior to the recent revision, it was especially problematic that there were to specific regulations that applied to goods imported from third countries when the biocide active substances used served to protect the material treated itself (internal effect). In these cases, the BPD did not apply, since these articles were not defined as biocidal products[5]. As a result, until recently, it was possible that consumers in the EU came into contact with articles for use in everyday life that had been treated with biocidal active substances that would no longer have been authorised for use or even been banned according to current EU norms. In future, manufacturers and suppliers from third countries must comply with EU law and treat their goods solely with active substances or biocidal products that are authorised for use in the EU, if they intend to place them on the EU internal market. To guarantee efficient import monitoring and transparency for consumers, requirements for labelling of treated articles have been introduced for the first time.

Box 4: **The BAuA Register lists:**

4 Microban® biocide products, including triclosan, silver, zinc pyrithione, quaternary ammonium compounds and 153 Sanitized® biocide products with silver, silicon-ammonium compound (silicon quat), zinc-pyrithione, permithrine, n-(trichlormethylthio) phthalimid / 2-(trichloromethylthio)isoindoline-1,3-dione (folpet), benzisothiazolinone (BIT). According to information supplied by Sanitized, triclosan is currently no longer in use: www.sanitized.com.

In Germany, biocidal products are listed, in keeping with the relevant regulation on registration, in a data base maintained by the Federal Institute for Occupational Safety and Health (BAuA): www.biozid-meldeverordnung.de/?lang=en (last accessed: 27 January 2013).

► **Labelling requirements for treated articles:** For the first time in the EU, under the provisions of Art. 58, treated articles must be clearly labelled by the distributor. This applies to goods for which either the distributor indicates the biocidal properties of the product (e.g., when an antibacterial effect is claimed) or when the specific conditions for use defined in the authorisation of the active substances stipulate that labelling is required (e.g. when human contact with the biocidal substance is possible or when the active substances are released into the environment). This requirement is therefore also applicable to goods that are protected from pests by an internal biocidal material treatment. (Box 5) summarises labelling requirements for these products.

Provided individual member states do not formulate other rules, the label must be supplied on the packaging, the warranty, or on the instructions for use, depending on the size and function of the specific article, and must be written in the language of the country in which the article will be placed on the market. If the article in question is made to meet an individual customer order, the manufacturer can reach an agreement with the consumer to provide the relevant information in an alternative form. If equivalent sector-specific requirements apply that are not described in the BPR, then these may have priority over the labelling requirements of the BPR. The Commission may implement further rules that clarify and specify labelling requirements as an implementing act.

► **Suppliers' obligation to inform:** Consumers' right to information has been enhanced with the new provisions on labelling and also with an obligation for retailers and suppliers to provide information. Art. 58 of the BPR requires any supplier who receives a consumer request for information on the biocidal treatment of a treated article to provide this data within 45 days and free of charge. This means that the obligation to provide information on hazardous industrial chemicals installed under REACH has now been extended to biocides.

► **Authorities' obligation to monitor and report:** Art. 65 stipulates that relevant authorities in the member states must monitor whether the requirements of the BPR have been complied with and report on the results of monitoring every five years to the Commission, beginning with 1 September 2015. The Commission will then publish the reports. The reports are to include results of official controls, information about risks to human health and the environment through use of biocides, and about measures taken to mitigate risks of poisonings (Art. 65). Information on the use of nanomaterials in biocidal products and their potential risks are also to be reported on, as are effects of biocides on vulnerable groups.

In Germany the federal states are responsible for monitoring marketing and labelling; the Bund/Länder-Arbeitsgemeinschaft Chemikaliensicherheit (BLAC) coordinates this work. In case of infringements, the EU member states are to provide for penalties (Art. 87) that are to be "effective, proportionate, and dissuasive".

Box 5: **Labelling requirements for treated articles in the EU** (according to BPR 528/2012/EC, Art. 58)

The label must include

- a statement that the treated article incorporates biocides,
- the name of all active substances or biocidal products used for the treatment of the article ,
- the name of all nanomaterials contained in the biocidal product(s), followed by the word "nano" in brackets (see box for definition),
- the biocidal property attributed to the treated article,
- any relevant instructions for use, including any precautions to be taken due to the biocidal products with which an article was treated or which it incorporates.

The label must be clearly visible, easily legible and appropriately durable; it must be written in the language of the member state in which the article is to be introduced.

These labelling requirements do not supersede the relevant instructions for use, including statement of safety measures to be taken, if necessary to protect humans, animals, or the environment.

Definition of nanomaterials
(BPR 528/2012/EC, Art. 3 (1)(z))

"Nanomaterial" means a natural or manufactured active substance or non-active substance containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.

* EU Regulation on chemicals 1907/2006/EC (REACH Regulation); REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals

► **Weighing the necessity for use of biocides:** Proper use of biocides is declared as ”limited to the minimum necessary” (see Art. 17, BPR), which includes avoidance of the biocides in favour of “rational application of a combination of physical, biological, chemical or other measures”. The question thus is raised whether and when there is a real need for and benefit from a biocide application, independent of whether the biocidal product was used directly or to treat articles.

The member states have been charged with providing the public with suitable information about the benefits and risks of biocidal products and about ways of minimizing their use. This obligation to provide information has been in place in Germany for more than ten years. One of the ways the relevant federal authorities have established to supply information is through an online biocide data base (see www.biozid-portal.de, www.biozid.info).

► **Demands for sustainable use of biocides in the EU:** Despite the revisions of biocides legislation, there are still no regulations in the EU for important aspects of the biocide use phase. One reason for this deficit is the lack of reliable data and information on the use of biocides, for example, to treat articles. The new BPR now requires the EU Commission to determine by 18 July 2015 whether additional harmonised measures must be implemented by the EU to ensure sustainable biocide use and, if so, to propose legislative instruments to be employed to this end (see Art. 18). The report should identify, for example, how best practices or technical innovations can be promoted as a means of minimizing the use of biocidal products or how risks can be reduced in schools, in kindergartens, or at the workplace. Questions about how the use of biocides can be effectively controlled, including handling and storage, are also to be addressed. This should involve collection and evaluation of market data and data on environmental and health risks.

