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Reduction of environmental risks from the use of biocides: Environmental sound use of disinfectants, masonry preservatives and rodenticides

Annex I: Legislative background

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Reduction of environmental risks from the use of biocides: Environmental sound use of disinfectants, masonry preservatives and rodenticides

Annex I: Legislative background

by

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Content

List of Abbreviations

BAT	Best Available Techniques
BPD	Biocidal Products Directive
BPR	Biocidal Products Regulation
BREF	Best Available Technique Reference Documents
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, and toxic to Reproduction
DIBt	Deutsches Institut für Bautechnik /(German Institute for Construction)
DIN	Deutsches Institut für Normung e. V.
EMA	European Medicines Agency
EQS	Environmental Quality Standards
GAP	Good Agricultural Practice
HACCP	Hazard Analysis and Critical Control Points (Regulation (EC) No 852/2004)
IPPC	Integrated Pollution Prevention and Control
NAP	National Action Plan
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PPP	Plant Production Products
REACH	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RCN	Risk Communication Network
RMM	Risk mitigation measure
SVHC	Substances of Very High Concern
TFI	Treatment Frequency Index
UBA	Federal Environment Agency (Germany)
VdL	Verband der deutschen Lack- und Druckfarbenindustrie e.V.
vPvB	very Persistent and very Bioaccumulative
VOC	Volatile Organic Carbon

1 Introduction

A comprehensive research into the legislative background has already been conducted as part of the preceding study (Gartiser et al. 2012). Here, the objectives of the Thematic Strategy and the Directive on sustainable use of pesticides have been analysed and compared with other regulatory areas and related legislative directives and regulations in order to identify suitable approaches for the biocide sector.

Consequently, this report does not intend to repeat the results obtained in the preceding study. In the following, only a short update of the current status in different legislations is summarised.

2 Plant protection products and biocides

2.1 Directive 2009/128/EC on Sustainable Use of Pesticides

The internet research provided additional information compared with the status reported previously (Gartiser et al. 2012) and reflects the progress of implementation. The website of the European Commission concerning sustainable use of pesticides provides information about the implementation of the Directive.[1] The National Action Plans (NAPs) of most of the 28 Member States have now been published. From 2014 on, the general principles of integrated pest management are being implemented for all professional users. For example, the German NAP on the Sustainable Use of plant protection products from 2013 has been further developed on the basis of the former plant protection product (PPP) reduction programme published in 2004 and 2008 (BMEL 2013).

The revised NAP refers to possible entries from the use of biocides containing active substances from plant protection products (e.g. herbicides in roofing felt or fungicides in paints applied to the exteriors of houses). They should be considered when evaluating emissions to the environment. The sustainable use of biocidal products is not addressed.

The German NAP focuses on risk reduction rather than setting specific quantity reduction targets. Otherwise, the use of a high-risk plant protection product which is effective in small quantities, would be more positively assessed than the use of a lower-risk product that has to be used in greater quantities. A target of a 30 % risk reduction in the environment (water bodies, the terrestrial environment) by 2023 has been defined, besides, a reduction of residues of plant protection products in agricultural products exceeding the maximum residue values of both, produced and imported food, to levels below 1 %. Further goals are (i) achieving a share of 20 % of agricultural area for organic farming, (ii) reducing adverse impacts for operators, workers, bystanders and residents, (iii) introducing and further development of an integrated plant protection by extending practicable non-chemical measure and (iv) limiting the use of PPP to the necessary minimum.

Some Member States such as Denmark have included both, plant protection products and biocides in their reduction programme for pesticides. Denmark has set quantitative targets: reduction of the environmental impact of pesticides used in agriculture by 25% in 2010 and reduction for biocides by 50%. The agricultural pesticide consumption is measured by a treatment frequency index (TFI). Furthermore, a pesticide tax was introduced in 1996 which is levied on sales prices and charged to manufacturers and importers. An ex-post case study on the Danish pesticide tax for agricultural pesticides revealed that the tax only had a small effect on the TFI (Pedersen et al. 2011). It was supposed that the developments in grain prices (increases some years) as well as pesticide prices (decreases) have counteracted the taxes. Poor crop rotation at some farms

[1] http://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/index_en.htm

and the appearance of new pests has even increased the consumption of pesticides in some areas. The Danish government intended changing the tax from an ad valorem tax to a tax based on toxicity, which will target environmental effects more directly. Biocides have not been addressed in this study. Thus, no information is available, whether the targets for biocide reduction have been achieved, so far (Pedersen et al. 2011). Meanwhile the pesticide tax has been adopted and is considered as being a strong basis for achieving a reduction in pesticide loads. The agricultural industry is obliged to pay for its pesticide load on human health, nature and groundwater. As a result, the majority of the farmers can reduce their costs by selecting the pesticides causing the lowest load. The Danish pesticides strategy is primarily financed by the revenues from the new tax on pesticides. Biocides are not addressed in the NAP (Danish Government 2013).

