ANNEX V

PT ANALYSIS – PT 8, 18, 19 & 21

Product Type 8 – Wood preservatives

This Annex sets out an analysis of available information on the uses, application, exposure risks and control measures applied to the specific product types 8, 18, 19 and 21. Based on this information, the identified risks and risk mitigation measures proposed for product types 8, 18, 19 and 21 is summarised in section 6.6 of the report.

Introduction

Biocidal products of PT 8 are used for the preservation of wood by the control of wood-destroying or wood-disfiguring organisms. Wood preservatives are used for both preventive and curative treatments of wood. The target organisms are wood-destroying or wood-disfiguring fungi and insects such as the house longhorn beetle or termites.

A case study on sustainable use of wood preservatives has been carried out in a research project that aims at analysing options for transferring elements of the Directive on sustainable use of plant protection products to the biocide field (Gartiser et al. 2012). Prior to this, the efficiency and practicability of risk mitigation measures for wood preservatives have been assessed by Gartiser and Jäger (2011). The example evaluation of PT 8 biocidal products is mainly based on these studies with an update to consider the progress of the review programme.

Uses:
Preventive treatments are usually applied to wood at industrial treatment plants before the wood is put into service whereas curative treatments are mostly applied to wood in-situ by professionals or amateurs. The use categories cover:

- industrial uses in sawmills, joineries or carpentry workers,
- specifically trained professional uses such as pest control technicians performing curative treatments against insects, and
- amateur uses by non-trained applicators (using household wood preservatives).

Composition and mode of application:
Wood preservative products are categorised by the type of formulation carrier. The OECD ESD (2003) distinguishes between four groups of formulation carriers, namely water, light organic solvent (white spirit type solvents), coal tar derivates and gases. With reference to water based preservatives a further distinction is made between non-fixating and fixating wood preservatives. Wood treated with non-fixating wood preservatives needs to be protected against weathering and is therefore only to be used indoors. In order to ensure the proper fixation of the active ingredient of the wood preservatives, fixation times need to be maintained after the impregnation and before the actual use of the treated timber. After this fixation time, the treated timber can be exposed to weathering or be used in applications in contact with the ground or water. Chromium has been extensively used as a fixative agent, especially in combination with copper and arsenic wood preservatives (copper chrome arsenate). During this process the carcinogenic chromium (VI) is turned into chromium (III).There have been discussions in the EU regarding the use of chromium and its efficacy as wood preservative active agent. Industry refers to Chromium use as a fixative below its effective concentration as a wood preservative (Groß 2012). Chromium(VI)-compounds as substances of very high concern are included in the authorisation list of Annex XIV of

REACH. Thus, chromium is an example of where the substance of concern is not the active substance but the fixative agent.

With respect to the treatment techniques deep penetrating via vacuum pressure or injection and surface treatments via fumigation (indoor), spraying, dipping, brushing, injection (indoor, outdoor) may be distinguished. Vacuum-pressure or double vacuum techniques are exclusively applied to wood in industrial treatment plants for preventive purposes (Groß 2012).

The equipment used for wood preservation in industrial treatment plants has to fulfil certain requirements laid down in different EC Directives and technical standards. Vessels for the pressure treatment of wood using water-soluble impregnating agents or coal tar oil (creosote) fall under the Pressure Equipment Directive (97/23/EC) and the Machinery Directive 2006/42/EC. In many European countries wood treatment plants need to be authorised for operation by national authorities according to environmental laws or regulations which describe in detail the required design of a treatment plants. In addition, industry associations have issued "Best Practice Guides for Treatment Plants".

In total 36 active substances have been approved for PT 8 so far under the BPR (status 9.1.15):

Substance name	CAS	CLP Excerp
4,5-Dichloro-2-octylisothiazol-3(2H)-one	64359-81-5	H317
Alkyl (C12-16) dimethylbenzyl ammonium chloride; C 12-16-ADBAC	68424-85-1	
Basic Copper carbonate	12069-69-1	H410
Bifenthrin	82657-04-3	H317, H351, H410
Boric acid	10043-35-3	H360
Boric oxide	1303-86-2	H360
Chlorfenapyr	122453-73-0	H410
Copper (II) oxide	1317-38-0	H410
Copper hydroxide	20427-59-2	H410
Creosote	8001-58-9	H350, H410
Cu-HDO	312600-89-8	H410
Cypermethrin	52315-07-8	H410
Cyproconazole	94361-06-5	H361, H410
Dazomet	533-74-4	H410
DDAC	894406-76-9	
Dichlofluanid	1085-98-9	H317
Didecyldimethylammonium chloride; DDAC	7173-51-5	
Disodium octaborate tetrahydrate	12280-03-4	
Disodium tetraborate	1330-43-4	H360
Disodium tetraborate decahydrate	1303-96-4	H360
Disodium tetraborate pentahydrate	12267-73-1	H360
Etofenprox	80844-07-1	H362, H410
Fenoxycarb	72490-01-8	H410
Fenpropimorph	67564-91-4	H361
Flufenoxuron	101463-69-8	H362, H410
Hydrogen cyanide	74-90-8	H410
IPBC	55406-53-6	H317, H410
K-HDO	66603-10-9	
Permethrin	52645-53-1	H317, H410
Propiconazole	60207-90-1	H317, H410
Sulfuryl fluoride	2699-79-8	
Tebuconazole	107534-96-3	H361
Thiabendazole	148-79-8	H410
Thiacloprid	111988-49-9	H351, H410
Thiamethoxam	153719-23-4	H410

Substance name	CAS	CLP Excerp
Tolylfluanid	731-27-1	H317

According to Regulation (EU) No.1062/2014 a further 5 active substances are still under review:

Substance name	CAS	CLP Excerp
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine)	2372-82-9	H410
Potassium (E,E)-hexa-2,4-dienoate (Potassium Sorbate)	24634-61-5	
Coco alkyltrimethylammonium chloride (ATMAC/TMAC)	61789-18-2	
Poly(oxy-1,2-ethanediyl), .alpha.-[2-(didecylmethylammonio)ethyl]- .omega.- hydroxy-, propanoate (salt) (Bardap 26)	94667-33-1	H410
N-Didecyl-N-dipolyethoxyammonium borate/Didecylpolyoxethylammonium borate (Polymeric betaine)	214710-34-6	

Of these active substances 4,5-Dichloro-2-octylisothiazol-3(2H)-one, Bifenthrin, Dichlofluanid, IPBC, Permethrin, Propiconazole, and Tolylfluanid have a harmonised or notified classification as skin sensitiser "may cause an allergic skin reaction" (H317), while several inorganic Boron containing compounds may damage fertility or the unborn child (reproductive toxicity Cat 1, H360) or are suspected to act so (Cyproconazole, Fenpropimorph, Tebuconazole, reproductive toxicity Cat. 2, H361). Creosote is a known carcinogen (Cat 1, H350) and Bifenthrin and Thiacloprid are suspected of causing cancer (Cat 2, H351). Further on, half of the active substances are classified in aquatic chronic 1 "very toxic to aquatic life with long lasting effects" (H410).[1]

Article 11 of Directive 2009/128/EC requires MS to ensure that, when pesticides are used in the vicinity of water bodies, preference is given to products that are not classified as dangerous for the aquatic environment. Several wood preservatives (e.g. Cyproconazole, Creosote) are considered a candidate for substitution. Because Creosote is classified as carcinogen category 1B and as PBT it must not be used in playgrounds, parks, gardens, and outdoor recreational and leisure facilities, garden furniture, or containers intended for growing purposes (REACH Annex XVII No 31).

Cypermethrin and Terbutryn are priority substances under the WFD, while Dichlofluanid, Chromium-trioxide, Thiacloprid, and Thiamethoxam are among the substances evaluated for their potential to be included in the 1st watch list for priority substances because the risk quotations for surface water were > 1 (Carvalho et al. 2015).

Only two opinions of the Biocidal Products Committee on PT 8 active substance approval have been submitted, because this is a new process and most active substances have previously been assessed:

<u>Permethrin (CAS 52645-53-1):</u> For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments: Labels, safety data sheets shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hardstanding, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal. Products shall not be authorised for

[1] The classification in further human health hazards or environmental hazard phrases H411-H413 are not documented in these tables.

wood that will be exposed to frequent weathering unless data is submitted to demonstrate that the product will meet the requirements, if necessary by the application of appropriate risk mitigation measures. Products shall not be authorized for treatment of outdoor constructions near or above water or for the treatment of wood that will be used for outdoor constructions near or above water, unless data are submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures. Treated article containing Permethrin with potential skin contact shall ensure that the label provides information on the risk of skin sensitization. Curative spray applications outdoors to wood may present a risk to bees to be addressed at product authorisation. Because the use of Permethrin as a wood preservative for Use Class 3 has demonstrated potential risks to the environment, suitable leaching study from treated wood and appropriate risk mitigation measures should be considered during product authorisation. The authorisation holder and professional end users shall monitor resistance incidents and report these to the Competent Authorities.

Potassium sorbate (24634-61-5): The environmental risk assessment indicates that the storage of wood treated with a wood preservative containing potassium sorbate results in unacceptable risks for the terrestrial compartment including groundwater. As a consequence, appropriate risk mitigation measures shall be applied. After application of potassium sorbate, treated timber has to be stored under roof and on impermeable hard standing to avoid run off from the treated wood and, by this, any release of potassium sorbate into the environment.[2]

The risk mitigation measures and conditions for product authorisation for PT 8 active substances have been assessed by Gartiser and Jaeger (2011) and categorised by the different life cycle steps. There are user restrictions to trained professionals or industrial operators. Restrictions of the area of application (use class, wood in contact to children, food or feedstuffs, near water bodies, groundwater protection areas, in-situ application) have also been proposed. While the usefulness of a fixative should be proven by leaching studies, there is no requirement to indicate a proper fixation duration before the treated wood is handled or marketed. Some wood preservatives should only be used in industrial facilities (dipping and/or vacuum pressure) and there are requirements that the area should not be connected to sewage treatment plants (STPs) and that all losses (including from cleaning of the equipment) should be collected and reused or disposed. The need for compliance with “good working practice” is mentioned and the development and harmonisation of a Code of Good Practice (for spray applications) has been proposed. Storage of treated wood on bare soil is not allowed but the level of protection proposed for preventing emissions during storage is different (concrete, impermeable hard standing surfaces, collection of leachates, under roof). Only a few CARs address options for waste water treatment of the leachates (mainly for boron containing preservatives). In the CASs top coating has been suggested as a RMM for use classes 3 and 4, but its long-term effectiveness has also been questioned by some CAs because obligatory top coating cannot be controlled and/or because the topcoat could be damaged by weathering or processing. In the inclusion directives top coating has not specifically been referred to as a risk mitigation measure. Regarding the disposal of treated wood, some CARs refer to incineration and national legislation.