► **Differentiating between biocidal products and treated articles:** According to the definition of what constitutes a biocidal product in the BPR, certain articles treated with biocides can themselves be biocidal products and thus require authorisation by the relevant authorities before they can be placed on the market (see Art. 3 (1) (a)). This important paragraph applies when the treated article has a ”primary biocidal function”. However, the precise meaning of this phrase is not formulated in the text. Unsurprisingly, various interests groups have interpreted this vague but very relevant legal term in very different ways. As a result, an important task for expert committees during the implementation phase will be the development of mandatory assessment concepts in order to ensure a greater degree of legal certainty for the relevant authorities, for manufacturers and suppliers as well as consumers and other stakeholders.

What does sustainability mean?

”Sustainable development means that environmental aspects are considered to be of the same significance as social and economic aspects. To manage the economy sustainably thus means: we must pass on to our children and grandchildren an intact ecological, social, and economic structure. We cannot have one without the other.”

(Rat für nachhaltige Entwicklung: www.nachhaltigkeitsrat.de/nachhaltigkeit/; accessed on 7 January 2013).

If an article treated with biocides is classified as a biocidal product, all provisions of the BPR for marketing and using such products within the EU internal market apply, including:

- Applying for authorisation: Depending on the area for which authorisation is desired and the product type, the application must be submitted to the national or EU authorities (Art. 17 & 42). A new Union authorisation process will be progressively introduced, depending on the product type, between 2013 and 2020. For products with antibacterial effects, applications for Union authorisation can be submitted to ECHA from 1 January 2017 if similar conditions of use across the Union are ensured. By 1 September 2013, the EU Commission is to define these conditions. Eligibility for the simplified authorisation is possible under very special conditions only, as specified in Art. 25 and 28. For example, no substances of concern may be included and use of the product does not require personal protective equipment.
- Time limits for the authorisation: Authorisation is granted for a maximum period of ten years at which time a new application must be submitted (Art. 17). For products containing active substances that are candidates for substitution, authorisation shall not exceed five years and can only be renewed once for a period that shall not exceed five years (Art. 23).
- Assessment criteria: During the authorisation procedure, the product is examined to determine possible environmental and health risks and whether it is sufficiently effective. Also considered are the risks of biocide mixtures and for vulnerable groups of people such as children. Special assessments are to be undertaken for products with nanomaterials (Art. 19).
- If the products contain active substances that are candidates for substitution, these can only be authorised if no other biocidal substance or non-chemical method exists that presents a significantly lower risk (Art. 23).
- All biocidal products for which an authorisation application has been submitted or denied or which have been authorised in the EU are listed in a register that is to be established by ECHA by 1 September 2013 at the latest (Art. 71).
- Advertising for these products may not be misleading or trivialise its properties. It must also include a clearly distinguishable warning: ”Use biocides safely. Always read the label and product information before use” (Art. 72).
- Limits pertaining to sales: Products with especially problematic properties cannot be authorised for being placed on the market for use by the general public (Art. 19).
- Provisions on classification, labelling, and packaging, which prescribe, besides the requirements of the CLP Regulation1272/2008/EC, further biocide-specific information (Art. 69 of the BPR). Products which may be mistaken for food are to be packaged so that they are unattractive for children. The label must also show information on categories of users and authorised uses, the names of the active substances or nanomaterials, and the shelf life. The instructions for use, first aid measures or special environmental risks must also be included, but can also be documented in the patient information leaflet.

The market for biocide-treated articles

Following a review of the websites of the Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) as the German competent authority[6], the web pages of Directorate-General for the Environment of the EU Commission[7], the data bases Eurostat[8] and Destatis[9], the website of Germany's Chemical Industry Association (Verband der Chemischen Industrie, VCI)[10] and of the German Retail Federation (Handelsverband, HDE)[11], and, finally, the biocide portal of the German competent authority[12] a significant deficit in information on biocide-treated articles was revealed. There are no publicly available compilations of data on sales or consumption, much less statistics that differentiate according to various types of use.

As a result, the situation for treated articles is similar to that for biocide products with respect to the lack of transparency. To date, reliable statistics on the amounts of biocidal active substances and biocidal products that enter the EU market each year and for what purpose can be found neither on the relevant websites of the competent authorities, nor in annual reports published by manufacturers, processors, or suppliers. Existing estimates for the EU are very incomprehensive and outdated. According to the COWI report conducted for the EU Commission in 2009, the estimated annual total volume of sales of biocidal active ingredients(production and imports) in the EU was about 400,000 tonnes; the majority of these biocides were disinfectants[13].

On the basis of a study on biocide-treated products also carried out for the EU Commission, one can infer that more than 48,000 tonnes of biocide active substances are used annually in the EU for internal material protection alone*[14]. The quantity of silver used annually for the antibacterial treatment of textiles is estimated to be between 400 and 500 kg; altogether, about 8,000 kg of silver are used for biocidal purposes (estimate for 2007) according to another study commissioned by the German Federal Environment Agency[15]. More recent information on the use of nanosilver in Germany is not available, at least from the sources consulted here. When the new BPR enters into force, however, nanoscale particles must, for the first time, be declared separately on the products, ensuring greater transparency for authorities and consumers. Information compiled in the Netherlands shows that the number of consumer products with nanomaterials has increased considerably in recent years (from 47 products in 2006 to 235 products in 2008)[16].

* Our calculations on the basis of data in the study Milieu & DTC(2006): p. 7ff.

Among the reasons for the lack of transparency is the fact that the biocides market is highly fragmented, due to the many different use forms*. Moreover, manufacturers generally treat sales and consumption data for individual products as confidential**. In the course of applying for authorisation, however, applicants must supply information on the predicted amount of the biocide active substance that will be brought on the market (see Annex II A of the current BPR), but this data is not published.

