EUROPEAN CHEMICALS AGENCY

EMISSION SCENARIO DOCUMENT

Emission Scenario Document for Product Type 19

Repellents and attractants

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Executive summary

The Biocidal Products Directive (Directive 98/8/EC) (hereinafter referred to as the 'BPD') of the European Parliament and of the Council concerning the placing of biocidal products on the market, which was adopted in 1998, was enforced by the Member States in national law before 14 May 2000.

The BPD has now been replaced by the Biocidal Products Regulation (Regulation (EU) No. 528/2012) (hereinafter referred to as the 'BPR'), which concerns the making available on the market and the use of biocidal products. The BPR was adopted on the 22 May 2012 and is fully implemented since the 1 September 2013. Both the BPD and the BPR aim to harmonise the European market for biocidal active substances and products, containing these substances.

Furthermore, the intention is to provide a high level of protection for human and animal health, as well as for the environment. The scope of the BPR has been extended compared to the former directive to include treated articles, i.e. materials and articles treated with biocidal products placed on the European market should only contain approved active substances.

When evaluating active substances to be included into a positive list (Union list of approved active substances), and authorising biocidal products for the European market, among other things, a risk assessment for the environment has to be performed.

According to Annex VI to the BPR, the 'risk assessment shall cover the proposed normal use of the biocidal product, together with a realistic worst-case scenario including any relevant production and disposal issues. The assessment shall also take account of how any 'treated articles' treated with or containing the product may be used and disposed of'.

One of the primary purposes of the Emissions Scenario Documents (ESDs) is to guide risk assessors in quantifying or estimating emissions (or releases) of active substances, degradation products and/or substances of concern within biocidal products to the primary receiving environmental compartment.

The current ESD was developed with the objective of providing methods for assessing emissions of active substances due to the product type (PT)19 end-use of biocidal products (repellents and attractants) containing these actives. This includes scenarios for repellent products used for human (applied either to the skin or clothes) or animal protection, products to repel arthropods or vertebrate animals from buildings or other shelters, repellent treated articles (industrially treated garments and gear), as well as scenarios for products containing pheromones.

The preparation of this ESD for PT 19 was initiated by the German Federal Environment Agency (hereinafter referred to as 'UBA' (Umweltbundesamt)), who contracted Dr Knoell Consult GmbH for the development of a first draft of this document (UBA reference number Z 6 – 81041/5, project number 22752). In October 2014, the European Chemicals Agency (ECHA) took over support for the finalisation of the ESD for PT 19 (ECHA contract number ECHA/2014/258).

The draft versions were revised taking into account the comments of the Member States. The final version was endorsed by the Environment Working Group in WG-II-2015 in March 2015.

Context

No harmonised ESD for assessing environmental emissions of PT 19 products and the active substances therein was available. However, PT 19 active substances – not eligible for the simplified authorisation procedure – had already been included in the Union list of approved PT 19 active substances and further substances are currently under evaluation for inclusion into this Union list. For reasons of consistency, there was an immediate need for an approved ESD at EU level, to define scenarios relevant for environmental emissions and include the respective basis for the emission calculations.

This document has therefore been developed in the framework of two projects entitled:

1. 'Entwicklung eines Emissionsszenariodokumentes für Repellentien und Lockmittel', which was initiated by the Federal Environment Agency Germany (UBA) in October 2012;

2. Finalisation of the ESD for PT 19, which was established by the European Chemicals Agency (ECHA) in October 2014.

The final version was endorsed by the Environment Working Group in WG-II-2015 in March 2015.

Table of contents

1 INTRODUCTION 8

1.1 Background 8
1.2 Borderline cases between products regulated under the BPR 528/2012 and those regulated under other legislative acts 9
1.3 Existing models and other relevant sources of information 10
1.4 Tonnage and consumption-based approach for assessing emissions to environmental compartments 11
1.5 Harmonised presentation 12

2 GENERAL INFORMATION ABOUT REPELLENTS AND ATTRACTANTS 13

2.1 Target organisms 13

2.1.1 Arthropods 13
2.1.2 Vertebrates 18

2.2 Mode of action 18

2.2.1 Repellents 18
2.2.2 Attractants 19

3 SELECTED USES FOR REPELLENTS AND ATTRACTANTS 19

3.1 Insect repellents applied to human skin and garments 20

3.1.1 Description of use area 20
3.1.2 Biocidal active substance typically applied in this area 20
3.1.3 Environmental release pathway 21
3.1.4 Emission scenarios 22

3.2 Insect repellents applied on animal skin 33

3.2.1 Description of use area 33
3.2.2 Biocidal active substance typically applied in this area 33
3.2.3 Environmental release pathway 34
3.2.4 Emission scenarios 34