Use restrictions:
The Water Framework Directive (WFD) 2000/60/EC sets environmental standards for priority substances such as Cypermethrin and Terbutryn. The inclusion directives for wood preservatives often state that treatment of wood intended for outdoor constructions near or above water will not be allowed (e.g. Cypermethrin). The establishment of drinking water protection zones for pesticides applies for both plant

[2] It should be noted that Potassium sorbate is mainly used as a food preservative (E202) and not proposed for classification to environmental hazards.

protection products and biocidal products. The replies of the Competent Authorities to the questionnaire concerning use restrictions in place or recommended, the Finnish CA referred to impregnated wood and timber close to the wells, in contact with food material and drinking water, as well in groundwater protection areas. The other responding CAs referred to the product authorisation scheme as a powerful instrument to control such uses or were not aware of any use restrictions for PT 8.

Health effects associated with wood preservatives:
Several active substances, such as 5-Dichloro-2-octylisothiazol-3(2H)-one, Bifenthrin, Dichlofluanid, Permethrin or Tolylfluanid have a harmonised or notified classification as skin sensitiser. Several Boron containing active substances may damage fertility or the unborn child or are suspected to do so (Cyproconazole, Fenpropimorph, Tebuconazole). Creosote is a known carcinogen (Cat 1, H350) and Bifenthrin and Thiacloprid are suspected of causing cancer (Cat 2, H351).

Hebisch et al. (2009) performed workplace measurements at 13 enterprises for assessing exposure to wood preservative from pressure impregnation plants with aqueous copper salts (partly with chromium) and creosote, hot cold immersions plants with creosote, and steeping with boron containing solutions. Highest exposure was determined during the charging and discharging phase. The exposure to copper was up to 0.0061 mg/m³, that to chromium up to 0.0073 mg / m³, The maximum exposure of PAH from creosote pressure plants was 16.9 mg/m³ (measured at workers level) and 72.5 mg/m³ (measured at impregnation plant level as a worst case assumption). During the placing of the impregnated sleepers on-site a significant lower exposure compared to the impregnation stage was determined (maximum of 1.76 mg/m³ at person level and 6.8 mg/m³ in the surrounding air).

Environmental effects:
Emissions to the environment may occur during the application/treatment phase, during the storage of treated wood before use, and during the service life. In the first period following the preservation procedure, the biocidal active ingredients have to react with the wood constituents to be fixed in the wood. During that period, the risk of leaching by precipitation is highest and thus has to be minimised by storing the treated wood in roof-covered and paved (= impermeable) storage areas. For most preserved wood, the most significant losses to the environment take place during the service life phase. ISO (2007) defines five use classes that represent different service situations to which wood and wood-based products can be exposed: Use class 1 refers to wood under cover and fully protected from the weather, use class 2 to wood fully protected from the weather but under occasional wetting, use class 3 to wood not covered and not in contact with the ground. Wood in use class 4 is in contact with the ground or fresh water and thus is permanently exposed to wetting, while use class 5 refers to wood which is permanently exposed to salt water. The adequate use of treated wood in their respective intended use classes determines the leaching of wood preservatives to water.

Leaching rates for wood preservatives have been determined by Schoknecht et al. (2002, 2004, 2014) both in laboratory and outdoor experiments. Wooden poles treated with Propiconazol were exposed to rainfall and cumulated losses of Propiconazol were found to range between 100 mg/m² and 150 mg/m² within 200 days with rainfall of between 350 L/m² and 400 L/m². This loss corresponds to daily emission rates of 0.4 mg/m² for short poles with a smooth surface and of 0.7 mg/m² for longer poles with a rough surface. In the leaching tests a Propiconazol loss of 0.1 to 6.5 mg/m² per litre of rainwater was observed. The leaching rate for wood preservatives depends mainly on the time required for the fixing process where the wood preservatives react with various constituents within the wood. During that period the risk of leaching by precipitation has to be minimised to ensure the efficacy of the preservation as well as to prevent emissions into the environment. The time necessary to reach a fixation level of 95%

typically is between 2 and 14 days depending on temperature and the active substance concerned (Schoknecht et al., 2003).

The active substances Propiconazol and Tebuconazol also used as wood preservatives have been detected in the effluent of WWTPs in Switzerland (Kahle et al., 2008). Propiconazol has also been included in groundwater monitoring programmes in Germany. The maximum concentration measured in groundwater samples Propiconazol was 1 µg/l. It was, however, not possible to allocate these values to specific emissions sources (Kahle et al., 2009).

Further monitoring data for wood preservatives were collected for the BIOMIK Project (Morf et al., 2007). In Canada, the QAC DDAC-C10 was detected in the Fraser River and downstream from four sawmills where the compound was used as wood preservative. DDAC-C10 concentrations in the sediment ranged from 0.52 mg/g to 1.26 mg/g dry weight with corresponding concentrations in the surface water of 446 µg/l close to the emission sources and <10 µg/l (LOQ) at a distance of 10 m from the emission source, respectively.

The incineration of impregnated wood does not always occur under controlled conditions in licensed thermal treatment plants (as example suggested in the German regulations concerning "used wood"). For example, wood may be burned to heat private homes or in outdoor fires. The control of such incineration would require the preparation of guidance intended for the general public.

The contribution of wood preservative to measured environmental concentrations is difficult to assess, because of the overlapping with other sources with similar use patterns (façade coatings and renders from PT 7 or 10). While Tebuconazole and Propiconazole are predominantly used in wood protection Terbutryn and Carbendazim are used in paints and renders. A mass balance in an urban catchment area reveled that constantly emitted biocides such as Terbutryn, Carbendazim, Isoproturon, Diuron, Tebuconazole, Propiconazole, and Mecoprop[3] are detected in most samples. These compounds are released from buildings and mainly released during stormwater events to the environment (Bollmann et al. 2014).

Best practices:
There are several good and best practices for wood protection and the application of wood preservatives. Some examples are:

- DIN EN 350-1 and 2 (1994): Durability of wood and wood-based products. Part 1: Natural durability of solid wood. Guide to the principles of testing and classification of natural durability of wood. Part 2: Guide to natural durability and treatability of selected wood species of importance in Europe
- DIN 68800: Protection of timber, Part 1-4 (2001-2012)
- TRGS 618 (1997): Ersatzstoffe und Verwendungsbeschränkungen für Chrom(VI)-haltige Holzschutzmittel
- TRGS 512 (2012): Fumigations.
- TRGS 523 (2003): Pest control using highly toxic, toxic and health hazardous substances and preparations.
- BREF Surface Treatment using Organic Solvents" (2007), Chapter 18: Wood Preservation
- CEN/TR 15003; DIN SPEC 68001 (2012): Durability of wood and wood-based products - Criteria for hot air processes for curative uses against wood destroying organisms (technical report).
- European Wood Protection Association (2011): Timber Treatment Installations – Code of Practice for Safe Design and Operation.

[3] Mecoprop, mainly used as a herbicide for roof protection is not supported under BPR.

- Wood and Tree Fungi: Biology, Damage, Protection, and Use (Schmidt 2006)
- Wood Preservation (Richardson 2002)
- Wood preservation with chemicals: Best Available Techniques (BAT) (Salminen et al 2014)

Under the Industrial Emissions Directive 2010/75/EU work has started for developing a BREF on "Wood and Wood Products Preservation with Chemicals".

Occupational insurance associations also provide useful information on safe use of wood preservatives. For dipping tanks the following technical safety measures are indicated: use of pumps for dosing the concentrate, use of water pipes which do not end in the working solution for filling, mixing through up and down movement of wood packages and not through compressed air. Freshly impregnated wood must be held by the fork lift truck above the dipping tank as long as liquid drips down. Afterwards the treated wood must be protected from weathering until the fixation time is completed. Special attention is given to the use of chromate as fixation agent (may not be used in dipping tanks) and solvent based wood preservatives (also because of the risk of fire and explosion) (Holz-Berufsgenossenschaft 2009).

Substitution by biocide-free alternatives:
The BPR (Article 17(5)) requires the proper use of biocidal products, which implies the rational application of a combination of physical, biological, chemical or other measures. The use of biocidal products should be limited to the minimum necessary and appropriate precautionary steps are taken. Examples are the application of hot air for curative treatment against wood-destroying insects for which a Blue Angel ecolabel exists (RAL-UZ 57) or the use of "weather resistant wood products" for which ecolabels have also been established by the Nordic Swan of the Austrian ecolabel. Wood may also undergo physical-chemical treatment (thermal modification of wood or acetylation) to improve resistance to weathering or insects.[4]

For wood in use class 1 not exposed to weathering and mechanically protected against insects no wood preservatives at all are required by the German standard DIN 68800. The main option for reducing the amount of wood preservatives is to apply construction rules such as considering an appropriate roof overhang.

Identified risks and risk mitigation measures proposed:
The risk mitigation measures proposed for biocidal products of PT 8 have been evaluated in a research project on behalf of the German Environment Agency (Gartiser et al. 2011).

The Inclusion Directives for active substances describe different risk mitigation measures which shall be considered during the authorisation of biocidal products:

- For industrial or professional users safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment if necessary (e.g. DDAC, Dazomet).
- Not to be authorised for industrial treatment by dipping or spraying of wood that will be exposed to weathering (e.g. Cypermethrin).
- User restriction of the fumigants such as sulfuryl fluoride or hydrogen cyanide to trained professionals and of K-HDO to industrial operators.
- Restriction K-HDO as wood preservative to industrial use in fully automated and closed equipment.
- Restriction of use for the treatment of wood that may enter in direct contact with infants (e.g. K-HDO).

[4] E.g. http://www.lunawood.fi/en/thermowood-ecological-wood-material/

- No in-situ treatment of wood outdoors with Boric acid, Propiconazole, Tebuconazole, or Tolylfluanid.
- Restriction of the use class for wood in continuous contact with water or weathering (e.g. Boric acid, Propiconazole, Clothianidin, Tebuconazole, Tolylfluanid).
- Not to be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions near or above water, continually exposed to the weather or subject to frequent wetting (e.g. DDAC, ADBAC).
- Restriction of in situ treatment of wooden structures near water, where direct losses to the aquatic compartment cannot be prevented, or for wood that will be in contact with surface water (e.g. Thiacloprid).
- Storage of timber freshly treated with wood preservatives under shelter or on impermeable hard standing to prevent direct losses to soil or water (most wood preservatives).
- Use of appropriate personal protective equipment for reducing human exposure through industrial and/or professional use (most wood preservatives).
- Appropriate risk mitigation measures for operators and bystanders exposed to the fumigants (e.g. Sulfuryl fluoride).
- Collection of any losses of wood preservative for reuse or disposal (most wood preservatives).
- Use of a topcoat to reduce emissions during their service has been challenged in some CARs. However, the effectiveness of this RMM has been questioned because the wooden structure may change under weathering.