Paragraph 3 of the German Biocide Registration Regulation stipulates that biocidal products and their active substances are to be registered with the national competent authority and added to an electronic data base with a registry number. This data base is to be made accessible to the public via a search interface, which supplies information to the general public on registered biocidal products and the substances they contain.[17]

If manufacturers publish data at all, it is generally heavily aggregated and summarizes information on various product groups; also, the data supplied is usually for the retail value, rather than the quantities of the products. According to information from the German VCI, the production value of the plant protection and household pesticides and disinfectants produced in Germany in 2011 totalled 2.8 billion Euro and has thus again increased in comparison to the previously year[18]. How high the portion of products used for material protection or for the antibacterial or insecticidal treatment of articles is cannot be determined from this data. According to another source, group PT 1 – 5, especially disinfectants, plays an outstanding role among all biocidal product groups (most of the biocidal products registered in Germany belong to this group)[19].

A recent report complied by the German federal government that the total number of registered biocidal products in Germany amounts to 35,000.[20] To date, there is no legal basis for the necessary differentiation and supplementation of this data, for example, a list of all biocidal products marketed in Germany for antibacterial treatment and a list of all antibacterially treated articles and their amounts. In the course of their consultations on nanotechnology in the last legislative period, the majority of representatives in the German federal parliament called on the federal government to at least consider establishing an obligatory registry for all products that contain nanoparticles[21]. This would apply to some, albeit the smaller part, of the antibacterially-treated articles.

Whereas manufacturers of pesticides (substances used to combat plant pests) are required by law to report their annual production volume to the authorities, this is not the case for biocides. However, the new Pesticide Statistics Regulation offers options for generating data on biocides. When this regulation was passed in 2009, biocides were not included. As soon as the revision of the biocide legislation has been completed, the Pesticide Statistics Regulation, as a further legislative instrument, should be applied to biocides***.

* According to Lanxess (2007), the ten largest manufacturers in the material protection sector, for example, generate 30% of the worldwide sales volume (see www.corporate.lanxess.com/uploads/tx_lxsmatrix/2007-1518.pdf; p.3).

** Gaps in data, for example, with respect to biocide consumption, are justified according to a study commissioned by UBA to evaluate cumulative effects (2011) with the purported confidential nature of the data. (see www.umweltdaten.de/publikationen/fpdf-l/4231.pdf, p. 45).

*** See Regulation No. 1185/2009/EC of the European Parliament and the Council from 25 November 2009 on statistics about pesticides.

Market check for biocide-treated articles used in daily life

Goal ► PAN Germany has conducted a survey of e-commerce which presents an overview of the spectrum of goods offered, their designated application, and the biocide active substances they contain. A further question addressed was whether and to what extent the suppliers provided, upon request, information about the biocidal active substances used and about the biocidal function of the articles sold. The survey is not intended to be representative; instead, it shows how diverse the biocide-treated articles currently on sale are; these can be used in normal households for various functions in daily life. A more detailed table with the results can be provided for interested readers on request.

Methods ► The product survey was conducted and written requests for information were sent to suppliers by e-mail between March and October 2012.

First phase: Searches were conducted using the terms ”antibacterial“, „antimicrobial“, and ”anti-odour“. In addition, the names of articles used in daily life, such as towel, kitchen knifes, or blanket, were entered into the search engines in connection with these three terms. Searched with these terms were also carried out on the websites of several large German online retail companies, including Otto, Neckermann, and Amazon.

Second phase: A list of suppliers for biocide products, for example Microban®, was compiled and information about products collected via searches with the biocide brand name. A total of 100 different articles with designated biocidal function were selected.

Third phase: The product descriptions on the websites were evaluated. The search for information was extended, if needed and feasible, to include the websites of the manufacturers and the BAuA data base for registered biocidal products*.

Fourth phase: In those cases in which the biocidal active substances could not be ascertained through these sources, and/or the exact intention of the biocidal function was unclear (internal or external protective function), the suppliers were asked to provide information per e-mail. If no response was forthcoming, a reminder was sent two to three months after the first e-mail.

Results ► The table shows the 100 products selected for this survey, relevant extracts from the product descriptions from the suppliers' websites, the relevant biocide active substances, and the suppliers' readiness to provide information. The articles are divided according to the household sphere in which they are used.

* List of registered biocidal products at: www.baua.de/de/Chemikaliengesetz-Biozidverfahren/Biozide/Produkt/Meldeverordnung.html

Table: **Online survey on consumer articles with designated biocidal function**

* Transparency: (+) biocide active substances are labelled in the product description; (-) biocide active substances are not labelled in the product description and no reaction or no information on the biocide active substances by the supplier following written request; (u.r.) ”upon request”: no statement about the biocide active substances in der product description, but information provided by the manufacturerer or supplier following written request.

	Product	Product description (extract)	Active substance/s	Transparency*
Bathroom				
1	shower curtain	antibacterial; avoids mould stains and fungus	silver additives	u.r.
2	toilet brush	antibacterial brush	silver ions	+
3	toilet seat	antibacterial coating	?	–
4	shower hose	hygiene; removes biofilm in hoses	silver	+
5	toiletries bag	antibacterial inner lining	?	–