According to a OECD study, only a few countries actually levy taxes on pesticides; notably Canada, Denmark, France, Norway, Sweden and the USA (OECD 2010).

In Belgium, the law on product standards since 1998 requires to promote sustainable production and consumption patterns and to protect the environment and public health.[2] The Belgian action plan to reduce the risks and impacts linked to pesticides from February 2014 considers biocides besides PPP and has set a quantitative target of 50% reduction of the environmental impact for non-agricultural pesticides. Among these measures, the NAP requires adaptation of legislation relating to PPP and biocides to cover also "borderline cases" (products not defined as a PPP or a biocide but sold for that purpose). Furthermore, monitoring of biocidal products that are intended for professional use only, the ones for which a prohibition of free access for the general public is deemed necessary, will be established. At the point of sale, well-balanced information for non-professional users, about the proper conditions of use and the risks for the public health and the environment must be provided. The minimum information required will be defined in 2014. The available information on PPP and biocides will be placed on the website for informing the public. For improving knowledge of the Belgium biocides market, sales data are regularly compiled which are based on the annual declarations of allowed and registered products (biocidal products and active substances). These data are reported and serve as a reference for creating several indicators with respect to the risks, the use and the impact of biocides on health and the environment. The establishment of a network for the (voluntary) exchange of data with the neighbouring countries for comparing market statistics and policy measures with respect to risk management is encouraged. The development of a structured communication plan in view of distributing information and ensuring awareness of the risk and of alternatives is envisaged (NAPAN Task Force 2014).

There is an intensive information exchange among experts concerning the different approaches for NAP, e.g. within the European “PesticideLife-Project” (2010-2014), which aims at supporting the Directive on sustainable use of pesticides with special emphasis on cereal plant protection, in northern Europe.[3]

2.2 Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.

Several amendments to the Plant Protection Products Regulation have been implemented such as Regulation (EC) No 547/2011 which concerns the labelling requirements and standard phrases for special risks for plant protection products. This is specified in Annex I and Annex II of Regulation (EC) No 1107/2009. Regulation

[2] http://www.health.belgium.be/eportal/Environment/Chemicalsubstances/PRPB/index.htm?fodnlang=en#.U9ea_TYU_cs

[3] See also http://www.nap-pflanzenschutz.de/nap-international/

(EU) No 545/2011 describes the data requirements for plant protection products and Regulation (EU) No 546/2011, the uniform principles for evaluation and authorisation. Sustainable use of plant protection products is not addressed in these regulations.

2.3 Directive 2009/127/EC on machinery for pesticide application

The new requirements set out in Directive 2009/127/EC have been applicable since 15. December 2011. The implementation will be achieved e.g. by further developing harmonised machinery standards. Some national guidance has been provided from authorities to manufacturers of new pesticide application equipment (e.g. BIS 2011). The European Commission published guidance documents with regard to the application of the Machinery Directive (European Commission 2010). However, the amendment concerning machinery for pesticide application will only be covered in the 3rd edition of that guidance. In Germany, the surveillance of machinery for the application of plant protection products is maintained by the Julius Kühn-Institut (JKI), which provides further information about standard development, research projects, examination of the equipment etc.[4]

The Directive 2009/127/EC does not yet consider biocides so far. However, it is stated that the scope of Framework Directive 2009/128/EC may be extended to cover biocidal products. Therefore an extension of the scope of the environmental protection requirements to machinery for the application of biocidal products should be examined by the European Commission by 31 December 2012. The deadline has been passed without submitting a report due to other priorities of the European Commission.

The authors suggest that the Directive on Machinery 2006/42/EC should be amended to include machinery and equipment for the application of biocides in order to facilitate the harmonisation of dosage and application apparatus for biocides where relevant.

2.4 Regulation (EC) No 1185/2009 concerning statistics on pesticides

The Regulation (EC) No 1185/2009 concerning statistics on pesticides, does not consider biocides so far, but indicates that the scope may be expanded at a later stage so as to include biocides. The transmission format has been specified by Regulation (EU) No 408/2011. The major pesticide groups and substances to be indicated are listed in Annex III to Regulation (EC) No 1185/2009 which has been implemented by Regulation (EU) No 656/2011. The authors suggest that the statistics regulation should be amended to cover also biocide uses in order to obtain data required for harmonised risk indicators and to follow the progress on sustainable use of biocides.