These risk mitigation measure are often subject to the clause "unless data is submitted to demonstrate that the product will meet the requirements."

The use of personal protective equipment (PPE) for reducing exposure and ensuring the safe use of the product is not considered acceptable for non-professional users. While spraying of wood preservatives by amateur users is not allowed in many Member States, most CAs suggest that spraying by non-professional users should not be allowed if the exposure resulted in the need to use PPE. The use of water soluble packaging for wood preservative concentrates has been suggested for avoiding exposure during the filling and loading phase (Gartiser 2011, 2012).

Conclusion

For many PT 8 active substances risks to human health and the environment have been identified, which require appropriate risk mitigation measures that may be difficult to control.

- Safe operational procedures shall be established for most wood preservatives used in industrial plants. This demands for developing best practices and education and training.
- Several active substances (e.g. Bifenthrin, Dichlofluanid, Permethrin, Tolylfluanid have a harmonised or notified classification as skin sensitiser
- Several inorganic Boron containing compounds may damage fertility or the unborn child (reproductive toxicity Cat 1, H360) or are suspected to act so (Cyproconazole, Fenpropimorph, Tebuconazole, reproductive toxicity Cat. 2, H361).
- Creosote is a known carcinogen (Cat 1, H350) and Bifenthrin and Thiacloprid are suspected of causing cancer (Cat 2, H351).
- Half of the PT 8 active substances are classified in aquatic chronic 1.
- Cypermethrin and Terbutryn are priority substances under the WFD.
- For most preserved wood, the most significant losses to the environment take place during the service life phase. Several risk mitigation measures have been proposed to reduce risks to the environment. The adequate use of treated wood in

their respective intended use classes determines the leaching of wood preservatives to water next to the use of top coats. For some active substances their use for outdoor constructions near or above water is not allowed.

- Impregnated wood becomes a treated article whose marketing and use in construction will not easily be controllable. The labelling of treated articles directly relates to the use phase of impregnated wood. While the provisions of the BPR on treated articles certainly improves the situation especially for treated wood imported, the market surveillance is challenging.
- Next to the service life also the end of life phase may significantly contribute to the overall emissions to the environment (e.g. incineration of treated wood).

These points demand for further measures to be implemented to ensure a sustainable use of PT 8 active substances.

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Product Type 18 – Insecticides, acaricides, and products to control other arthropods

Introduction

Biocidal products of PT 18 are mainly used indoors to control arthropod pests such as cockroaches, pharaoh ants, termites, fleas, spiders, dust mites, or bed bugs. Outdoor uses for the control of wasps and hornets (the last being considered protected animals) are less common. Large or local scale mosquito control through the treatment of water bodies with larvicides and the control of the oak procession moths are further examples for outdoor applications. Insecticides used in animal housing and manure storage systems are closely linked to veterinary hygiene biocidal products (PT 3). Products used for the control of external parasites of humans and animals are medicinal products. Manure-breeding flies are controlled by larvicides and/or adulticides. Other insects and arthropods cause serious problems in animal breeding such as e.g. bloodsucking flies, lice, mites (acarids), louse flies, fleas, and cattle crubs.

A case study on sustainable use of insecticides has been carried out in a research project that aims at analysing options for transferring elements of the Directive on sustainable use of plant protection products to the biocide field (Gartiser et al. 2012).

Uses:

Product type 18 covers professional and non-professional users. Household insecticides are mainly applied by consumers. Professional users such as house caretakers, building cleaning professionals, or farmers may have some background on pest control from their professional education. Specifically trained professionals and/or certified professionals are used to apply insecticides routinely. To this group belong pest control technicians and applicators which should regularly receive further training.

Agricultural insecticides are used for both the application in animal housings and in manure storage systems (larvicides). Application of manure to soil is considered the main emission route, while some insecticides may also be emitted to sewers and STPs. Non-agriculture insecticides are generally used in or around buildings where the presence of insect pests is unwanted. Insecticides are applied in private houses but also in public buildings, such as hospitals or restaurants. For indoor application to surfaces, insecticides generally do not directly reach environmental compartments. However, surface cleaning will lead to releases either to wastewater or to general waste. Therefore, STPs are considered as one of the main receiving compartments (Gartiser et al. 2012).

Composition and mode of application:

There are several modes of application. Hand-held spray applications via aerosol dispensers or trigger spray are manually applied next to knapsack sprayers. One-shot aerosol cartridges ("foggers") release their entire contents as a fog for space treatments. Dusters are ready-to-use products which distribute powder insecticides through a shaker or rotary pumps. Diffusers consist of a reservoir (e.g. impregnated paper or stick pack) from which the insecticide evaporates passively or via electric vapourising heaters. Smoke generators consist of a mixture of the insecticide with combustible filler. Most fogging devices are exclusively applied by professional users and produce fine insecticide droplets (5 to 30 µm) which are suspended into air for air space treatments. Springling of granulates or smearing with a brush ("brushing") are often applied in animal breeding stables next to gel applicators and baits.

The active substances belong to different chemical groups such as Organophosphates (e.g. Azamethiphos), Neonicotinoids (e.g. Acetamiprid, Clothianidin, Imidacloprid), Carbamates (Bendiocarb), Pyrethroides (e.g. Cypermethrin, Bifenthrin, Cyfluthrin, Deltamethrin) as well as inorganic and organic gases (e.g. carbon dioxide, sulfuryl fluoride, hydrogen cyanide) or phosphine releasing compounds (aluminium phosphide).

In total 27 active substances have been approved so far under the BPR (status 9.1.13):

Substance name	CAS	CLP Excerp
1R-trans phenothrin	26046-85-5	H410
Abamectin	71751-41-2	H361, H410
Aluminium phosphide releasing phosphine	20859-73-8	
Bendiocarb	22781-23-3	H410
Carbon dioxide	124-38-9	
Decanoic acid	334-48-5	
Deltamethrin	52918-63-5	H410
Diflubenzuron	35367-38-5	H410
Fipronil	120068-37-3	H410
Hydrogen cyanide	74-90-8	H410
Imidacloprid	138261-41-3	H410 watch list priority substances WFD
Indoxacarb		
Lambda-cyhalothrin	91465-08-6	H410
Magnesium phosphide releasing phosphine	12057-74-8	
Margosa extract	84696-25-3	
Metofluthrin	240494-71-7	
Nitrogen	7727-37-9	
Octanoic acid	204-677-5	
Permethrin	52645-53-1	H317, H410
Pyriproxyfen	95737-68-1	H410
S-Methoprene	65733-16-6	
Spinosad	168316-95-8	H410
Sulfuryl fluoride	2699-79-8	
Synthetic amorphous silicon dioxide (nano)	112926-00-8	
Thiamethoxam	153719-23-4	H410 watch list priority substances WFD
Transfluthrin	118712-89-3	H410

According to Regulation (EU) No.1062/2014 further 30 active substances are still under review:

Substance name	CAS	CLP Excerp
Piperonyl butoxide/PBO	51-03-6	H410
Geraniol	106-24-1	H317, H410
Sodium dimethylarsinate (Sodium Cacodylate)	124-65-2	H410
Cyanamide	420-04-2	H317
d-Tetramethrin	1166-46-7	H410
Tetramethrin	7696-12-0	H410
Pyrethrins and Pyrethroids	8003-34-7	H410
Prallethrin	23031-36-9	H410
Azamethiphos	35575-96-3	H317, H410
Cyphenothrin	39515-40-7	H410
Cypermethrin	52315-07-8	H410 Priority substance WFD
Empenthrin	54406-48-3	H410
Triflumuron	64628-44-0	H410
Cyromazine	66215-27-8	
Cyfluthrin	68359-37-5	H361, H410
Chrysanthemum cinerariaefolium, ext.	89997-63-7	H410
Hexaflumuron	86479-06-3	H410

Substance name	CAS	CLP Excerp
Imiprothrin	72963-72-5	H317, H361, H410
Clothianidin	210880-92-5	H410 watch list priority substances WFD
Bacillus sphaericus 2362, strain ABTS-1743	143447-72-7	
Bacillus thuringiensis subsp. Israelensis		
d-Phenothrin	188023-86-1	H410
Silicon dioxide (as a nanomaterial)	68909-20-6	
Silicium dioxide (Silicium dioxide/Kieselguhr)	61790-53-2	
d-Allethrin	231937-89-6	H410
Esbiothrin	260359-57-7	H410
Acetamiprid	160430-64-8	Watch list priority substances WFD
Esfenvalerate	66230-04-4	H317, H410
alpha-Cypermethrin	67375-30-8	H410 Priority substance WFD
Chlorfenapyr	122453-73-0	H410

Of these active substances Permethrin, Geraniol, Cyanamide, Azamethiphosand, Imiprothrin, and Esfenvalerate have a harmonised or notified classification as skin sensitiser "may cause an allergic skin reaction" (H317), while Abamectin, Cyfluthrin, and Imiprothrin are suspected of damaging fertility or the unborn child (reproductive toxicity Cat. 2, H361). Further on, most active substances are classified in aquatic chronic 1 "very toxic to aquatic life with long lasting effects" (H410).[5] Article 11 of Directive 2009/128/EC requires Member States to ensure that, when pesticides are used in the vicinity of water bodies, preference is given to products that are not classified as dangerous for the aquatic environment. Cypermethrin is a priority substance under the WFD, while Imidacloprid, Thiamethoxam, Clothianidin, and Acetamiprid are among the substances evaluated for their potential to be included in the 1st watch list for priority substances (Carvalho et al. 2015).

The Biocidal Products Committee submitted the following opinions on PT 18 active substance approval:

For alpha-Cypermethrin (CAS 67375-30-8) when considering human health, acceptable risks were only identified for professional users when wearing protective clothing (at least overalls and protective gloves). With respect to the environment, the use of alpha-Cypermethrin is not deemed safe as total surface application or barrier application even when restricting the use to 1 to 2 applications per year. Crack and crevice treatment can only be considered acceptable when taking into account a restriction of 1 to 2 applications per year. Cypermethrin (including the isomer alpha-Cypermethrin) is introduced as a priority substance within the Water Framework Directive (WFD) in Directive 2013/39/EU amends Directive 2000/60/EC and Directive 2008/105/EC. An annual average environmental quality standard (AA-EQS) of s 8 x 10^{-8} mg/l and a maximum allowable environmental quality standard (MAC-EQS) of 6 x 10^{-7} mg/l have been derived. No monitoring data for this substance are available. Among the elements to be taken into account when authorising products a label restriction of the use of biocidal products containing alpha-Cypermethrin in a sensitive area (hospital, kitchens, restaurants, food-processing and storage areas) is required to avoid residue contamination of food (e.g. "Do not contaminate foodstuffs, eating utensils or food contact surfaces"; "Keep away from food, drink and animal feeding stuffs").