6	bathrobe	antibacterial	?	–
7	bath towel	antibacterial	?	–
8	epilator/shaver/trimmer	hygiene, antibacterial	silver ions	+
9	floor cleaning cloth	hygiene, odour-inhibited	silver	+
10	bathroom cleaning cloth	antibacterial; kills bacteria and fungus; pure nature	silver ions	+
11	washing ball	blocks energy production and reproduction in protozoa; prevents unpleasant odours from developing while textiles are worn	silver ions	+
12	washing machine	germ-free laundering and long-lasting protection against bacteria	silver	+
13	grout whitener	prevents mildew growth	BIT, MIT, Bronopol[1)]	–
Living area				
14	carpeting	antibacterial hygiene treatment; permanently hygienic	? (Microban®)[2)]	–
15	carpeting	combats bacteria and dust mites by natural means; for better health	silver ions (BalsanSilverCare®)	+
16	carpet tiles	antimicrobial treatment	? (Intersept®)	–
17	wool carpet	International wool Seal (Author note: requirement for the seal is moth-proofing, usually with the insecticide permethrine)	?	–
18	laminate flooring	Cleancare system	? (Microban®)	–
19	hoover	antibacterial hygiene protection; essential contribution for a healthier home	? (Microban®)	–
20	air dehumidifier bag	antibacterial (Author note: The product description was modified by the supplier after PAN requested information, since it was uncertain whether the product had antibacterial properties)	"Does not contain biocides"	u.r.
21	light switch	antibacterial; deprives pathogens of nutrients and inhibits reproduction of bacteria and funguses; prevents the reproduction and mutations of pathogen cells (author note: suppliers notes in particular product use in hospitals, nursing homes, etc.)	silver ions	+
22	radiators	antimicrobial, durable coating; significantly reduces the risk of infection	silver additive	+
23	wallpaper	antibacterially treated; offers protection from bacteria in the household and prevents the growth of mould and funguses on surfaces	silver ions	+
24	wallpaint	highly resistant against infection by germs and bacteria, does not pollute the air	nano silver (BioniHygienic®)	+
Bedroom				
25	blanket	antibacterial; destroys the cell membrane, deactivates metabolism, and inhibits cell division. Permanently prevents the reproduction of all kinds of bacteria; reduces perspiration odour	silver	+
26	pillow	prevents bacteria growth, i.e., bacteria don't find nutrients and are starved; the active substance is a completely natural product	"acetate manufactured from cellulose"[3)] (Microfresh®)	u.r.
27	duvet	constant hygienic function offers lasting protection from bacteria, odours, and dust mites	? (Sanitized®)	–
28	waterbed mattress cover	antibacterial effect, suitable for allergy suffers, antistatic effect, protection from electromagnetic waves; certified Oeko-Tex 100	silver (µ-Func®)	+
Wardrobe				
29	underclothes	antibacterial and neutralises odours	silver Ions (Silverfresh®)	+
30	women's socks	antibacterial; reduces unpleasant odours; ensures hygiene and freshness	silver ions	+
31	compression ho-siery for pregnant women	antibacterial treatment	? (Sanitized®)	–
32	pregnancy panties	significantly reduces odours	silver (Sensil® Bodyfresh)	+
33	vest	antibacterial, inhibits bacteria growth which causes body odour; the antibacterial properties last for at least thirty laundering cycles	silver chloride (Sensil® Bodyfresh) („AlphaSan®")	u.r.
34	anti-cellulite shirt	a kind of antibacterial effect – product does not take up the body's perspiration particles and therefore has an odour-neutralising effect	nanosilber	+
35	shirt for sports	antimicrobial	silver	+
36	cycling shorts	antibacterial	silver ions	u.r.
37	sweat band	antimicrobial; prevents intensive odours	?	–
38	socks	antibacterial (permanently prevents unpleasant foot odour) and is antimycotic (combats funguses funguses)	?	–
39	shoe insoles	anti-odour	?	–

40	sandals	antibacterially treated insole	dimethyloctadecyl[3-(trimeth-oxysilyl)propyl] ammoniumchloride	u.r.
41	flip-flops	combats the risk of athlete's foot	zinc pyrithione ("Sanitized MB LPE 23-70")	u.r.
42	gloves	prevents odours and reduces perspiration	silver	+
Kitchen				
43	food storage containers	antibacterial	?	–
44	rubbish bags	antibacterial; due to an antibacterial ingredient, prevents the growth of bacteria on the bag; rubbish disposal becomes more hygienic	triclosan	u.r.
45	cutting boards	antibacterial surface	"not a biocide, antibacterial thanks to a smooth surface made of wood fibre"	u.r.
46	grater	antibacterial protection; growth of bacteria and germs are greatly inhibited	? (Microstar®)	–
47	kitchen knife	hygienic protection	? (Microban®)	–
48	breakfast board	Microban	? (Microban®)	–
49	washing-up brush	antibacterial	?	–
50	saucepan	antibacterial surface; especially suitable for allergy suffers	silver ions	u.r.
51	washing-up sponge	antibacterial	?	–
52	oven glove	antibacterial; prevents the growth of bacteria	"not a biocide, antibacterial thanks to Flexapren"	u.r.
53	kitchen sink	better hygiene; growth of bacteria and microbes reduces by 99%	silver Ions (Sanitized®)	+
54	dishwasher	antibacterial door seal	"Zn-based active ingredient"	u.r.
55	refrigerator	effectively prevents the growth and spread of bacteria; the antibacterial effect persists throughout the lifetime of the refrigerator	silver ions	+
56	refrigerator air filter	antimicrobial; removes odours and bacteria	? (Microban®)	–
Nursery- / Children's bedroom				
57	nursing bra pads antibacterial	antibacterial	„confidential company data"	u.r.
58	nursing top	antibacterial (author note: following the PAN request for information, the antibacterial claim was removed from the website)	?	–
59	baby mattress	naturally antibacterial; suited for allergy sufferers; 3% silver stitched into the product; certified Oeko-Tex 100	silver	+
60	synthetic bed	permanently antimicrobial; prevents odours; recommended for allergy sufferers; certified Oeko-Tex 100	silver ions	+
61	baby booties	antibacterial; 100% natural	?	–
62	nappy bag	antibacterial changing pad; antibacterial wet compartment	?	–
63	bag for baby dummy	treatment prevents the development and growth of bacteria	? "tested and shown to be free of pesticides"	u.r.
64	nappy bin	antibacterially coated packaging foil for nappies	silver ions	u.r.
65	baby teething ring	made of medicinal thermoplastic; non-toxic, an-tibacterial	?	–
66	baby teething ring (2)	antibacterial polypropylene	?	–
67	baby sleeping bag	antibacterial fleece	? "treated with Sanitized®"[4]	u.r.
68	baby rattle	antibacterial, especially suited for children and babies	silver	+
69	baby drinking cup	antibacterial effect, especially suited for small children	silver	+
70	baby bottle brush	antibacterial brushes	silver ions, („Ciba® Irgaguard® Antimicrobials")	u.r.
71	pushchair seat cover	antibacterially treated cover guarantees optimal absorption of perspiration	bamboo fibres	u.r.
72	school scissors	permanent antibacterial protection	silver additive (Microban®)	u.r.
73	children's trainers	antimicrobial protection	?	–