2.5 Biocidal Products Regulation (EU) 528/2012

In September 2013 the Biocidal Products Regulation (BPR) replaced the Biocidal Products Directive (BPD). As been stated in the title of the BPR, the Regulation refers to *"the making available on the market, and use of biocidal products"*. During the consultation about the BPR, the European Parliament (EP) proposed to include measures concerning sustainable use of biocidal products in the Regulation and requested that the Commission should submit a legislative proposal for the framework directive (European Parliament 2011). This was finally implemented into the BPR by Article 18. According to Article 18, the Commission shall submit a report to the European Parliament and the Council by 18 July 2015, which clarifies how the Regulation is contributing to the sustainable use of biocidal products. The report may also promote the need to

[4] http://www.jki.bund.de/en/startseite/institute/anwendungstechnik.html

introduce additional measures - in particular for professional users - to reduce the risks posed to human health, animal health and the environment by biocidal products. Moreover, that report shall, inter alia, examine the

- promotion of best practices for reducing the use of biocidal products to a minimum,
- most effective approaches for monitoring the use of biocidal products,
- development and application of integrated pest management principles,
- risks posed by the use of biocidal products in specific areas (e.g. schools, workplaces, kindergardens, public spaces, geriatric care centres or in the vicinity of surface water or groundwater), and
- the role that improved performance of the application equipment could play in sustainable use.

A PREP-BPR-Group (Preparation for the Entry into Force of the Biocidal Products Regulation) on sustainable use has been established on EU level which intends to submit the report on sustainable use in mid-2015. At the end of 2013 the European Commission commissioned a study to analyse measures for the sustainable use of biocidal products aiming to support drafting this report.

Thus, the BPR considers a sustainable use of biocides within its scope and has included further instruments such as provisions for treated articles, which shall be implemented in the future.

3 Other substance groups

3.1 Regulation (EC) No 1907/2006 (REACH) and CLP-Regulation (EC) No 286/2011

The implementation of the Regulation, (EC) No 286/2011, on classification, labelling and packaging of substances and mixtures (CLP regulation) into REACH has induced initiatives of the European Chemical Agency (ECHA). Article 123 of REACH requires member states to inform the general public about the risks arising from substances where necessary. In 2010, the ECHA published a guidance document on the communication of information on the risks and safe use of chemicals (ECHA 2010). Later on a study on the communication of safe use of chemicals to the general public was published (ECHA 2012). One objective of the project was to enhance the general public's understanding of the new CLP-Regulation in order to obtain an adequate hazard perception through awareness-raising activities. By 2015, the date when the new CLP pictograms will replace the old ones, EU citizens should be aware of the risks which are communicated with these pictograms. The research also proposed a training activities scheme aimed to enhance best practice in communication campaigns for the general public and the establishment of a website to promote a better understanding of the new CLP hazard pictograms. The ECHA also launched a "Risk Communication Network" (RCN) as an information exchange platform of competent authorities involved in the communication of risks and safe use of chemicals to the general public. These activities will certainly also be of importance for the risk communication for biocidal products.

The substitution or reduction of hazardous substance with high environmental risks is one objective of sustainable use. Within REACH a candidate list of substances of very high concern (SVHC) is being elaborated. To date the ECHA has submitted to the Commission three recommendation lists of SVHC, which in future should not be used without authorisation. Fourteen of these substances have so far been included in Annex XIV of REACH (so called "authorisation list"; status of January 2013). These substances are all classified because of their carcinogenic, mutagenic, and toxic to reproduction (CMR) as well as their persistent, bioaccumulative, and toxic (PBT), or very persistent and very bioaccumulative properties (vPvB). No substance has so far been selected due to other serious effects with an equivalent level of concern such as endocrine effects. Due to the fact that the actual candidate list for SVHC only includes few biocidal active substances

(boric acid and disodium tetraborate, anhydrous) no short term impact through the identification of SVHC under REACH on the authorisation of biocidal products is expected.

In summary, the provisions of REACH and the CLP regulation in terms of classification and labelling, substitution of hazardous substances, as well as risk communication among others should be considered when developing measures for a sustainable use of biocides.

3.2 Medicinal products for human and for veterinary use

The European Medicines Agency (EMA, until 2009 EMEA) specifies, in its revised EMA guidelines on environmental impact assessment for veterinary medicinal products, that risk mitigation "can be used to restrict the risk associated with a product to an acceptable level, or even to completely remove such a risk" (EMEA 2008). The EMA guideline for the environmental risk assessment of medicinal products for human use, specifies that when the possibility of environmental risks cannot be excluded, precautionary and safety measures such as an indication of potential risks presented by the medicinal product for the environment have to be presented on the product label with recommendations on product storage and disposal (EMEA 2006). These EMA guidelines focus on risk mitigation measures (RMM) and risk-benefit assessments to be considered in the authorisation procedure.