[5] The classification in further human health hazards or environmental hazard phrases H411-H413 are not documented in these tables.

Bacillus sphaericus is used as a biological larvicide specific to the larvae of mosquito larvae (like Culex spp. and Anopheles spp.) and should be applied during the 1st to the early larval stages. Treatment is restricted to a maximum of 5 treatments per season. The occurrence of resistance has been reported in a field study. Considering that all microbials should be regarded as potential sensitisers the statement "Microorganisms may have the potential to provoke sensitising reactions" should be placed on the label. Further on, resistance management measures should be included in the authorisation.

Bacillus thuringiensis is a larvicide intended for both professional and non-professional use for the control of mosquito and black fly larvae in aquatic breeding habitats and filter fly midges in sewage treatment plants. Treatment is restricted to a maximum of 5 treatments per season. In the laboratory, resistance to individual toxins has been observed, but not to whole cultures of Bti. Considering that all microbials should be regarded as potential sensitisers the statement "Microorganisms may have the potential to provoke sensitising reactions" should be placed on the label. Further on, resistance management measures should be included in the authorisation.

Clothianidin (CAS 210880-92-5) fulfils the criteria for being a very persistent (vP) toxic substance, but is not bioaccumulative and thus does not meet the criteria for being a PBT pollutant. However, Clothianidin is considered a candidate for substitution in accordance with Article 10 of the BPR (two of three PBT criteria met). The potential resistance of target insects to Clothianidin should be considered by developing resistance management measure. As Clothianidin is a neonicotinoid, special attention needs to be paid to bees at the product authorisation stage especially when outdoor uses are envisaged.

Also dinotefuran (CAS 165252-70-0), another neonicotinoid being vP and toxic is being considered a candidate for substitution.

Permethrin (CAS 52645-53-1): The possibility of skin sensitisation should be addressed at product authorisation, since the active substances is classified as a potential sensitiser. The aquatic compartment should specifically be taken into account and direct emissions via drains to water bodies or indirectly via a sewage treatment plant must be avoided. Application solutions shall be collected and re-used or disposed as hazardous waste and Member States shall ensure that these risk mitigation measures are practical.

Use restrictions:
The Water Framework Directive (WFD) 2000/60/EC sets environmental standards for priority substances. The establishment of drinking water protection zones for pesticides applies for both plant protection products and biocidal products. The restriction of the use to indoor crack and crevices treatment that are inaccessible to cleaning has been mentioned in some CARs as RMM. Also the minimisation of the potential exposure of humans, of non-target species and of the aquatic environment has been challenged by avoiding drainage and runoff of biocides as well as by ensuring proper disposal of unused products. There are few examples of direct applications to water bodies (e.g. mosquito control and liquid manure) which should be carefully examined. For indoor treatment, the conflicting recommendation concerning the cleaning of surfaces from a human health and environmental point of view should be examined by European experts.

In Germany, *Bacillus thuringensis* toxins for mosquito control may be applied in natural habitats for wild fauna and flora (Natura 2000) by aerial application of ice granulates or manual spraying after approval by local authorities (Gartiser et al. 2012). In contrast, the use of plant protection products for the control of oak procession moths in Natura 2000 sites is not allowed. The biocidal control of oak procession moths near human habitats for human health reasons (skin irritation through contact with hairs) is only allowed as last resort, when alternative measures, such as the establishment of access exclusion zones or vacuum removing of crawlers and nests, are not feasible. When the use of biocides cannot be omitted, the use of the biological agent based on *Bacillus thuringiensis kurstaki*, which specifically acts against larva stages, should be preferred. Depending on the active substances used, minimum distances to surface waters and nature conservation areas of 25 m to 100 m have been suggested (Anonymous 2014).

The replies of the Competent Authorities to the questionnaire do not specifically refer to use restrictions of PT 18 biocidal products, but more generally state that permission for the use of pesticides in certain areas, such as around apartment buildings, school yards, play grounds and water protection areas is required (Sweden). In the United Kingdom, the CA consider generalised prohibitions and restrictions as not appropriate, since the active substance approval and product authorisation is powerful enough to control uses where necessary. Another CA stated that the REACH Annex XVII on the restriction uses of certain dangerous substances is applied to restrict and prohibit the use of certain biocides and their treated articles in certain areas (Ireland).

Health effects associated with insecticides:
Several active substances, such as Permethrin, Geraniol, Cyanamide, Azamethiphosand, Imiprothrin, and Esfenvalerate have a harmonised or notified classification as skin sensitiser. The biological agents such as *Bacillus thuringiensis* or *Bacillus sphaericus are also suspected* to act as sensitiser. Other active substances (Abamectin, Cyfluthrin, and Imiprothrin) are suspected of damaging fertility or the unborn child.

In Germany, professional pest controllers are subjected to accident insurance and health prevention memberships. Experts of these insurance and health prevention associations gathered information on PT 18 ingredients of biocide products. The evaluation of around 185 biocidal products revealed that products against arthropods are classified as harmful or toxic for human health, especially those applied as sprays. For fogging products containing the solvent Dichoromethane (CAS 75-09-2), which has a harmonised classification as suspected for causing cancer (category 2, H351) (Eickmann et al. 2008). However, several identified hazardous active ingredients, such as Chlorpyrifos of Dichlorphos, are not supported under the BPR and meanwhile have been removed from the market.

Within two research projects on behalf of the German Federal Institute for Occupational Safety and Health dermal and exhalative exposure was estimated quantitatively for typical scenarios and activities of professional users of PT 18 products. The focus was set on spray applications of unspecialised professional users, pest controllers, and farmers. The results showed that the users are exposed with relevant amounts of PT 18 depending on the application machinery and the personal protection equipment used (Koch et al. 2004, Schneider et al. 2008). The risk to human health from pest control products is mainly based on the toxicological properties of their active substances, the coformulants being of less concern. Regarding intoxications through insecticides, the group of Pyrethroids is of particular importance next to fumigants containing Phosphane releasing metal Phosphides, Hydrogen cyanide, or Sulfuryl difluoride. A short literature review performed by Pieper et al. (2014) revealed several case description of intoxications resulting from the use of Pyrethroids and of fumigants. Household insecticides used in the form of bait boxes, powders or liquid preparations to control crawling insects and in the form of sprays and evaporators to control flying insects most commonly belong to categories of Pyrethroids (e.g., Tetramethrin, Allethrin, Prallethrin, etc.) and Organophosphates (e.g., Chlorpyrifos, Cichlorvos, Phoxim, etc.).[6] The margins of exposure were considerably lower (indicating higher risks) for the Organophosphates than for the Pyrethroids (Hahn et al. 2009). Exposure from use of commercially available insect sprays, following 10 seconds of application, resulted in an inhalation intake of 2–60 µg for several active substances (Berger-Preiß et al. (2009). These

[6] These organophosphates are not supported under the BPR and have been removed from the market.

exposure data have still not been quantitatively linked with hazard data for a risk assessment.

In private homes, the application of insecticides by consumers and the residential exposure of bystander to insecticides are relevant points. Therefore, private homes could be considered as a “sensitive area” per se. For example, metabolites of Pyrethroides resulting from pest control uses, preservation of wool carpets, or ant-flea treatment of pets are routinely found in the urine of private home habitants (reference values for selected metabolites are in the range of 1-2 µg/l, Anonymous 2005). Krieger et al. (2001) analysed different exposure sources of Chlorpyrifos pesticides used indoors via fogger, spray and crack-and-crevice treatments (meanwhile Chlorpyrifos has been removed from the market for biocidal uses). In the German Environmental Survey of Children, several biocides have been analysed in the 63 µm dust fraction. Despite the fact that Pentachlorophenol (PCP), DDT and Lindane have been banned, they are still present in house dust samples of households. Chlorpyrifos and Methoxychlor were quantifiable in 32% and 24% of the samples, respectively (Müssig-Zufika et al., 2008).

Environmental effects:
Insecticides are rarely detected in surface water and thus there are few monitoring data. However, it is known from several studies, that pesticide losses from urban areas may exceed that from agricultural areas, especially when considering insecticides (Hoffmann et al. 2000).

For Cypermethrin, an environmental quality standard (EQS) of 0.08 ng/l has been stated in Directive 2013/39/EU amending Directive 2008/105/EC on priority substances in the field of water policy. In a study of the Sacramento-San Joaquin Delta in USA, the maximum concentrations from the outflow of WWTP were reported as 12.3 ng/l Cypermethrin. Other concentrations found in the same study were 3.5 ng/l Deltamethrin, 4.3 ng/l Esfenvalerate (4.3 ng/l), Fenpropathrin (6.1 ng/l), 3.5 ng/l Lambda-cyhalothrin, and 45.8 ng/l Permethrin (Weston et al. 2010). Only about 6% of the total load of Pyrethroids measured in the outflow of STP is dissolved in water, the main fraction being adsorbed to particles (Parry et al. 2013). Although for Permethrin removal efficiencies in STP were reported to be between 84% and 99%, discharges from STP may not be within the permitted limits (EQS of 10 ng/l in UK) if the plant has limited dilution (Parry et al. 2013). However, the contribution of biocidal uses is not easily to estimate, Permethrin covering a broad range of non-agricultural uses, such as mothproofing in the textile and carpet manufacturing, wood preservative, veterinary and human pharmaceutical against fleas in dogs and head lice and scabies in children (Turner et al., 2011). Thus, it is not possible to determine if the indoor Pyrethroid use is sufficient to account for all residue found in wastewater. However, a single fogger in just 1 out of 700 homes would account for an average daily load of Cypermethrine in wastewater from residential areas if only 2% of the foggers content were drain disposed (Weston et al. 2013). A study performed in Denmark on the occurrence of the recently established new priority substances revealed that Cypermethrine concentrations in freshwater were below the detection limits of 0.4 ng L^{-1} (Vorkamp et al. 2014).

Best practices:
There are several good and best practices and integrated pest management (IPM) for the control of arthropods which have been summarised by Gartiser et al. (2011). Some examples are

- WHO 2008 Public Health Significance of Urban Pests (Bonnefoy et al. 2008)
- Handbuch für den Schädlingsbekämpfer (Karg 2014)
- Mosquitoes and Their Control (Becker et al. 2010)
- Malis Handbook of Pest Control (Malis et al. 2011)
- Complete Guide to Pest Control with and without Chemicals (Ware 2005)

- Pesticide Applicator Core Training Manual - Certification, Recertification and Registered Technician Training - Part A: Required reading for: Private pesticide applicators, Commercial pesticide applicators, Registered technicians
- Healthy Hospitals - Controlling Pests Without Harmful Pesticides (Owens 2003)
- Health and Safety Agency for Northern Ireland (1995). The Safe Use of Pesticides for Non-agricultural Purposes. Approved Code of Practice.
- Draft EN 16636 Pest management services - Requirements and Competences (2013)

Substitution by biocide-free alternatives:
The BPR (Article 17(5)) requires the proper use of biocidal products, which implies the rational application of a combination of physical, biological, chemical or other measures. The use of biocidal products should be limited to the minimum necessary and appropriate precautionary steps are taken. The implementation of IPM also covers these obligations.