74	children's drinking cup	antibacterial lid and valve cap	silver (SteriTouch®)	u.r.
75	children's sandals	antibacterially treated insole	?	–
76	pushchair	antibacterial seat padding	?	–
77	play carpet	combats harmful and odour-producing bacteria	? (Microban®)	–
78	school backpacks	antibacterial	? „active substance can no longer be traced"	u.r.
Office supplies / electrical goods				
79	notebook	antibacterial	nano silver	+
80	school calculator	antibacterial keypad	?	–
81	stamp	enhanced hygiene; the silver components protect you invisibly and for a long time	silver (Microban®)	+
82	mousepad with hand rest	additional protection from bacteria	triclosan (Microban®)	u.r.
83	Mousepad	antibacterial construction	triclosan	+
84	Fingeranfeuchter	antibacterial	?	–
85	biro	long-lasting effectiveness against bacteria, viruses, and funguses; kills 99,9% of bacteria within 24 hours	zink pyrithione	u.r.
86	foot rest	antimicrobial product protection to reduce grime and odours that lead can to uncontrolled bacteria growth on the foot rest	triclosan (Microban®)	u.r.
87	waste-paper basket	antimicrobial protection for the entire life of the product	silver (Microban®)	u.r.
88	desk chair	antibacterial, antimycotic, antimicrobial	?	–
89	nano sealing set (cloths)	antibacterial cleaning of devices; cleaning cycle becomes significantly longer; bacteria, germs, and viruses can no longer attach themselves to surfaces (confirmed by expertise); physiologically non-hazardous	ethanol, triclosan	+
90	iPod cover	antibacterial coating	?	–
91	headphones	made from antibacterially treated material	?	–
Pet supplies				
92	cleaning cloth for dogs	antibacterial, antifungicidal	? "Byotrol"[5)]	–
93	feeding bowl	antibacterial	?	–
94	dog sofa bed	antibacterial stuffing; certified Oeko-Tex 100	?	–
95	dog lead	for hygiene and freshness in every situation; fights odours caused by bacteria	silver Ions (Silverplus®)	+
96	cat litter tray mat	antibacterial; prevents the spread of bacteria and funguses	silver	+
97	cat litter	antibacterial effect prevents odours	"contains no biocides"	u.r.
Other articles				
98	exercise mat	Sanitized®	? (Sanitized®)	–
99	contact lens case	removes bacteria; disinfects	silver ions	+
100	glasses cleaning cloth	removes up to 99,97% of all bacteria, yeast, and funguses	silver	+

1) The declaration does not clearly state whether a preservative is responsible for the designated fungicidal function and if so, which of the substances named (BIT= benzisothiazolinone, MIT = methylisothiazolinone).
2) Microban® is a trade name which refers to a large number of biocidal products containing different active subtances.
3) According to the BAuA register, the three Microfresh products registered there all contain exclusively the active substance triclosan (as of 27 January 2013).
4) Sanatized® is a trade name which refers to a large number of biocidal products containing different active subtances.
5) Byotrol is a product name, not the name of an active substance; according to BAuA data, five Byotrol products with different mixtures of active substances are registered under this trade name (as of 27 January 2013).

In the product descriptions about one-third (34) of the articles selected, the biocidal active substance is named on the supplier's website or can be determined via a simple search. The active substances used or named most frequently are silver and silver ions. In the product descriptions, silver is often described as a non-chemical, natural substance that is especially suited for products for babies, children, and allergy sufferers. The positive image of silver compounds is further supported by reference to certification with the Oeko-Tex 100 seal and used to advertise the products' purported environmentally-sustainable features.

For 23 of the selected articles, suppliers provided information about which biocidal active substance was present or reported that the article had not been biocidally treated in response to our written request. In two cases, i.e. the product descriptions of the air dehumidifier bag and the nursing top, claims that the products were antibacterial were removed from the texts found online after PAN requested information on the biocidal active substance. The majority of suppliers (43) did not reply to the PAN Germany's written requests for information.

It was striking that in the product descriptions and in the replies from suppliers, trade names and biocidal active substances were frequently used synonymously. The relatively widely used trade names Microban® and Sanitized® are used to market a variety of biocidal products with different mixtures of active substances. Only a single supplier (Table no. 41) was able to report on the exact specifications of the Sanitized product used by the manufacturer in response to our request. With this information, we could then determine the active substance contained in the product through the BAuA data base for registered biocidal products. No product data is available in the BAuA data base for other trade names such as µ-Func® or SteriTouch®. One reason for this might be the fact that to date imported products from non-EU countries were not covered by the data base.

Another interesting observation is that the product descriptions frequently do not clearly state whether people are to be protected from microorganisms or the material itself, even though the texts, by using the word "antibacterial", suggest that the product ensures a hygienic or health benefit for the consumer. But this use or benefit is not always applicable. For example, the manufacturer of the rubbish bag advertised as being antibacterial emphasizes that treatment with the active substance triclosan is intended solely to protect the bag from bacterial growth and thus constitutes preservation of the bag itself. Only two suppliers responded to our question about whether the biocidal function of the products were internal or external.

In 2012, the Swedish Chemical Agency KEMI conducted a similar survey to compile information on biocide-treated articles for everyday use offered to Swedish consumers online[22]. Suppliers of biocide products with trade names like Microban® or Sanitized® supply information on the spectrum of possible uses online and refer to partner companies that treat their brand name products with trademarked biocidal technologies. Via this kind of information online, the Swedish authorities were able to

Example **triclosan**

Triclosan is used as a disinfectant and preservative in textiles and plastics as well as in hygiene articles. The BAuA has compiled 204 biocide products with triclosan in its register, including products from Microban®, the market leader for biocidal treatments for plastic products. As in the case of silver, the assessment of triclosan in the context of the authorisation process for specific types of products is still underway.