The "Reflection paper on risk mitigation measures for veterinary medicinal products" requires that RMM should mitigate exposure to the environment. Furthermore, it ought to be in line with good agricultural practice (GAP) and legislation and it should be quantifiable by re-evaluating the exposure assessment. GAP is defined as applying the available knowledge to address environmental, economic and social sustainability for on-farm production and post-production processes resulting in safe and healthy food and non-food agricultural products (EMA 2011). Regulation (EC) No 73/2009 on common rules for direct support schemes for farmers under the common agricultural policy in Article 6 refers to the "good agricultural and environmental condition". Member states shall ensure that all agricultural land, especially land which is no longer used for production purposes, is maintained in good agricultural and environmental condition. For this, member states shall define, at the national or regional level, minimum requirements for good agricultural and environmental conditions. Annex III describes compulsory optional standards for good agricultural and environmental conditions; among them the establishment of buffer strips along water courses for protecting water against pollution. Other aspects are maintaining the organic matter and structure of soil through arable management, crop rotations, and appropriate machinery use. GAP also includes compliance with existing legislation such as soil protection laws or regulation concerning the application of wet or dry manure as a fertiliser to agricultural soil (in Germany "Bundes-Bodenschutzgesetz and Düngeverordnung").

The consideration of life cycle aspects of pharmaceuticals and the proposal of an environmental classification system has been suggested by Kümmerer and Hempel (2010). The use of appropriate package sizes, the establishment of take-back-systems for out-dated drugs, and the consideration of environmental aspects such as biodegradability in the development of new active substances are examples to promote a sustainable use of pharmaceuticals. Further accompanying measures consist of providing information to patients, doctors, farmers etc. or in the establishment of monitoring programmes.

The provisions of good agricultural practice, although focussing on nutrient control through manure management, has a decisive influence on the fate of veterinary disinfectants applied in stables (next to insecticides and veterinary medicinal products which also end up in manure).

3.3 Regulation (EC) No 305/2011 on construction products

The Construction Products Regulation requires that construction products covered by harmonised standards or European Technical Assessments may only be placed on the market when accompanied by a declaration of performance in relation to its essential characteristics in accordance with the relevant harmonised technical specifications. Paragraph 15 indicates that health and safety aspects during service life should be taken into account by performance testing of construction products. Where applicable, the declaration of performance should be accompanied by information (e.g. CE-label) on emission and the content of hazardous substances in order to improve the possibilities for sustainable construction and to facilitate the development of environment-friendly products. According to paragraph 25, hazardous substances in construction products should be further investigated with a view to complete the range of substances in order to ensure a high level of protection. In a first review, the focus is put on substances which are subject to authorization according to Article 57 of REACH and substances or preparations classified as dangerous or persistent, bioaccumulative and toxic or very persistent and very bioaccumulative (see Article 31 of REACH). However, the possibility for extending the substance list is kept open and therefore Regulation 305/2011 could be extended.

For the assessment of the sustainable use of resources and of the impact of construction works on the environment, “Environmental Product Declarations” should be used if available.

Annex I refers to the basic requirements for construction works. It is prescribed that construction works must be designed, built and demolished in such a way that the use of natural resources is sustainable throughout their life cycle without an exceedingly high impact on the environmental quality including the reuse or recyclability and durability of the construction works as well as the use of environmentally compatible raw and secondary materials. Specifically, requirement 3 (d) highlight the release of dangerous substances into aquatic systems and soil, (f) faulty discharge of waste water and disposal of waste, and (g) the dampness in parts of the construction works or on surfaces within the construction works. Based on the EC mandate M/366, CEN/TC351/WG1 drafted an indicative list of regulated dangerous substances possibly associated with construction products and which could be potentially released under the intended conditions of use to soil, surface water and ground water (CEN TC 351 2012). The list covers substances notified under national regulations or under European regulations including chlorinated biocides (e.g. Diuron) and other biocides. The latest news indicates that biocides will not be assessed under the Construction Products Regulation since the risk assessment under BPD is completely satisfying and double regulation not intended.