In Germany, the eco-label RAL-UZ 34 on non-toxic indoor pest control and prevention applies for non-toxic measures and methods for preventing or killing harmful arthropods and rodents indoors. Electroacoustic systems for the control (expulsion) of pests are excluded. Biocides must not be used, except the fumigants nitrogen and carbon dioxide. The proof of efficacy (usability) of the measures and methods must be evaluated by an accredited laboratory. Currently, there is a large deficit in the capacity to evaluate the efficacy according to RAL-UZ 34 due to the lack of appropriate laboratories. No other existing Ecolabel considering PT 18 pest control are known (Gartiser et al. 2014).

Identified risks and risk mitigation measures proposed:
The risk mitigation measures proposed for biocidal products of PT 18 have been evaluated in a research project on behalf of the German Environment Agency (Gartiser et al. 2011).

The Directives for insecticidal active substances and (draft) CARs refer to the use restrictions for fumigants to specifically trained professionals while applying appropriate personal and respiratory protective equipment. Phosphine releasing compounds may only be applied by professionals in the form of ready-to-use products. The use of applicators may be a measure to reduce risks. Additional RMM are the information of potential bystander and the removal of food before application, the keeping of waiting periods which ensure compliance with the Maximum Residue levels (MRLs) on food and feed allowed and the proper disposal of unused products. The minimisation of exposure of insecticides to humans, to non-target species and to the aquatic environment has been challenged. For example, products shall be positioned away from external drains and unused products shall be disposed properly and not washed down the drain. The CARs also describe restriction of the application areas such as only indoor use in crack and crevices or in concealed locations inaccessible to man and domestic animals for avoiding secondary exposure. Other RMM concern the restriction of use in animal housings to those without an effluent to the sewer system or direct release to surface water.

In March 2014, a project on the harmonisation of RMM of PT 18 biocides started by initiative of the French authorities, which aims categorising general RMM (good practices) and specific RMM (applicable if a risk is identified) next to elaborating a guidance similar to those RMM guidance for PT 14 and PT 1-5. The project was intended to be completed by November 2014, but no results are available so far (CA-March14-Doc.5.10)

Conclusion

For some PT 18 active substances risks to human health and the environment have been identified, which require appropriate risk mitigation measures that may be difficult to control.

- For some active substances, such as alpha-Cypermethrin, acceptable risks for professional users are only achieved when wearing protective clothing.
- The environmental risks of some active substances, such as alpha-Cypermethrin, require a restriction of the application frequency for total surface treatment or barrier application or crack and crevice treatment to 1 to 2 applications per year, which is difficult to control.
- Alpha-Cypermethrin is a priority substance of water policy for which a phasing out of discharges, emissions and losses is envisaged.
- A label restriction of the use of alpha-Cypermethrin in sensitive areas, such as hospitals, kitchens, restaurants, food-processing and storage areas is required to avoid residue contamination of food.
- The neonicotinoids Clothianidin (CAS 210880-92-5) and Dinotefuran CAS 165252-70-0) fulfil two of the PBT criteria and thus are considered candidates for substitution in accordance with Article 10 of the BPR. For both being neonicotinoids, special attention needs to be paid to bees at the product authorisation especially when outdoor uses are envisaged.
- Several active substances, such Permethrin, Geraniol, Cyanamide, Azamethiphosand, Imiprothrin, and Esfenvalerate next to the biological agents such as *Bacillus thuringiensis* or *Bacillus sphaericus.*have a harmonised, notified or suspected classification as skin sensitiser. Other active substances (Abamectin, Cyfluthrin, and Imiprothrin) are suspected of damaging fertility or the unborn child.

These points demand for further measures to be implemented to ensure a sustainable use of PT 18 active substances.

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Product Type 19: Repellents and attractants

Introduction

Biocidal products of PT 19 are used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals. Several of the actives are naturally occurring substances such as oils and extracts. For some actives such as Decanoic acid or Geraniol, both being approved for PT 18 and PT19, there is a fluent transition from the repellent to the insecticidal effect.

Uses:
The product type 18 covers professional and non-professional users. The application to children is of specific concern.

Composition and mode of application:
Repellents are used as aerosols, pump sprays, creams, and moistened paper or cloth. Products may be designed to be applied to the exposed skin and thus dermal absorption may be important. Repellents are also used in treated articles such as clothes or mosquitos nets intentionally incorporating an insect repellent. Whether such a product is a biocidal product or a treated article depends on whether the biocidal function is primary (see below) or not.[7] Further on, there are products with cosmetic purpose, which serve an equally important biocidal purpose such as insect repellent sunscreens. These products are regulated by the cosmetics and by the biocides legislation.[8]

In total 8 active substances have been approved so far under the BPR (status 9.1.15):

Substance name	CAS	CLP Excerp
(Z,E)-tetradeca-9,12-dienyl acetate	30507-70-1	
Cis-tricos-9-ene (Muscalure) (pheromone attractant against flies)	27519-02-4	H317
Decanoic acid	334-48-5	H412
Ethyl butylacetylaminopropionate (IR 3535®)	52304-36-6	H317
Lauric acid	143-07-7	H412
Methyl nonyl ketone	112-12-9	H410
N,N-diethyl-meta-toluamide (DEET)	134-62-3	H412
Nonanoic acid, Pelargonic acid	112-05-0	

According to Regulation (EU) No.1062/2014 further 7 active substances are still under review:

Substance name	CAS	CLP Excerp
Geraniol	106-24-1	H317, H410
Carbon dioxide	124-38-9	
Pyrethrins and Pyrethroids	8003-34-7	H410
Mixture of cis- and trans-p-menthane-3,8 diol (Citriodiol)	42822-86-6	H317, H412
Margosa extract	84696-25-3	
Lavender, Lavandula hybrida, ext./Lavandin oil	91722-69-9	H317, H411
sec-butyl 2-(2-hydroxyethyl)piperidine-1-carboxylate/Icaridine (Icaridine)	119515-38-7	

Of these active substances Cis-tricos-9-ene, Ethyl butylacetylaminopropionate, Geraniol, Citriodiol, and Lavender have a notified classification as skin sensitiser "may cause an

[7] Note for Guidance: Frequently asked questions on treated articles. CA-Sept13-Doc.5.1.e
[8] Note for Guidance: Borderline between the legislation for cosmetics and biocides. CA-Jul13-Doc.5.1.h

allergic skin reaction" (H317). Further on, Methyl nonyl ketone, Geraniol, and Pyrethrins/Pyrethroids are classified in aquatic chronic 1 "very toxic to aquatic life with long lasting effects" (H410).[9] Article 11 of Directive 2009/128/EC requires MS to ensure that, when pesticides are used in the vicinity of water bodies, preference is given to products that are not classified as dangerous for the aquatic environment.

The Biocidal Products Committee has still not submitted opinions on PT 19 active substances. The evaluation of the CARs revealed the following provisions for product authorisation:

<u>Cis-Tricos-9-ene:</u> For products that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels. No comprehensive environmental risk assessment was carried out since only indoor use was considered and exposure to all environmental compartments is considered to be insignificant. Products with active substance concentrations leading to classification as skin sensitising (≥1%w/w) must not be put on the market for general public use.

<u>Ethyl buthylacetylaminopropionat</u>: The product must not be applied to children's hands. Direct emissions to surface water by swimmers should be assessed during product authorisation. Recommendation on ventilation or avoiding breathing in spray must be included in product labels for sprays.

<u>Decanoic acid:</u> The CAR covers both PT 18 and PT 19 uses. With reference to repellents general strategies to monitor and manage resistance development are required for product authorisation. If the evaluation at product authorisation stage indicates risk for eye irritation risk mitigation measures such as avoidance of spray application, labelling with "not for use on children" may be considered. Any potential for direct exposure to surface water as a consequence of swimming etc. has not been assessed. For product authorisation information on the degradation rates in a waste water treatment plant (preferably by monitoring influent and effluent concentrations or by means of simulations tests) is required.

<u>Lauric acid:</u> Proposed classification as acute toxic to aquatic life (cat. 1). Therefore, it cannot be proposed to be included in category 6 of Annex I of the BPR. As soon as the new ESD for PT 19 is endorsed at EU level, the direct emission pathway to surface water should be considered in the environmental risk assessment when relevant.

<u>Methyl nonyl ketone:</u> Restriction to indoor application by nonprofessional users, unless data allow the assessment of other uses. A warning statement should be added to the label that the biocidal product should not be used on areas where food is prepared, stored or consumed.

<u>N,N-diethyl-meta-toluamide (DEET):</u> Primary exposure of humans shall be minimized by instructions for the amount and frequency of application of the product on human skin. Exposure in children < 12 should be reduced: no use in children < 2 years, reducing the extent of use in children < 12 years by recommendations on maximum area to be applied, unsuitable exposure areas (i.e. hands, and around eyes and mouth), and on maximum daily number of applications. In the specific case of areas of high risk to the general population from insect borne diseases, conditions of authorisation allowing reducing the restrictions may be considered only after a thorough consideration of the possible risks from using the product compared with the possible benefits in limiting the effects of the insect borne-disease. MS should pay particular attention to skin irritative properties of products during product authorisation. Member States may need to consider inclusion of DEET in national programs for monitoring groundwater. Any

[9] The classification in further human health hazards or environmental hazard phrases H411-H413 are not documented in these tables.

potential for direct exposure to surface water as a consequence of swimming etc. has not been assessed. Available monitoring data from The Netherlands for a few samples (3 out of 189 samples) indicated concentrations above the drinking water limit (0.1 µg/l, but the accuracy of these results could not be evaluated.

Nonanoic acid, Pelargonic acid: No special provisions are required.

(Z,E)-Tetradeca-9,12-dienyl acetate: Because of lacking residue studies the biocidal product should only be applied where food and feed-stuff is stored in closed or re-closed package. No comprehensive environmental risk assessment was carried out since only indoor use was considered and exposure to all environmental compartments is considered to be insignificant.

Use restrictions:
There are no use restrictions known except the risk mitigation measures to reduce exposure of DEET to children (see above).