The widespread utilisation of triclosan has already led to significant contamination; for example, it has been found in human breast milk.[31] The biocide has also been detected very frequently in bodies of water and in aquatic organisms (for example, in the Elbe river basin, at 75% of all monitoring points). The researchers who studied the Elbe basin concluded on the basis of these findings that triclosan assumes sixth place among the five hundred substances that are to be treated as priority substances.[32] According to the EU classification, triclosan can irritate the skin and eyes and is an environmental hazard, since it has long-term damaging effects on aquatic organisms.[33] The Austrian Environmental Agency characterizes high doses of triclosan as responsible for long-term liver damage; it also curbs the activity of the central nervous system.[34] An allergenic potential has been attributed to triclosan. Laboratory tests have indicated that triclosan has negative effects on the

identify a large variety of biocide-treated articles for everyday use from the areas of textiles and bedding, construction products, kitchen utensils, bath utensils, cleaning utensils, office supplies, and toys and other articles for babies and children.

In both surveys, significant deficits in suppliers' knowledge about the active substances used in the products by both suppliers and manufacturers were revealed. This is important information that does not reach consumers. Moreover, there is reason for concern due to indications that many suppliers are, so far, inadequately prepared to act in accordance with governmental regulations that will be in place shortly, especially with respect to their obligation to comply with labelling and information requirements in marketing biocide-treated goods.

Disadvantages of biocide treated articles

The use of products treated with biocides in private households is appropriate and useful in a very limited number of cases only. It is therefore the responsibility of manufacturers and commercial suppliers and retailers to become conscious of the uses as well as the possible disadvantages of biocidal treatment for their products. It may be that there are disadvantages that are incompatible with their own company philosophy, for example, when the company attaches great importance to sustainability and protecting the environment. Frequently, the purported specific advantage of a biocide treatment is questionable. This is especially the case for consumer products with designated additional antibacterial or odour-preventing properties. In view of the possible hazards of biocides for human health and the environment and in keeping with European regulations, the use of biocides should be limited to the necessary minimum. The authorities are expected to make information available that promotes reduction of their use. But these political goals are incompatible with the spectrum of biocide-treated consumer products for everyday life currently available. Most of these articles are also on sale without a biocide function as products that are supposed to be washed or cleaned regularly. Experience shows that these classic cleaning and hygiene measures are sufficient to protect consumers from odours and dangerous pathogens. In general, the risk of infection by other means, such as via direct body contact, through airborne transmission of droplets, direct contact with blood, or via food is much higher than by way of contact with plastic articles, wallpaper, radiators, or textiles.

To date, the effectiveness of the specific biocide treatment of an article is not assessed by an independent authority and even in future, this assessment will generally be conducted only for selected sample cases. Moreover, effectiveness of the treatment can diminish during the article's use-life. The Swedish Chemical Agency KEMI studied, for example, how quickly the biocides silver, triclosan, and trichlorcarbane were washed out of textiles. They determined a loss of more than 50% and up to 100% after ten washing cycles.[23] These substances, which are highly hazardous for aquatic organisms, enter the environment via wastewater treatment plants and can also lead to a rise in bacterial resistence (see text on silver and triclosan).

The advertised hygienic functions can also induce consumers to neglect normal household hygiene routines, which in turn may lead to health risks. As a result, some products labels have absurd warnings stating that the antibacterial treatment is not a substitute for normal cleaning. These labels neglect to note that consumers can indeed do without antibacterial treatments if normal cleaning practices are adhered.

muscle activity of the heart and the skeletal muscles.[35] Triclosan can be degraded in wastewater to methyltriclosan, which persists in the environment and accumulates in organisms (bioaccumulation).[36] There is considerable evidence that under the influence of chlorine, triclosan is degrade to become carcinogenic or hormone-disruptive substances (chloroform or 2,4 dichlorophenol).[37]

The BfR has pointed out that triclosan, which has bacteriostatic effects, is frequently present in consumer products with antibacterial properties in doses that are too low to kill all pathogens.[38] With widespread use, the danger therefore increases that these pathogens will become resistant (for example, through activation of the mechanisms that export toxins from the cells).[39] Laboratory studies have shown that relevant pathogens such as Salmonella enterica, Eschericha coli, Pseudomonas aerogiosa, and Staphylococcus aureus develop resistance against triclosan. There are also signs of cross-resistance; that is, the pathogens can also become resistant to important antibiotics such as tetra-cyclines, or to quinolones. The Scientific Committee on Consumer Safety of the EU Commission (SCCS) has been unable to date to supply reliable proof of risks for human health due to the increase in resistance from triclosan, but it emphasizes the need for further research by industry.[40] The BfR warns that for precautionaly reasons and because of existing alternatives, triclosan should not be used except where there is a medical need.[41]

Example **silver**

Our online investigation shows that silver and silver ions (for example, silver chloride, silver nitrate, silver zinc zeolite) are used relatively frequently for antibacterial treatments. According to the BAuA registry, 1093 biocidal products that contain silver are registered in Germany.

Despite the widespread use of silver compounds as biocides, the risks for human health and environment have not yet been carefully assessed. Although the new BPR requires assessment procedures that take the special risks of nanoscaline forms into account, a concept for examining and evaluating them still has to be developed.[24] Increasingly, there are indications that the unlimited use of silver is problematic.

Silver is highly cytotoxic; it binds to vital proteins and blocks them. Silver ions can act like a broadband antibiotic. Skin contact, which occurs when textiles are worn, can cause permanent skin damage. An especially significant problem is the fact that the widespread use of silver and nanosilver in consumer products can promote the development of resistance to silver in bacteria. Recognized environmental problems are the accumulation of silver on fish gills, causing asphxiation and disruption of bacteria activity during sewage treatment. Sewage sludge that contains silver is useless as fertilizer, since silver cannot be degraded.[25] According to a study funded by the UBA, there is a lack of knowledge about key issues, such as the amounts in used, the release of silver compounds into the environment, and their behaviour in the environment. Moreover, researchers have recognized that there is evidence of unacceptable risks for soil and sediments.[26] The BfR has stated that, because of nanosilver's special physico-chemical properties, it has additional toxic effects in comparison to silver.[27] As long as the health risks cannot be reliably assessed, the BfR advises against using nanosilver.[28] The BfR has also repeatedly emphasized that silver compounds used in antimicrobially treated consumer products have no advantages for consumers. Their recommendation is to instead improve classic hygiene behaviour as a means of avoiding infectious diseases.[29]

Recommendations for stakeholders

Numerous efforts by various stakeholders will be necessary in order to successfully implement the new legal provisions, to minimize the risks of products that contain biocides for consumers and the environment, and to achieve sustainable consumption by promoting articles that are biocide-free or have a low biocide content.