In Germany, the Institute for Construction Technique (Deutsches Institut für Bautechnik, DIBt) grants national technical approvals for construction products and has developed several guidance documents. The guidance for the evaluation of impacts of construction products on soil and groundwater (DIBt 2011) describes an approach for deriving “insignificant threshold levels” for ingredients in construction products. These threshold levels are based on the existing classification of substances and on the results from leaching tests. Reference is given to the German Federal Soil Protection Act (Protection against Harmful Changes to Soil and on Rehabilitation of Contaminated Sites - BBodSchG) which aims at protecting or restoring the functions of oil on a permanent sustainable basis. Similarly, the guidance for the evaluation of indoor health effects from construction products describes an approach for evaluating ingredients from construction products and the determination and evaluation of volatile organic carbon (VOC) and non-volatile organic carbon emitted from construction products (DIBt 2010). Guidelines and technical standards could be implemented which provides a general description for biocides emission from coatings (e.g. biocide release tested by EN 16105). Similar objectives could be implemented in VdL RL 01 (3rd revision) guidelines for the declaration of ingredients in paints, architectural coatings and related products, in DIN 18 363 (painting and varnishing work), in DIN 18 558 (plasters: definitions, requirements, designs) or in DIN 55 945 (paints and varnishes - Terminology and definitions for coating materials and coatings).

4 Limitation of emissions and best practices

4.1 IPPC Directive 2008/1/EC and Industrial Emissions Directive 2010/75/EU

The Directive 2008/1/EC concerning integrated pollution prevention and control (IPPC) has been revised by the Industrial Emissions Directive 2010/75/EU (see below) which also includes other directives dealing with emissions such as the former Solvents Emission Directive. One aim of integrated pollution prevention and control is to bring forward a more sustainable balance between human activity and socioeconomic development, on the one hand, and the resources and regenerative capacity of nature, on the other hand.

The BREF-documents on "Intensive Rearing of Poultry and Pigs" (2003) and "Slaughterhouses and Animals By-products Industries" (2005) cover also application areas of PT 3 disinfectants. The first is currently being revised. In the draft of the revised BREF it is stated that the use of evaluated cleaning agents and disinfectants could reduce the harmfulness of the waste water.[5] Providing more details about the selection criteria for disinfectants or other biocides into the BREFs while considering also environmental concerns is one option to promote a sustainable use of biocides. However, considering biocides in BREF documents would require a shift in BREF development because (with a few exceptions), these do not relate to specific substances but focus on emission control as a whole.

The production of plant protection products or biocidal products is included in Annex I on categories of activities covered by Directive 2010/75/EU on industrial emissions. Further categories related to biocides involve operating slaughterhouses (carcass production > 50 t /day), processing of animal raw materials (> 75 t/day), vegetable raw materials (>300 t/day), preservation of wood (> 75 m^3 / day) or intensive rearing of poultry or pigs (>40 000 places for poultry, > 2000 places for pigs, >750 places for sows). Biocides are also considered in the list of polluting substances (Annex II). Unlike the IPPC Directive, the Directive on industrial emissions does not refer to the strategy of sustainable development.

The application of PT 2 disinfectants, film and masonry preservatives (PT 7 and 10) and rodenticides (PT 14) are not likely to be covered by the Industrial Emission Directive.

4.2 Regulations related to the hygiene of foodstuffs

The Regulation (EC) No 852/2004[6] lays down general hygiene requirements to be respected by food businesses at all stages of the food chain. Additionally, it is part of a bunch of further regulations such as Regulation (EC) No 853/2004 on the hygiene of food of animal origin and Regulation (EC) No 854/2004 laying down rules for the organisation of official controls on products of animal origin intended for human consumption. The use of disinfectants is only referred to in the context that the facilities must be easy to clean and disinfect and that the equipment and surfaces must be disinfected in reasonable frequencies (e.g. at least once a day). Slaughterhouses must provide disinfecting tools with hot water supplied at a minimum of 82ºC. The requirement to implement and maintain procedures based on hazard analysis and critical control point (HACCP) principles is a central part of the regulations.

[5] http://eippcb.jrc.es/reference/

[6] REGULATION (EC) No 852/2004 of 29 April 2004 on the hygiene of foodstuffs.

The purpose of Directive 2003/99/EC[7] is to ensure that zoonoses, zoonotic agents and related antimicrobial resistance are properly monitored, and that food-borne outbreaks receive proper epidemiological investigation, to enable the information necessary to evaluate relevant trends and sources. The Directive covers the monitoring of zoonoses and antimicrobial resistance as well as the epidemiological investigation of food-borne outbreaks and the exchange of information. Disinfectants are not specifically mentioned, but monitoring of antimicrobial resistance provides data which could serve as indicator for a sustainable use of disinfectants and could also trigger the selection of suitable disinfectants. Similar, Regulation (EC) No 2160/2003 on the control of Salmonella and other specified food-borne zoonotic agents does not refer to disinfectants. The principles of the HACCP and training / instruction of food business operators and food handlers in food hygiene matters are considered in Article 5 and Chapter XII of Regulation (EC) No 852/2004.Several guidance documents on how to implement and maintain the HACCP management system are available (e.g. European Commission 2009).