Health effects associated with repellents and attractants:
Several active substances, such as Cis-tricos-9-ene, Ethyl butylacetylaminopropionate, Geraniol, Citriodiol, and Lavender have a notified classification as skin sensitiser. Because repellents may be directly applied to skin, dermal absorption is an important aspect of risk assessment for human health. Faulde et al. (2001) recommend the following application restrictions for DEET: maximum concentration for adults 30% and for children aged 5-7 years 5%. Large-scale application of more than 20% of the body-surface should be avoided. Not to be used in pregnant women or nursing mothers.
Health risks from the application of repellents should also be assessed against the risk resulting from vector-born diseases transmitted by mosquitos, ticks and fleas.

Environmental effects:
No environmental emission scenario is available for PT 19 biocides. PT 19 biocides are also used within areas used for animal housing. Thus, exposure via drinking water or feeding stuffs should be assessed according to the data requirements. For some actives such as Lauric acid exposure to surface water should be considered during product authorisation, for others such as cis-Tricos-9-ene an environmental risk assessment is deemed unnecessary because only indoor use are intended.

Within literature on micro-pollutants the insect repellent DEET is regularly reported in effluents from sewage treatment plants and surface water (van Beelen 2007). In the inflow and outflow of a WWTP in Hamburg concentrations of 210 ng/l and 130 ng/l, respectively, have been detected, indicating that DEET is not effectively removed during wastewater treatment (Weigel et al., 2004). In a US study on the persistence of organic wastewater contaminants the occurrence and fate of 106 organic wastewater-related contaminants during drinking water treatment was assessed. DEET has been detected in stream and raw water samples (Stackelberg et al., 2004). In an EU-wide monitoring survey of wastewater treatment plant effluents a maximum DEET concentration of 15.8 µg/l was determined. The median concentration of 196 ng/l identifies DEET as an emerging polar organic contaminant in wastewater treatment plants. Similar values were also reported from Swiss studies (Loos et al. 2013).

Best practices:
Several good and best practices and integrated pest management (IPM) for the control of arthropods by PT 18 biocidal products partly also cover repellents of PT 19. Some examples are

- Insect Repellents: Reducing Insect Bites (US EPA)[10]
- Safety tips on using personal insect repellents (Health Canada 2003)
- WHO 2008 Public Health Significance of Urban Pests (Bonnefoy et al. 2008)
- Mosquitoes and Their Control (Becker et al. 2010)
- Mallis Handbook of Pest Control (Mallis et al. 2011)
- Pesticide Applicator Core Training Manual - Certification, Recertification and Registered Technician Training - Part A: Required reading for: Private pesticide applicators, Commercial pesticide applicators, Registered technicians
- Draft EN 16636 Pest management services - Requirements and Competences (2013)

Industry offers information on proper application of DEET, the active ingredient most widely applied as insect repellents.[11] In the USA concentrations ranges from 5% to 100 DEET are marketed. The 5% product lasts 60-90 minutes, while a 30 percent product lasts 5-6 hours. Using separate sunscreen and repellent products may reduce the effectiveness of either or both. Thus, the repellent should be applied first. Once it dries on the skin, sunscreen may be applied. The following advice is given:
"Do not randomly spray repellent around your child. Instead, apply it to your hands, then smooth it evenly onto your child's exposed skin. There's no need to apply beneath clothing. Do not apply repellent to your child's mouth, hands or eyes. Keep repellents out of the reach of young children. Do not assume that insects are not biting your children just because they are not biting you. You may need to reapply repellent to your youngsters, as needed. Always check children for ticks and insect bites after time spent outdoors. Apply repellent sparingly and take additional preventative measures."

Further on some recommendation on how to reduce the incidence of insect and tick bites such as "avoid heavily wooded, high-grass areas", "dress in light-coloured clothes", or "wear collared, long-sleeved shirts and long pants with cuffs" are given.

Substitution by biocide-free alternatives:
The BPR (Article 17(5)) requires the proper use of biocidal products, which implies the rational application of a combination of physical, biological, chemical or other measures. The use of biocidal products should be limited to the minimum necessary and appropriate precautionary steps are taken. Precautionary measures such as using mosquito nets or wearing long-sleeved shirts and long pants might be considered as biocidal-free alternative.

Identified risks and risk mitigation measures proposed:
For some active substances the (draft) CARs refer to their potential of being skin sensitisers. Other active substances such as Ethyl buthylacetylaminopropionat or DEET should not or only carefully be applied to children. DEET has also been identified as emerging polar contaminant in the outflow of sewage treatment plants and should be included in routine monitoring programmes.

The following risk mitigation measures for the use of repellents have been recommended by the US EPA: [12]

- Apply repellents only to exposed skin and/or clothing. Do not use under clothing.
- Do not apply near eyes and mouth, and apply sparingly around ears.
- When using sprays, do not spray directly into face; spray on hands first and then apply to face.
- Never use repellents over cuts, wounds, or irritated skin. Do not spray in enclosed areas.

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[10] http://www2.epa.gov/insect-repellents
[11] http://www.deetonline.org/
[12] http://www2.epa.gov/insect-repellents/using-insect-repellents-safely-and-effectively

- Avoid breathing a spray product.
- Do not use it near food.
- After returning indoors, wash treated skin and clothes with soap and water.
- Do not use any product on pets or other animals unless the label clearly states it is for animals.

No suitable risk mitigation measures for the environment have been proposed so far.

Conclusion

For some PT 19 active substances hazards to human health have been identified, which require appropriate risk mitigation measures that may be difficult to control.

- Some active substances, such as Cis-tricos-9-ene, Ethyl butylacetylaminopropionate, Geraniol, Citriodiol, and Lavender have a notified classification as skin sensitiser. Products classified as skin sentisizer should not be marketed to the general public.
- The environmental hazard of some active substances, such as Methyl nonyl ketone, Geraniol, and Pyrethrins/Pyrethroids (classified as H410) under the SUD requires that direct exposure to water should be avoided by giving preference to products that are not classified as dangerous for the aquatic environment. This may not be relevant for active substances exclusively applied indoors such as cis-Tricos-9-ene, although a cleaning step, as for indoor uses of PT 18 products, cannot be disregarded. No exposure scenario document has been elaborated for PT 19 biocidal products so far.
- Products containing e.g. Ethyl buthylacetylaminopropionat may require use restrictions such as "not to be applied to children's hands" or "avoid breathing spray".
- For Decanoic acid applied both for PT 18 and PT 19 a general strategy to monitor and manage resistance development has been demanded for.
- The application of DEET requires limitation of primary exposure to human skin, especially for children (restriction of concentration, treated area and frequency). DEET should not be applied at all to children below 2 years. DEET has been identified as an emerging polar contaminant, as it is regularly detected in the outflow of municipal treatment plants.

Although PT 19 biocidal products do not seem to present a priority product type, further measures to ensure a sustainable use of PT 19 biocidal products certainly would help to consider these points.

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Product Type 21 – Antifouling Products

Introduction

Antifouling products are used to prevent surfaces from unwanted growth and settlement of fouling organisms. Target organisms are all microbes and higher forms of plant or animal species, micro- and macro-organisms (bacteria, algae and crustaceans) in seawater and freshwater that may settle on ship hulls and other surfaces. Fouling in general is unwanted, as e.g. increased flow resistance on ships leads to an increase of fuel consumption. The frictional resistance can raise fuel consumption by up to 40% and this will result in increased bunker costs, expenses due to lost earnings or time delay. Also, manoeuvrability is decreased and the possibility of premature corrosion is increased. Another negative effect is the potential for transmigration of species (EC 2007).

Uses:
This product type covers professional and non-professional user. About 95% of the worldwide total amount of antifouling product is used for ship hulls (commercial and pleasure) followed by offshore construction. Drilling platforms are considered as the most important after the use on ship hulls with approximately 2.5 %, followed by aquaculture equipment (e.g. fish nets), pipelines, and harbour constructions. Elements of sustainable use of antifouling products have been analysed in more detail in a research project focussing on environmental impacts on behalf of the German Environment Agency (Lüskow, 2012). The application of anti-fouling products and paints for ship hulls takes place in ship building yards and maintenance and repair yards. For the latter, yards for commercial and for pleasure boats can be distinguished. Professional application on vessels of > 25 m and < 25 m length is carried out by both trained and untrained workers. The treatment of vessels < 25 m is mainly done by untrained professional users and amateurs (Lüskow 2012).

In general, only professional users (painters and ship building craftsmen) are trained, but in many cases untrained staff are engaged in ship yards (Bleck et. al 2008). Maintenance and repair in particular are carried out by specialised corrosion companies. These companies however often engage untrained workers because of the hard work and the low pay in this sector.[13] Pleasure boats are often treated and painted by the untrained ship owner (consumer) unless the owner pays professional boat repair shops. Training for non-professional users (owners of small vessels) is not usual (Lüskow 2012).

The use of antifouling agents has been introduced by ancient civilizations of the Romans and the Greeks who coated their vessels with lead sheathing secured by cooper nails or pitch and tallow coatings. The development of antifouling paints began in the mid-1800s through the introduction of iron ships on which copper sheathing caused corrosion. Paints were prepared by adding toxicants such as copper. In the late 1950s and early 1960s, a new formulation using tributyltin (TBT) proved to be excellent in the prevention of fouling, but gave reason for environmental concern (Konstantinou 2006). Organotin compounds for antifouling have been restricted by Commission Directives 1999/51/EC and 2002/62/EC. The International Convention on the Control of Harmful Antifouling Systems on Ships developed by the International Maritime Convention Organisation entered into force on 17 September 2007 and prohibits the use of organotin compounds globally. Nevertheless, sealed organotin antifouling paints and other antifouling substances that are no longer allowed to be used in the EU can still be found on ship hulls and can be released during maintenance and repair and metal recycling (Lüskow 2012).

13 However, it should be noted that the majority of ship repairs are carried out in Asia and the Middle East (see ESD for PT 21, van de Plassche et al. 2004, p. 41).

Composition and mode of application:
Antifouling substances used for ship hulls are often added to liquid paints or are offered stand-alone and have to be mixed with paints and thinners before application. The main forms of application are sprayers with airless spray guns or brushing and rolling. For fish nets also dipping into antifouling products is applied. For building new commercial or pleasure ships only professional users apply antifouling, while for maintenance and repair of pleasure ships also non-professional users apply antifouling products.

For large scale application airless spray guns which generally have a pressure of 160 to 200 bar are used. It is assumed that airless-spray with these high pressures generate a significant overspray (Koch et al. 2004) of up to 30% of the material (EC 2007).

From non-eroding coatings the antifouling agents are continuously released from an insoluble polymer matrix into the water over a lifetime of 12 to max. 24 months. From eroding coatings the biocide is released from a soluble matrix together with the plasticizer or from self-polishing (acrylic) co-polymers with a polishing rate of 5 and 20 µm per month. The efficiency can be increased by adding booster biocides. The lifetime of self-polishing antifouling agents is about 3 to 5 years.