Recommendations for policy makers

In implementing biocide law in the years ahead, a number of specific provisions in amending laws (as delegated acts or implementing acts) and guidelines must be put in place. Some of these will affect directly or indirectly biocide-treated articles, for example defining the term primary biocidal function, details on labelling treated articles, or the implementation of monitoring and reporting.

Despite the fact that legislative competence has been transferred to a large extent to the EU level, decision-making options still remain on the national level, especially with respect to implementing measures on use and monitoring or decisions on exemptions (e.g. in labelling). In Germany, the parliament, together with the federal government and the federal council should work to ensure that the requirements on the EU level for the authorisation process and also for registration procedures for treated articles are designed to meet high standards.

In November 2012, the German federal government presented draft legislation in order to create the necessary conditions for implementing the BPR in Germany, especially with respect to responsibilities in the relevant competent authorities[42]. PAN Germany pointed out in its position paper that binding framework conditions for the extent and the quality of controlling, monitoring, and reporting should be set in the implementing legislation and formulated the relevant suggestions for changes in the draft[43].

The Environmental Directorate General of the EU Commission presented a suggestion for guidelines for regulating biocide-treated articles in December 2012. The aim was to prepare, in the relevant expert committee, a common position with the competent authorities in the member states on important terms, responsibilities, and procedures such as labelling.[44]

► **Clarifying the term ”primary biocidal function”:** In the context of implementing the new BPR, the definition of what a product with a so-called ”primary biocidal function” is must be spelled out in a legally binding definition. The regulation text introduced this term but lacks a definition. Only if a treated article has a „primary biocidal function“ is it considered to be a biocidal product and it becomes subject to the new authorisation requirement. Whether a primary biocidal function is given is rather easy to decide for certain articles, since they either do not have a biocidal function or have only one such specific function. The EU draft refers to one example: furniture that is made of biocide-treated wood but does not have a biocide function itself (but which does have the biocidal property of being protected for a longer period against insect damage). Other examples are articles such as insecticide-treated mosquito nets or toilet-cleaning cloths with disinfectants, which obviously have the main function of being vehicles for a biocide and therefore are themselves a biocidal product.

But what about articles that have more than one function for users, such as biocide-treated textiles or plastic articles for the kitchen or bath? The EU Commission has suggested an interpretation for these cases that considers the term ”primary” to be significant, in the sense of a specific priority in comparison to other functions of the article. In this sense, a ”primary biocidal function” is given

- when the biocidal function, in comparison to other properties or functions of the article, is especially designated or emphasized, or
- when a health-related claim is made, so that consumers can assume that the use of the biocide-treated article protects or promotes protection from pests or pathogens that are relevant to human health. In these cases, the EU Commission holds, assessment of sufficient effectiveness must be guaranteed. Since this does not apply otherwise to biocide-treated products, but is instead only binding for biocidal products, these articles must be considered to be biocidal products. Examples of such general, health-related statements are ”combats bacteria”, ”kills/inhibits 99% of bacteria, ”antibacterial”, or ”controls fungus growth”. A statement such as ”contains a protective substance against bacterial degradation”, in contrast, would constitute the description of a biocidal porperty and not of a biocidal function;
- when other criteria apply; these still have to be defined. With respect, for example, to the concentration of the active substance in the product, its mode of action, or the designated properties, especially when they are identical with an existing biocidal product or are related to a pest to be effected, especially if the pest in question does not damage the product itself.

CIRFS, the European Man-Made Fibres Association, has formulated a position that clearly rejects this proposal. According to the CIRFS, all textiles have the primary function of covering and warming the body, so that a biocidal function is always a secondary function. This means that biocide-treated textiles or fibres are not biocidal products.[45] This definition of the term ”primary” would mean that for every biocide-treated article a non-biocidal function could be defined as primary. Even hygiene cleaning cloths could be declared by the manufacturers as having, as their primary function, cleaning, rather than the antibacterial function of the cloth.

If this interpretation of industry were to be adhered to, then there is a danger that lawmakers' intention of installing an authorisation procedure that included assessment of effectiveness and risks for certain biocide-treated products would be undermined. So the more broad interpretation of the EU Commission is a step in the right direction. However, it is important that the Commission's suggestion is supplemented by further criteria. The experts from the competent authorities have, to date, agreed within the context of the Manual of Decisions that at least those products are to be considered to be biocidal products that have an external biocide effect (for example, antibacterially-treated toilet seat covers, rubbish bags, or tissues).[46] So the assessment criteria that are dependent on concentration and exposition should be included in the scheme for future decisions as "or" option, as was the case in the experts' decisions to date. If, instead, the manufacturers themselves are allowed to decide based on their product designation, when an article is considered to be a biocidal product and when it is not, then there is reason for concern that the protective standards will be significantly weakened in comparison to the previous legislative period. This is because we can expect manufacturers to modify the product designations without actually changing the products, in order to avoid a complex and costly authorisation assessment, even though this would mean further exposure of people and the environment to biocidal substances.

► **Labelling of biocide-treated articles:** Consumers must be able to see with one look at the label whether and with which substance an article has been treated and what the purpose of the treatment is. Where applicable, safety and hazard information must be included, besides the name of the active substance. Nanoscaline treatments must be specifically mentioned.