4.3 EU Water Framework Directive (2000/60/EC)

According to the EU Water Framework Directive 2000/60/EC (WFD), proposals for emission control measures and environmental quality standards shall be elaborated for priority substances. Point source discharges into surface waters should be controlled by setting emission limit values and emission control standards based on best available technique (BAT) according to the Industrial Emission Directive.

Directive 2006/11/EC on “pollution caused by certain dangerous substances discharged into the aquatic environment” aims at eliminating pollution through the discharge of the various dangerous substances described in List I of Annex I and to reduce further dangerous substances, families and groups of list II of Annex I. For list I substances emission limit standards concerning discharges to surface water or into sewers were fixed through Annex IX of the WFD. For list II substances, all discharges containing these substances shall require authorisation by the competent authority and the Member States shall define emission standards and environmental quality standards for water bodies. Where appropriate, member states may take more stringent measures than those provided under this Directive. The list I substances include, e.g. organohalogenic and organophosphorus compounds which also have an antimicrobial effect. List II of Annex I refers to limit values for water bodies laid down in Annex IX of the WFD as well as to certain categories of substances such as biocides. Annex IX of the WFD, e.g. includes Diuron and Isoproturon both used as PPP and biocides and some “old” biocides removed from the market.

In 2012 the European Parliament and the Council submitted a proposal for amending Directive 2008/105/EC on priority substances in the field of water policy which included some biocides and which has partly been implemented by Directive 2013/39/EU. [8] Within this last amendment of the list of priority substances further biocidal active substances have been included and inland surface water EQS of 0.0025 µg/L for Irgarol (Cybutryne), of 0.065 µg/L for Terbutryn and of 0.00008 µg/L for Cypermethrin have been established.

In Germany, these requirements have been implemented by the Ordinance for the protection of surface waters (Oberflächengewässerverordnung – OGewV) from 20.07.2011. Annex I of the OGewV refers to the environmental quality standards (EQS) of 167 individual substances. A memorandum of the water supply associations, initiated by the German technical and scientific association for water and gas (DVGW 2010),

[7] DIRECTIVE 2003/99/EC of 17 November 2003 on the monitoring of zoonoses and zoonotic agents.

[8] http://ec.europa.eu/environment/water/water-dangersub/lib_pri_substances.htm#prop_2011_docs

recommended a unique EQS for biocides, pesticides and their metabolites of 0.1 µg/L. The consideration of biocides in the OGewV would be an appropriate mean for reducing emission of hazardous biocides into surface water. Similarly, Directive 98/83/EC which governs the quality of water for human use, in Annex I, Part 2 refers to maximum threshold values of 0.1 µg/L for a single pesticide and of 0.5 µg/L for the sum of all pesticides. The term "pesticides" includes insecticides, herbicides, fungicides, nematocides, acaricides, algicides, rodenticides, slimicides and related products and relevant metabolites. Most of these substance groups are also used as biocides, but not all biocidal product types are mentioned. For example, disinfectants or some preservatives are not covered. Besides the term "pesticide" also the term "biocide" in Annex Part B, all biocidal products such as disinfectants, film preservatives, etc. would be covered by the Directive.

The consideration of biocides in the selection process for priority substances as well as in monitoring programmes is a prerequisite for identifying their occurrence in the environment as a result of biocide use.

4.4 Marine Strategy Framework Directive (2008/56/EC)

Similar to the WFD, the EU Marine Strategy Framework Directive, which has been developed within the Thematic Strategy on the Protection and Conservation of the Marine Environment, aims to take the necessary measures to achieve or maintain good environmental status in the marine environment by the year 2020 at the latest.[9] Each member state shall develop a marine strategy for each marine region or subregion concerned and develop a programme of measures designed to achieve or maintain a good environmental status by 2015. Annex I refers to qualitative descriptors for determining good environmental status of the marine environment, including the concentrations of contaminants in water and in fish and other seafood.

The use of biocides will only be considered by the Marine Strategy Directive if biocides contain priority substances (similar as to the WFD). The consideration of biocides in monitoring programmes and the selection procedure for priority substances is suggested.