Two active substances have been approved so far under the BPR:

Substance name	CAS	CLP Excerp
Zineb	12122-67-7	H317, H335
Dichloro-2-octyl-2H-isothiazol-3-one (DCOIT)	64359-81-5	H317, H400

According to Regulation (EU) No.1062/2014 eight active substances are still under evaluation:

Substance name	CAS	CLP Excerp
Copper	7440-50-8	H301, H302, H400, H411, H412
Copper thiocyanate	1111-67-7	H332, H400, H410
Copper pyrithione	14915-37-8	H302, H315, H318, H330, H400
Cybutryne	28159-98-0	H317, H400, H410
Dichlofluanid	1085-98-9	H317, H319, H332, H400
Dicopper oxide	1317-39-1	H302, H400, H410
Tolylfluanid	731-27-1	H315, H317, H319, H335, H400
Zinc pyrithione	13463-41-7	H301, H318, H332, H400

All these active substances have been regarded as substitutes for tributyltin.

Maintenance and repair:
The application of new antifouling coatings during maintenance and repair is realised after cleaning the surface with high pressure water washing and removal of old paint and preparation of the surface through abrasive blasting or manual abrasive techniques. About 30% of the paint film is removed during this treatment. A complete removal is necessary if a different kind of coating such as a silicone coat is applied. The emission routes from maintenance and repair (removal of old paint and application of new paint)

depend on the working place (factory work room or roofed area with hard standing or dockyard near to surface water. The collected waste water should be adequately treated (e.g. by ultrafiltration, adsorption, electrochemical or biological treatment, solvent extraction, photo-degradation (Kotrikla 2009; Pangam 2009), but no information is available on whether this recommendation is followed in practice (Lüskow 2011).

The BREF Document on “Surface Treatment Using Organic Solvents” refers to maintenance operations causing emissions to air (mainly VOC) and to water. The wastewater originates from contaminated blasting agents, paint residues, used containers, and overspray. When water blasting or slurry blasting is used to avoid dust emissions from blasting, the process water is commonly treated either in integrated equipment or at a waste water treatment plant. Several techniques can be applied to reduce emissions from contaminated wastewater. The treated water is either disposed of as waste water or re-used. During the painting of ships, especially in maintenance operations, large amounts of contaminated blasting agents are generated. Heavy metals and TBT from blasting and grinding dusts are of special environmental significance. Water blasting generates only 1.5 % of the amount of waste arising from conventional grit blasting (EC 2007). In Germany a draft wastewater regulation considering the "cleaning, preservation, repair work and construction of ships” has been established. This draft reflects best available techniques and has partly been implemented in some federal states and considers maximum concentrations of the organic load (150 mg/l COD), hydrocarbons (10 mg/l), zink (2 mg/l) and copper (0.5 mg/l) next to limit values regarding ecotoxic effects (Anonymous 2008).

Use restrictions:
Several European countries such as Denmark, Sweden and the United Kingdom have already implemented restrictions on the use of or even bans on boat paints which contain Irgarol, or a general ban on the use of antifouling paints with biocides in inland waters. In Germany there are only a few isolated instances of regional bans on the use of these coatings, for example in Ratzeburger See in Schleswig-Holstein (UBA 2014a).

In Sweden the use of antifouling compounds was restricted from the end of the 1990’s. No paints containing antifouling biocides are approved for use on pleasure boats that are used in the Baltic Sea. A preliminary evaluation of the efficiency of these restrictions revealed that the concentrations of copper (≈ 6 µg/l) and zinc (≈ 20 µg/l) considerably increased from 1993 to 2004, while the concentration of Irgarol (≈ 0.17 µg/l) remained on the same level. The main source of antifoulings in the 1990s was attributed to local boats, but in 2004 to visiting boats. It could not be excluded that the increased copper concentrations were a result of illegal use of copper containing paints purchased outside of Sweden (Kylin et al. 2010).

In the UK, Diuron, Irgarol 1051, TCMTB, chlorothalonil, TCMS pyridine, and Sea-Nine registrations have been removed from the market for boats less than 25 m. In Denmark, Diuron and Irgarol 1051 were banned for use on pleasure craft in 2000 (Konstantinou 2006).

The reply of the Finnish CA to the questionnaire states that antifouling products are not allowed to be used in freshwater since 2004 because the fouling phenomenon is negligible in freshwater and these products are not needed there. In Sweden the use of antifouling products on leisure boats differs depending on e.g. the salinity. Antifouling paints used on the west coast are generally more hazardous than the paints used on the east coast. A lot of the paints used on the east coast are not classified as hazardous at all. The Swedish CA states that consumer’s attention needs to be directed more to the labelling and to keeping children out of reach when using hazardous paints. Moreover, labelling for east coast versus west coast should be more protruding; to date this specification is hard to detect. In Germany several local regulations restrict the use of antifouling products. Examples are the delegated acts concerning the Lake Constance, the Wakenitz and Ratzeburger lakes as well as several water reservoirs of the Ruhrverband. In these acts mainly certain active substances or more generally any substances hazardous to water are not allowed for underwater paints. However, no federal regulation on antifouling agents for all inland waters exists.

Health effects associated with antifouling agents:
A field study on primary exposure (rolling and spraying) and secondary exposure (during sand blasting) to antifouling paints was carried out in boatyards and dockyards. The exposure during sand blasting and the removal of old paint layers containing copper was included in this study. Inhalation of copper amounted to 3 mg/m^3 during spraying and to 0.8 mg/m^3 during sand blasting. Potential body exposure loading amounted to 272 mg/h copper during spraying and 33 mg/h during sand blasting. For dichlofluanid the inhalation exposure loading was 0.14 mg/m^3 during rolling, whereas the potential body exposure loading was 267 mg/h and potential hand exposure loading 277 mg/h. The use of personal protective equipment should be considered (Links et al. 2007).

In another study, interviews and dockyard inspections were carried out in order to gain information on realistic exposure scenarios and protective measures during the application of antifouling agents. Mixing and loading of airless spray-guns with large amounts of antifouling paint turned out to be associated with high exposure of hands, feet and fronts of legs. The spraying direction in relation to the worker as well as the tightness of the working space was important factors for the amount and the patterns of aerosol deposition onto the sprayers' bodies. Contact to contaminated surfaces during the spraying process resulted in comparable exposure of both hands and body. Personal protective equipment was generally worn according to the instructions if frequent controls by a supervisor were to be expected. Gloves were used in all cases, although they did not fully meet the specifications of the safety data sheets (Bleck and Müller, A. 2008).

According to CEPE, it is best working practice to:

- Wet dry spray with water and remove it. Don't allow dry spray to fall or blow around onto people.
- Use of protective sheeting or screens in the dry-dock (cotton overall and second disposable overall next to long sleeve gloves).
- Use of respiratory protection (full face mask with tear off vision strips)
- Skin protection (people wearing half masks should use a barrier cream, but it is always better to cover skin than to use barrier creams).

As people do not change behaviour and ways of working as the result of a single instruction, best practice needs to be introduced with full training for all personnel and will need clear procedures plus constant reinforcement from management and supervision (CEPE 2009).

Environmental effects:
The eco-toxicity of antifouling active substances is well known and documented in several review books (Konstantinou 2006; Arai 2012). All antifouling products that are currently used for underwater coatings are classified as "environmentally hazardous" and must be marked with the symbol "N" (Watermann et al. 2010).

In Germany about 206.000 mooring places exist in 3091 marinas. The concentrations of Irgarol® (cybutryne) in 35 of 50 marinas were higher than the environmental quality standard (mean EQS) of Directive 2013/39/EU of 0.0025 µg/l. On 5 sites also the maximum allowable EQS of 0.016 µg/l was exceeded. Considering effect thresholds for zinc and copper of about 8 µg/l, this value was exceeded at 6 (copper) and 9 (zinc) of 50 sites included in the study. For the active substances DCOIT, Zineb and pyrithione the concentrations were below the limit of detection. From the active ingredients dichlofluanid and tolylfluanid only degradation products were detected in some ports, which are not considered being ecotoxicological relevant. The use of antifouling products in inland waters is questioned (Feibicke et al. 2014).

For example, the antifouling Irgarol® (cybutryne), which has been detected in concentrations of up to 4.2 µg/l in both coastal waters and inland waters (harbours, marinas, etc.), had strong effects to aquatic plants and freshwater communities in pond mesocosms in concentrations above 0.2 µg/l (UBA 2014b).

The phasing out of tributyltin antifouling agents results in huge amount of wastes near ports and shipyards. Considering the removal of TBT from shipyard wastes and from the sediment only the efficiency of incineration for the treatment of solid sandblast wastes has been proven. Land deposition is only a feasible option for low-polluted sediments and must take into account the risk of contamination of groundwater and the surroundings. Other treatment methods, such as thermal and electrochemical treatment, are promising options, but due to the large amount of dredged material they have high capital and operational costs (Kotrikla 2009).

Best practices:
There are several good and best practices and best management practices on antifouling products available which have been summarised by Lüskow (2011). Some examples are

- International Maritime Convention Organisation: Draft Guidance on best Management Practices for removal of Anti-Fouling Coatings from Ships, including TBT hull paints – submitted by the United Kingdom, 21 July 2008
- HSE: Health and Safety Executive: Safe use of tin-free, marine anti-fouling coatings. Information document HSE 730/15
- ANZECC: Code of Practice for Antifouling and in-water hull cleaning and main using
- British Coatings Federation Ltd (BCF): Safe use of antifouling coatings
- CEPE: Personal health protection during application of antifouling paints and Guidance on the Safe Application of Yacht Coatings – Personal and Environmental Protection

Substitution by biocide-free alternatives:
In a feasibility study for new ecolabels according to DIN EN ISO 14024 several biocide-free antifouling products have been examined. It was recommended to create an ecolabel for these products in order to facilitate the entry to the market of new technologies. However, no ecolabel on biocide-free antifouling systems has been established so far (Watermann et al. 2004). On the other hand the award criteria of RAL UZ 141 "Environmentally friendly ship design" as well as of RAL UZ 110 "Environmentally friendly ship operation" suggest the use of biocide-free antifouling paints and coating systems under the optional requirements for granting the ecolabel award.