► **Improved controls:** Monitoring structures and concepts, which are the responsibility of the German federal states, must be improved, in order to ensure that requirements for labelling, marketing, and product advertisements are effectively implemented. The competent authorities of the federal states should act according to a harmonised national standards and publish an annual common report on the results of monitoring (similar to the plant protection control programme*).

► **Collect data on the market and on use:** For improved assessment of possible exposure of the population and the environment to biocidal substances, and in order to develop sustainable use, that is, use that ensures reduced quantities and risks, detailed market data is needed. To this end, a registration obligation for placing biocide-treated products on the market and publication of annual statistics must be introduced.

► **Inform the public and raise awareness of the issues:** Activities to inform consumers about alternatives and about the risks of using biocide-treated consumer products must be intensified. The resources needed to do so must be made available. Retailers, suppliers, and manufacturers must also receive targeted information about the new legal rules and requirements. The UBA has already made such information available at their information portal: www.biozid.info.

► E**stablishment of a sustainability concept:** As is already the case for pesticides, an EU harmonized framework for the sustainable use of biocides should be installed through an EU directive. Reporting on the use and environmental and health monitoring should occur annually and be conceived of as supplements to the planned EU reports on nanobiocides and to measures aimed at ensuring sustainable use of biocides.

* Plant Protection Control Programme: www.bvl.bund.de/DE/04_Pflanzenschutzmittel/01_Aufgaben/06_Pflanzenschutzkontrollprogramm/psm_Pflanzenschutzkontrollprogramm_node.html

► **Promoting research:** The risks involved in using and disposing of biocide-treated articles, for example with respect to their potential for promoting the development of resistance to the respective biocidal substances, their allergy potential, or their adverse environmental effects, must be studied in further research financed by industry.

► **Establishment of strict criteria für authorisation:** In the case of disinfectants, among other things the risks of combination effects, special risks for vulnerable groups such as children (for example, allergies), resistance, the special risks of nanoscale substance and technologies, and environmental effects must be taken into account. It is also essential that, when the first application for approval of an active substance is submitted, the applicant be required to state all planned uses of the biocide-treatment of articles. Since not all possible uses are assessed, it is important that the assessment of a biocidal product for selected cases is chosen in the course of the approval in such a way that use types with realistic worst case risk scenarios can be taken into consideration.

Recommendations for producers of biocide-treated articles

► **Ensure implementation of all requirements on schedule:** Manufacturers and importers of treated articles are called on to inform themselves about and implement the relevant measures on product labelling, product designation, supplying information for trade and consumers (for example via a free telephone hotline) and, if necessary, to change the biocide treatment of their goods. Information on the specific procedures and deadlines can be received on request from the German authorisation authority BAuA and from suppliers and manufacturers of the biocidal products used.

► **Evaluation of the advantages of biocide treatment:** Critical scrutiny of whether a relevant advantage results, in terms of quality and shelf life of a product or protecting consumer health, can be achieved by biocide treatment or whether biocide treatment can be avoided, if it proves to be unnecessary, ineffective, or even linked to risks. For example, it is highly questionable whether plastic articles that persist in the environment for about four hundred years before they are degraded need an additional protection from bacterial degradation. As is the case for retailers and suppliers, industry, following the lead of especially environmentally conscious companies and industry associations, should strive to raise awareness about the fact that biocide treatment of an article is not necessarily a sign of quality but may frequently be viewed as negative.

► **Enhancing transparency:** Manufacturers and importers should actively support greater transparency and the establishment of a registry for biocide-treated articles; in Germany, this should be under the auspices of the competent federal authority, the BAuA. This will also lead to improved opportunities for controlling goods imported from third countries.

Recommendations for retail business / e-commerce

► **Improve advice for consumer:** The retail trade should ensure it is comprehensively prepared to meet the new requirements it faces in informing customers. Companies should acquire written information or safety data sheets from suppliers and manufacturers. Labelling of the products offered to meet the new legal requirements must be in place by 1 September 2013. On the level of retail associations or trade chains, sales personal should be regularly offered training about risks, precautions, and alternatives to biocides and biocide-treated articles, about labelling, and about quality certificates, in order to enable employees to advise customers competently.

► **Critical scrutiny of the articles offered:** If products prove to be problematic, if biocide treatments proved to be unnecessary, when alternative products are available that are less problematic for the environment and human health, or when suppliers are unable to provide more detailed information, then removing the articles in question from stocks is the best course of action. We would urgently recommend a review of antibacterial or anti-odour-building articles, since such treatments are unnecessary for everyday use and, from the standpoint of health and the environment, especially questionable.

Recommendations for consumer and other civil society organisations

► **Making use of one's right to be informed:** Consumers should be encouraged to make use of their right to be informed and ask suppliers and retailers for details of biocide treatment, its purpose, and risks, and about biocide-free alternatives. The new requirements on labelling and the obligation to inform consumers greatly enhance consumers' rights. Non-governmental organisations of civil society like consumer advice centre should draw the public's attention to the new rules with information campaigns or should support similar initiatives by other organisations.

► **Examine practices in buying goods:** On the local level, municipal administrations and other public institutions should take steps to reduce procurement and unnecessary use of biocide-treated products. Especially where vulnerable groups of people such as small children or the elderly are effected, classic hygiene practices like proper methods for washing hands should be the focus of attention.

► **Reassess and adapt quality seals and certificates:** Seals and certificates attest to the special quality or safety of a product. The German Verbraucher-Initiative offers an overview of such seals on its website*. But such seals are not always a reliable or simple guide with respect to biocide treatments. This is why the current criteria for these seals and certificate should be made more concrete and transparent with respect to the substances involved as they relate to biocide law. We recommend revision of seals like the Oeko-Tex Standard 100, the Blue Angel, or the EU Ecolabel and to award these only to such products that are biocide-free or that contain only such low-risk biocide active substances that have been authorised according to the simplified procedures of Annex I, BPD. Development of a new seal to label biocide-free, low-pollutant alternatives and give them a competitive edge on the market should also be considered.

* Statements from those who provide labels on biocide content are in part presented by the Verbraucher-Initiative without any further evaluation (access to information on labels from the Verbraucher-Initiative: www.label-online.de/startseite).

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