3.3 Application of repellents in the environment of humans and animals 44

3.3.1 Description of use area 44
3.3.2 Biocidal active substance typically applied in this area 45
3.3.3 Environmental release pathway 45
3.3.4 Emission scenarios 46

3.4 Insect repellents used for factory-treated textiles 56

3.4.1 Description of use area 56
3.4.2 Biocidal active substance typically applied in this area 56
3.4.3 Environmental release pathway 57
3.4.4 Emission scenarios 58

3.5 Attractants 64

3.5.1 Description of use area 64
3.5.2 Biocidal active substance typically applied in this area 65
3.5.3 Environmental release pathway 65
3.5.4 Emission scenarios 65

4 FURTHER RESEARCH 66

5 REFERENCES 66

6 APPENDIX 73

6.1 Application amounts of repellent products for use on human skin 73
6.2 Market share of repellents for use on human skin/garment and fraction of inhabitants

using a repellent product for human skin/garment ... 76
6.3 Development of parameter for the 'swimming scenario' ... 76

Table of figures

Figure 1: Tonnage and consumption-based approach for assessing environmental emissions at the stage of inclusion of an active substance into the Union list and at the product authorisation stage ... 12

Figure 2: Relevant life-cycle stages to be considered for PT 19 products when assessing environmental emissions due to the use on human skin or clothes ... 22

Figure 3: Relevant life-cycle stages to be considered when assessing environmental emissions due to industrially repellent-treated garments and gear ... 58

Table of tables

Table 2-1: Summary of arthropod vectors for human vector-borne diseases (according to Rozendaal, 1997; Govere & Durrheim, 2007; Talley, 2008) ... 16

Table 3-1: Emission scenario for calculating the release of repellents used on human skin and garments based on the annual tonnage applied (according to van der Aa & Balk, 2004) ... 23

Table 3-2: Pick list for number of applications per day ... 25

Table 3-3: Default values for the surface area of a standard adult person (EC, 2013c) ... 25

Table 3-4: Default values for the surface area of garments ... 26

Table 3-5: Pick list for the fraction of inhabitants using repellent products for skin and garment application ... 26

Table 3-6: Emission scenario for calculating the release of repellents used on human skin and garments based on the average consumption (according to van der Aa & Balk, 2004) . 27

Table 3-7: Emission scenario for calculating the release of repellents used on human skin due to swimming activities in surface water bodies ... 30

Table 3-8: Calculation of surface water concentrations following swimming of humans having used an insect repellent on their skin ... 32

Table 3-9: Treated skin areas for horses, cats, and dogs as well as soil areas for emissions ... 35

Table 3-10: Emission scenario for calculating the release of repellents used on horses or pets due to spray drift: Emissions to bare soil ... 36

Table 3-11: Calculation of the concentration in soil following emissions to bare soil from spray applications of repellents on horses, cats and dogs ... 37

Table 3-12: Emission Scenario for calculating the release of repellents used on horse skin due to spray drift: Emissions to paved ground ... 39

Table 3-13: Calculation of surface water concentrations (slow moving surface water body) due to emissions to paved ground following spray applications of repellents on horses ... 40

Table 3-14: Emission scenario for calculating the release of repellents used on horses due to abrasion when rolling on pasture ... 42

Table 3-15: Emission scenario for calculating the release of repellents used on horse skin due to hosing: release to adjacent soil ... 43

Table 3-16: Emission scenario for calculating the release to wastewater from surface spray repellents used indoors – application step (according to OECD ESD No. 18; OECD, 2008) ... 48

Table 3-17: Frequency of use of insecticides in households (taken from the OECD ESD No. 18; OECD, 2008, section 2.7) ... 49

Table 3-18: Emission scenario for calculating the release to wastewater from surface spray repellents used indoors – cleaning step (according to OECD ESD No. 18; OECD, 2008) 50

Table 3-19: Emission scenario for calculating the release to wastewater from diffuser repellents used indoors – application step (according to OECD ESD No. 18; OECD, 2008) 51

Table 3-20: Emission scenario for calculating the release to wastewater from diffuser repellents used indoors – cleaning step (according to OECD ESD No. 18; OECD, 2008)...................... 52

Table 3-21: Emission scenario for calculating the releases of repellents used outdoors for dispelling vertebrates – emission to paved ground 54

Table 3-22: Emission scenario for calculating the release of repellents used outdoors for dispelling vertebrates – application on unpaved ground/in soils (according to Larsen, 2003) 55

Table 3-23: Emission scenario for calculating the release during the industrial application of insect repellents to textiles/fibres based on the annual tonnage applied (based on TGD, IC=13; EC, 2003) 59

Table 3-24: Emission scenario for calculating the release during the industrial application of insect-repellents to textiles/fibres - consumption approach.. 60

Table 3-25: Emission scenario for calculating the release of repellent factory-treated garment via washing based on the average consumption 61

Table 3-26: Emission Scenario for calculating the release of repellents leached out of tent textile .. 63