In another study on behalf of the German Federal Environment Agency a market analysis of nanomaterials used for antifouling paint systems was carried out. For all antifouling systems and underwater coatings on the market, the specification of the used nanomaterials was not indicated e.g. in the Technical Data Sheets or Safety and Health Data Sheets. A clear labelling for the consumer would be helpful and necessary. Actually, nanotechnology based antifouling systems on the leisure boat market and on the professional market cannot be regarded as alternatives to antifouling systems due to the lacking evidence of efficacy, the fact that some products contain biocides without declaring them, some of them are even not allowed to be used as biocides in antifouling paints (e.g. zinc oxide and silver), and due to the lack of specified nanomaterials, which make a risk assessment or ecotoxicological evaluation impossible. Metals like copper, silver and zinc used as nanoparticles release more easily ions compared to the bulk material, which is a precondition for their biocidal effects (Watermann et al. 2010).

A study carried out at the Lake Constance, where 50,000 boats and ships are registered, the application and limits of non-toxic biocide-free underwater paintings has been analysed. The Lake Constance provides drinking water for 4.5 million people and is considered as a particular sensitive area. The legal situation at present still allows to use coatings containing copper or Irgarol®, despite the existence of the „law of avoidance". More rigorous laws are needed to preserve the quality of Lake Constance as drinking water reservoir. Modern methods of controlling foulings include non-biocide coatings preventing the development of biofilms. PTFE-additives and silicone-paints have proved to be of value. New coatings are being tested in Lake Constance and analysed by scientists. Mechanical alternatives to antifouling agents such as regular boat washing stations, repeated cleaning on land or craning of boats when not used are all expensive alternatives that are not yet mature. From 10 biocide-free antifouling agents tested some were completely inappropriate while others were well usable. Fouling must be removed by external mechanical forces. The problem in pleasure boats is their low activity in relation to commercial vessels. The best results for cleaning sports boats were achieved using brushes (scrubbers) or high-pressure cleaner. Previous tests have shown that antifouling coatings based on silicon are most efficient, showing a self-cleaning effect at a speed of over 10 knots. However, they are more expensive, mechanically less durable and have a time-consuming processing (Global Nature Fund 2003).

Silicones as biocide-free antifouling coatings are especially applied on cruise ships, ferries, and container cargo ships. Many products are offered for professional uses. In contrast, silicones have not been successfully established in the recreational boat sector and there exist only a few products on the market. The reason is the difficulty of application and the softness of silicones. In the recreational boat sector, the primarily "biocide-free" antifouling products used are those made of eroding coatings with zinc oxide. In addition, there are also cleanable coatings in conjunction with respective cleaning equipment for use in freshwaters. It should be noted that also antifouling agents based on Teflon (Polytetrafluoroethylene) cause environmental problems due to the persistence of fluorocarbon compounds and the solvents used. The obvious lack of interest from the industry to apply for an ecolabel is also due to the fact that the manufacturers also offer conventional antifouling agents in their product portfolio next to silicon coatings (personal communication Dr. Watermann, Fa. Limnomar from 1.9.14, cited in Gartiser et al. 2014).

Identified risks and risk mitigation measures proposed:
According to competent authorities, the first assessment reports of antifouling active substances demonstrated some unacceptable risks either for human health (during professional use), and/or for the environment (in the harbour or marina during the service life, or during the application or maintenance and repair activities).[14] The suitability of the proposed risk mitigation measures has raised questions, with no clear conclusions in the assessment reports. Among the conditions to be considered during product authorisation the following elements have been described:

- Despite concerns and risks arising from their use, antifouling products are nevertheless needed to prevent the growth of marine life on ships and boats allowing their safe and efficient operation. They contribute to the prevention of invasive species spreading as well as reducing fuel consumption and related greenhouse gases emissions. Thus it has been suggested to approve all active substances for PT21 on the basis on the same generic conditions. Additional specific conditions could be added on a case-by-case basis (for instance, if the substance is a skin sensitizer, the standard paragraph related to treated articles would be added).[1] In addition, it was suggested to launch a study on comparative

[14] CA-March14-Doc.4.2: Antifouling (PT21) Way forward for the management of active substances and the authorisation of biocidal products.

assessment and risk mitigation measures for antifouling products to be taken into account for the renewal of approvals and of authorisations.

- Considering human exposure it was proposed to add the following sentence: "Persons making products containing [the substance] available on the market for non-professional users shall make sure that the products are supplied with appropriate gloves." This measure aims at spreading a standard good practice, which is to use antifouling products with gloves, whatever the level of risk. However, Member States (MS) may decide to refuse granting authorisation of antifoulings to the general public if wearing of personnel protective equipment (PPE), such as gloves, is the only risk mitigation measure to reduce exposure to acceptable levels.
- For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
- Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry. The application, maintenance and repair activities shall be conducted within a contained area, on an impermeable hard standing with bunding or on soil covered with an impermeable material to prevent losses and minimize emissions to the environment, and that any losses or waste containing antifouling agents shall be collected for reuse or disposal.
- For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. This measure in particular refers to antifoulings used for fishnets coatings or small professional boats used in mussels/oyster production or paints used in artificial ponds for growing fish or seafood products).
- On a case-by-case basis additional provisions can be added, depending on the active substance and the risks linked to its use (e.g. skin sensitizers).

In addition, the possible risks mitigation measures proposed would also be summarised in each assessment report in the elements to be taken into account at the product authorisation stage. This could include among others:

- Recall of the obligations to apply provisions coming from the IPPC rules for marina, harbour or yachting areas.
- Implementation of a specific area for paint application (ex: signals to inform bystanders, restricted area for professional application, etc.).
- For shrouding, application on hard standing or protection of the application area with impermeable material (ex: plastic tarpaulin) or foils and/or fine meshed nets.
- Thorough cleaning of dock floor with collection of solids and wastewater (ex: yachts and commercial ships).
- Good spraying practices such as good maintenance and control of sprayers by trained people, taking into account wind speed (professional application to yachts and commercial ships).
- Information to be provided to the users of painted boats, in case there are some restrictions for the service-life of the paint (ex: if the paint is meant for a use on boats that will travel only in specific seas).

According to competent authorities the control and monitoring of the implementation of all these risks mitigation measures should be part of the control plans of Member States. The experience gained on the matter will have to be taken into account for the day-to-day authorisation of these biocidal products, as well as for the review of the approval of the active substances.

So far three Competent Authority assessment reports (CARs) have been published by ECHA: dichloro-2-octyl-2H-isothiazol-3-one (DCOIT)[15], Zineb[16], and Tralopyril[17]. The following preconditions for product authorisation have been proposed in the CARs for DCOIT AND Zineb:

DCOIT: The human health risks for professional users of the real product were acceptable for all scenarios except the one for ancillary worker (borderline risk) and potman as long as suitable risk management measures are followed. These include process optimisation, engineering control and appropriate and suitable PPE/RPE. Training in correct use, removal and storage of the equipment and establishing of routines for regular replacement of contaminated equipment is needed. For the environment, risks were identified for marinas and commercial harbours based on application and removal activities alone and in combination with in-use emissions from commercial vessels. However, in the surrounding waters of the modified adapted marinas and harbours safe use could be demonstrated. For Annex I listing, it has been decided at TM level that a risk within the harbour/marina can be accepted as long as safe use can be demonstrated in the surrounding waters. Due to the identified risk to surface water and sediment (suspended matter) from industrial removal and application activities of antifouling paint within the harbour scenarios, certain risk mitigation measures to prevent losses to surface water from these activities can be proposed at MS level. Examples of these measures include implementation of a specific area for paint application with hard standing, protection of the application area, thorough cleaning of dock floor with collection of solids and wastewater, good spraying practices, wastewater collection and pre-treatment, low emission paint removal techniques. Another possible risk mitigation measure could be the restriction of the use of antifouling products in especially sensitive areas. Local authorities might enforce restrictions when establishing marinas in those areas.

Zineb: Acceptable human health risks have been identified for professional users up to 10% concentration of the active substance. For non-professional human health, risks are only acceptable if the antifouling product contains a maximum concentration of up to 4%. Considering the environmental risk identified for marinas and harbours, risk mitigation methods such as “dock floor discipline” or “use of containment nets and good spraying practices” may be needed at product authorisation. According to the antifouling industry a lot of activities are carried out in boatyards and marinas, which are regulated by the Industrial Emissions Directive (formerly IPPC). The code of practices and best practices are incorporated within BREFs (the Best Available Techniques (BAT) reference documents). In practice dockyard and boatyard abatement systems (e.g. removing waste paint and flakes from beneath the vessel, filtering waste washing water etc.) will minimise the emission of antifouling paint to the environment. Therefore, the worst case scenarios are unlikely to be realised at facilities in Europe. However, some Member States think that facilities exist which do not have sufficient risk mitigation measures in use.

Further opinions on active substances Medetomidine, Copper pyrithione and Tolylfluanid have been published by the Biocidal Products Committee (BPC).

[15] Assessment Report_ DCOIT (March 2014)
http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/0022-21/0022-21_Assessment_Report.pdf
[16] Assessment Report Zineb (December 2013)
http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/1409-21/1409-21_Assessment_Report.pdf
[17] Assessment Report Tralopyril (April 2014)
http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/1403-21/1403-21_Assessment_Report.pdf

Conclusion

For most antifouling active substances evaluated under the BPR risks on human health and to the environment have been identified, which cannot be tackled only during product authorisation:

- For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
- For non-professional human health risks these are only acceptable if PPE such as masks or gloves are used, which cannot be ensured or enforced in practice.
- For marinas and commercial harbour, risks have been identified for most antifouling active substances during service life application, maintenance and repair activities. This led to the decision of Competent Authorities that these risks may be acceptable if no risks for the surrounding waters are expected.
- A major fraction of the emissions does not originate from the application of antifouling agents but is emitted during service life and during maintenance and repair (cleaning of the surface under high pressure water washing, removal of old paint through abrasive blasting or manual abrasive techniques). This also concerns "old active substances" such as tributyl tin, which have been removed from the market but are still present in underwater coatings of boats and ships.
- Risk mitigation methods such as "dock floor discipline" or "use of containment nets and good spraying practices" are needed, but difficult to be enforced in practice. The code of practices and best practice are incorporated within BREFs related to the Industrial Emissions Directive. Some of the risk mitigation measures proposed are implementation of a specific area for paint application with hard standing, protection of the application area, thorough cleaning of dock floor with collection of solids and wastewater, wastewater collection and pre-treatment, low emission paint removal techniques.
- Labels and, where provided, safety data sheets of products authorised shall indicate that application, maintenance and repair activities shall be conducted within a contained area, and on impermeable hard standing with bunding or on soil covered with an impermeable material to prevent direct losses and minimise emissions to the environment, and that any losses or waste shall be collected for reuse or disposal.
- Member States may restrict the use of antifouling products in sensitive areas and local authorities might enforce restrictions when establishing marinas in those areas.
- The control and monitoring of the implementation of all these risks mitigation measures should be part of the control plans of Member States.

These points demand for further measures to be implemented to ensure a sustainable use of antifouling products.

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