5 Waste disposal

5.1 Directives on (hazardous) waste

The Directive 2008/98/EC on waste lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use (Article 1). For this, member states should take into account the general environmental protection principles of precaution and sustainability, technical feasibility and economic viability, protection of resources as well as the overall environmental, human health, economic and social impacts. Wastewater is excluded from the scope of this Directive to the extent that it is covered by other Community legislation such as Directive 2006/11/EC (see above) or Directive 91/271/EEC on urban wastewater. Directive 91/689/EC on hazardous waste was also integrated and replaced by the Framework Directive 2008/98/EC. Article 4 describes the waste hierarchy to be considered which shall apply with decreasing priority: prevention > preparing for re-use > recycling >other recovery, e.g. energy recovery > disposal. The waste classification following the list of the waste types established by Commission Decision 2000/532/EC includes several hazardous wastes from biocide origin (e.g. 06 13 01: inorganic plant protection products, wood-preserving agents and other biocides; 07 04: organic plant protection products, wood preserving agents and other biocides). No specific waste treatment technologies have

[9] http://ec.europa.eu/environment/marine/eu-coast-and-marine-policy/marine-strategy-framework-directive/index_en.htm

been attributed in these documents to hazardous wastes. Assigning specific disposal options such as incineration or biological treatment might help that the biocidal products are properly disposed of. Annex III of Directive 2008/98/EC describes 15 properties of waste which render them as hazardous, among them the classification as carcinogenic (H7), toxic for reproduction (H10), mutagenic (H11), toxic (H6) or ecotoxic (H14). The classification of waste as hazardous waste follows inter alia, on the Community legislation on chemicals, in particular concerning the classification of preparations as hazardous, including concentration limit values used for that purpose. For example, the CLP Regulation 1272/2008 in Annex VI refers to Diuron as a potentially carcinogenic substance.

Regulation 396/2005/EC defines the maximum residue levels of pesticides in or on food and feed. Pesticide residues include active substances, metabolites and/or breakdown or reaction products of active substances used in plant protection products, veterinary medicines and biocides.[10] Similar provisions could also be defined for other end-of life stages of biocides such as waste, e.g. by prescribing maximum residue levels of biocides in waste. In case of exceeding the threshold values, waste must be disposed of separately. Re-use of construction materials containing biocides will not be allowed when testing reveals that if threshold values are exceeded. This is in agreement with the Construction Products Regulation or DIBt guidance documents for construction materials.

The control of hazardous waste during production, collection and transportation, as well as storage and treatment must be traceable in the entire lifecycle from the production to final destination. Hazardous wastes are not allowed to be mixed with other waste or materials (Article 17 and 18 of Directive 2008/98/EC on waste).

5.2 Sewage Sludge Directive 86/278/EEC

The Directive 86/278/EEC on the protection of the environment and in particular of soil, when sewage sludge is used in agriculture (last amendment by Regulation (EC) No 219/2009) aims to regulate the use of sewage sludge in agriculture in such a way as to prevent harmful effects on soil, vegetation, animals and man, thereby encouraging the correct use of such sewage sludge (Article 1). The Directive prescribes limit values for heavy metals in soil, for sewage sludge to be used in agriculture, and for the maximum amounts of heavy metals which may be added annually to agricultural land (10 year average). To date, heavy metals are the only contaminants considered in the Directive, but in principle the list of contaminants in Annex I could be extended to cover also biocides or veterinary medicinal products.

The European Commission is currently assessing whether the current directive should be reviewed because since its adoption, several Member States have enacted and implemented stricter limit values for heavy metals and set requirements for other contaminants.[11]

6 Immission based legislation

6.1 Directive 2008/105/EC on environmental quality standards in the field of water policy

Annex 1 of Directive 2008/105/EC sets EQS for priority substances and certain other pollutants for inland and other surface waters while prescribing EQS based on the annual average concentration and the maximum

[10] http://ec.europa.eu/food/plant/pesticides/max_residue_levels/index_en.htmx

[11] http://ec.europa.eu/environment/waste/sludge/

concentration allowed. The substances correspond to priority substances as defined in Annex X of the WFD (see chapter 4.3).

6.2 Directive 2006/118/EC on the protection of groundwater against pollution and deterioration

The Groundwater Directive lays down quality criteria for the assessment of groundwater chemical status in Europe. These include groundwater quality standards set at Community level (Annex I) and threshold values/quality standards to be set by member states for pollutants causing a risk of not meeting the requirements of the WFD. Annex I refers to pesticides including biocides and their relevant metabolites, degradation and reaction products and establishes groundwater quality standards of 0.1 µg/L for the single substance and 0.5 µg/L for the sum of all pesticides and biocides and their metabolites. In Germany, the Directive was implemented by the Groundwater Ordinance (Grundwasserverordnung – GrwV, from 09.11.2010).