Table 6-1: Application amounts for repellents and cosmetic products applied onto human skin..... 74

Table 6-2: Classification of inland surface waters (according to DWA, 2006) 77

Table 6-3: Wind speed and resulting speed of transported water layer (according to Schwoerbel and Brendelberger, 2013) 78

Table 6-4: Surface water volumes and number of swimmers: average and 90^{th} percentile........... 79

Table 6-5: Bathing seasons of selected European countries 80

1 Introduction

1.1 Background

Emission Scenario Documents are available for almost all product types (PTs), giving instruction on the release estimation of substances from biocidal products to the environment. The risk assessment has to be carried out for all relevant life-cycle stages of the biocidal product.

According to Annex VI (14) to the Biocidal Products Regulation (BPR) ((EU) No 528/2012), the 'risk assessment shall cover the proposed normal use of the biocidal product, together with a realistic worst-case scenario including any relevant production and disposal issues. The assessment shall also take account of how any 'treated articles' treated with or containing the product may be used and disposed of' (EU, 2012a).

As is stated in Annex V to the BPR, product type 19 comprises of 'products 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' (EU, 2012a). This includes products applied to human skin and apparel or animal coat to repel annoying or harmful arthropods (e.g. vectors for diseases), products applied in the surrounding environment of humans e.g. to detain cats and dogs from fouling or to repel insects from houses.

Products that fall under PT 19 include repellent-treated textiles, garments and gear intended to be used in areas densely populated by mosquitoes.

Repellents for birds and fish species are not dealt with in this ESD. Emissions arising due to the use of repellents for birds can be assessed based on the ESD for PT 15 (Rolland & Deschamps, 2003). Nevertheless, repellents for birds are in most cases used to protect plants or products of plant origin and thus fall under the scope of the Plant Protection Products Regulation ((EC) No 1107/2009). Repellents against fish have not been identified as a relevant application within the EU, and are therefore not under the scope of this ESD.

1.2 Borderline cases between products regulated under the BPR ((EU)528/2012) and those regulated under other legislative acts

It is important to identify the borderline between products regulated under diverse legislative acts such as the Biocidal Products Regulation (BPR) ((EU) 528/2012) (EU, 2012a) and those regulated under Directive 2001/83/EC (medicinal products for human use; EU, 2001a), Directive 2001/82/EC (veterinary medicinal products; EU, 2001b), the Plant Protection Products Regulation ((EC) No 1107/2009) (EU, 2009a), and the Cosmetic Products Regulation ((EC) No 1223/2009) (EU, 2009b).

Article 2(2) of the BPR excludes products that are defined in or within the scopes of other legal acts like the Veterinary Medicinal Products Directive, the Medicinal Products for Human Use Directive, the Plant Protection Products Regulation and the Cosmetic Products Regulation from the scope of the regulation. Furthermore, Article 2(5) excludes food and feed which is used as repellent or attractant from the scope of the regulation.

The borderline between PT 19 biocidal products and human and veterinary medicinal products is defined as such that products having a repelling activity **without** any lethal effect **and** which also **do not** have a medicinal claim are in line with the biocidal products definition (EU, 2008; EU, 2011).

Active substances fall under the Plant Protection Products Regulation if their main purpose is to protect plants and plant products against harmful organisms (EU, 2012b). In contrast to this, biocidal products have a general hygiene purpose and are normally not applied directly to protect plants or plant products. The goal of its application i.e. protection is therefore a decisive criterion for the regulation of a product as a plant protection product (PPP) or as a biocidal product (BP).

Repellents and attractants, which are applied before or during a pest attack, are considered to be PPPs if they are used to prevent pests that can damage plants or plant products. Equally repellents against animals causing harm to plants or plant products are regulated by the Plant Protection Products Regulation, whereas repellents against cats and dogs fall under the BPR.

The borderline between the BPR and the Cosmetic Products Regulation is similarly based on the primary function of the product. Cosmetic products with only a secondary biocidal activity and claim are regarded to comply with the cosmetic legislation as long as their primary function is a cosmetic one, and all requirements of the cosmetic legislation have been met (EU, 2004; EC, 2013a).

According to EC (2013a) and EU (2012a) there might be cases when biocidal products have a dual function, i.e. products fall under the scope of two different legislative instruments. One example is a sun blocker with an insect repellent. This product complies with the biocides and the cosmetic legislation.

1.3 Existing models and other relevant sources of information

The following existing documents and models are the basis for the emission scenario document (ESD) for product type (PT) 19:

- EC (2003): TGD Part II. Technical Guidance Document (TGD) in support of Commission Directive 93/67/EEC on risk assessment for new notified substances and on Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances and on Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.

- EC (2005a): Report of the leaching workshop (open session), Arona, Italy, 13 and 14 June 2005. European Commission, Joint Research Centre, European Chemicals Bureau – Biocides.