7 Regulatory initiative for supporting sustainable consumption

In 2008, the European Commission presented its "Sustainable Consumption and Production and Sustainable Industrial Policy Action Plan". It includes a series of proposals on sustainable consumption and production that will contribute to improving the environmental performance of products and increase the demand for more sustainable goods and production technologies. In 2011, an evaluation of the Action Plan has been elaborated summarising the objectives obtained so far. Several policy instruments and opportunities are referred to for increasing the rate of improvement in key areas. Pesticides or other substance groups such as biocides are not mentioned specifically - the focus being on energy saving (Williams et al. 2011). The Action Plan covers the Ecodesign Directive 2005/32/EC, the Energy Labelling Directive 92/75/EEC, the Energy Star Regulation (EC) No 2422/2001, and the Ecolabel Regulation (EC) No 1980/2000 among others. Thus, one option would be to include biocides used in the private and industrial sector in an update or new action plan on sustainable consumption and production.

8 References

BIS 2011. The supply of machinery (safety) (amendment) regulations 2011. Government Guidance Notes, Department for Business, Innovation and Skills (BIS), NOVEMBER 2011, www.bis.gov.uk

BMEL 2013. National action plan on sustainable use of plant protection products. Federal Ministry of Food, Agriculture and Consumer Protection
http://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/docs/nap_germany_en.pdf

CEN TC 351 2012. Indicative List of Regulated Dangerous Substances possibly associated with Construction Products under the CPD. N 040322.03.2012

Danish Government 2013. Protect water, nature and human health Pesticides strategy 2013-2015. National action plan February 2013. http://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/docs/nap_denmark_en.pdf

DIBt 2010. Grundsätze zur gesundheitlichen Bewertung von Bauprodukten in Innenräumen (Oktober 2010)

DIBt 2011. Grundsätze zur Bewertung der Auswirkungen von Bauprodukten auf Boden und Grundwasser (September 2011)

DVGW 2010. Memorandum – Forderungen zum Schutz von Fließgewässern und Talsperren zur Sicherung der Trinkwasserversorgung. http://www.dvgw.de/fileadmin/dvgw/wasser/ressourcen/memorandum2011.pdf

ECHA 2010. Guidance on the communication of information on the risks and safe use of chemicals. Version 1, December 2010 http://echa.europa.eu/documents/10162/13639/risk_communications_en.pdf

ECHA 2012. Study on Communication on the safe use of chemicals to the General Public. Submitted by the Agency according to Article 34 (1) of the CLP Regulation, Helsinki, 20 January http://echa.europa.eu/documents/10162/17203/clp_study_en.pdf

EMEA 2006. Guideline on the environmental risk assessment of medicinal products for human use. Committee for Medicinal Products for Human Use (CHMP). London, 01 June 2006 http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500003978.pdf

EMEA 2008. Revised guideline on environmental impact assessment for veterinary medicinal products in support of the VICH Guidelines GL6 AND GL 38. Committee for medicinal products for veterinary use, Doc. Ref. EMEA/CVMP/ERA/418282/2005- Rev.1 http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004386.pdf

EMEA 2011. (Draft) Reflection paper on risk mitigation measures related to the environmental risk assessment of veterinary medicinal products. Committee for Medicinal Products for Veterinary Use (CVMP), 10 May 2011, EMA/CVMP/ERAWP/409328/2010 http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500106454

European Commission 2010. Guide to application of the machinery directive 2006/42/EC. 2nd edition, June 2010 guide_application_directive_2006-42-ec-2nd_edit_6-2010_en[1]

European Parliament 2011. Recommendation for second reading on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (05032/2/2011 – C7-0251/2011 – 2009/0076(COD)) A7-0336/2011, 10.10.2011

Gartiser, S., Lüskow, H., Groß, R. 2012. Thematic Strategy on Sustainable Use of Plant Protection Products – Prospects and Requirements for Transferring Proposals for Plant Protection Products to Biocides. Final report FKZ 3708 63 400, UBA-Texte 6/2012. http://www.umweltbundesamt.de/sites/default/files/medien/461/publikationen/4261.pdf

Kümmerer, K., Hempel, M. (Eds.) 2010. Green and sustainable pharmacy Springer-Verlag Heidelberg, 313 p.

NAPAN Task Force 2014. National Belgian action plan to reduce the risks and impacts linked to pesticides 2013-2017 (English version) February 2014 http://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/docs/nap_belgium_en.pdf

OECD 2010. Taxation, Innovation, and the environment. OECD Green Growth Strategy, 240 p.

Pedersen, A. B. Helle Ørsted, N. Nielsen, Andersen, M- S. 2011. The Danish Pesticide Tax. WP3 EX-POST Case studies. FP7 project for the European Commission Grant Agreement no. 265213, Aarhus University, Department of Environmental Science, 14.12.2011