- EC (2010a): Guidance note on leaching rate estimations for substances used in biocidal products in product types 07, 09 and 10. Document endorsed at the 36th meeting of representatives of Member States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market, 10-12 March 2010.

- EC (2011): Emission Scenario document for product type 3. European Commission, Joint Research Center, Institute for Health and Consumer Protection.

- Larsen, J. (2003): Supplement to the methodology for risk evaluation of biocides. Emission scenario document for biocides used as rodenticides. CA-Jun03-Doc.8.2-PT14.

- Migné,V. (2002): Supplement to the methodology for risk evaluation of biocides: Emission scenario document for biocides used as masonry preservatives. (Product type 10). Institut National de l'Ènvironnement Industriel et des Risques, INERIS-DRC-02-25582-ECOT-VMi-n°02DR0270.

- OECD (2002a): OECD Series on Emission Scenario Documents Number 2, Emission Scenario Document for Wood Preservatives, Parts 1, 2, 3, and 4.

- OECD (2004): OECD Series on Emission Scenario Documents Number 7, Emission Scenario Document on textile finishing industry. ENV/JM/MONO(2004)12.

- OECD (2006): OECD Series on Emission Scenario Documents Number 14, Emission Scenario Document for insecticides for stables and manure storage systems. ENV/JM/MONO(2006)4.

- OECD (2008) : OECD Series on Emission Scenario Documents Number 18, Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses. ENV/JM/MONO(2008)14.

- OECD (2013): OECD Series on Emission Scenario Documents Number 2, Revised Emission Scenario Document for wood preservatives. ENV/JM/MONO(2013)21

- Tissier, Ch., Chesnais, M., and Migné,V. (2001) : Supplement to the methodology for risk evaluation of biocides: Emission scenario document for biocides used as preservatives in the textile processing industry. (Product type 9 & 18). Institut National de l'Ènvironnement Industriel et des Risques, INERIS-DRC-01-25582-ECOT-CTi/VMi-n°01DR0176.

- Van der Aa, Eefje & Balk, Froukje (2004): Supplement to the methodology for risk evaluation of biocides: Environmental emission scenarios for biocides used as human hygiene biocidal products (product type 1). Report 4L1784.A0/R016.

- Van der Poel, P. (2001): Supplement to the methodology for risk evaluation of biocides: Emission scenario document for product type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector). RIVM report 601450008.

1.4 Tonnage and consumption-based approach for assessing emissions to environmental compartments

Repellents and attractants are consumed by the non-professional user of the general public. Environmental emissions of active substances within biocidal products used by the general public and resulting in emissions via municipal sewage treatment plants (STP) can generally be assessed by two approaches, i.e. the tonnage and the consumption-based approach.

For PT 1 and 2, both approaches have been included for the use stage in the respective ESDs (van der Aa & Balk, 2004; van der Poel, 2001). In Appendix 1 of the ESD for PT 2, the differences of the alternatives are depicted as well as the pros and cons of both approaches.

A discussion concerning these two options for calculating emissions took place at the 'Workshop on environmental risk assessment for Product Types 1 to 6' in Arona, 2008 (EC, 2008a). The workshop aimed to find a harmonised approach for assessing emissions of active substances in the framework of their inclusion into Annex I to the BPD (now the Union list of approved active substances of BPR. In summary, no consensus was reached about the merit of one approach compared to the other. It was agreed that both approaches could be used in support of each other.

The current ESD for repellents and attractants will contain both options, i.e. the tonnage and the consumption-based approach, where applicable.

The tonnage based approach is in most cases only appropriate for emission assessments at the stage of inclusion of an active substance into the Union list. Only at that stage, could sales figures be expected for the use of an active substance for a certain purpose.

At the product authorisation stage, applicants will most probably only have the sales figures of the active substance used within their products but not the tonnage of the active substance marketed in the EU for that special purpose. Hence, the basic input parameter for assessing emissions via the tonnage approach is not available.

One disadvantage of the consumption-based approach is that it gives a fixed outcome, which is independent from the tonnage used for the active substance in that product. This is especially the case for products with low sales or 'niche' products, where the consumption-based approach may lead to an overestimation of emissions if information on the market share and on the fraction of inhabitants using the product is not available and default values have to be taken.

Furthermore, repellent products for use on human skin or clothes are sometimes sold in the EU, yet they are intended to be used in foreign/tropical regions to prevent insect bites which subsequently minimises the risk of disease infection (e.g. such as malaria which is carried by *Anopheles* mosquitoes). Consequently, emissions from the use of these products are not to be expected within the EU but generally in non-EU countries with a high incidence of disease carrying vectors. Further research is therefore recommended on the appropriate use of sales figures at the product authorisation stage to achieve a more realistic emission calculation.

In summary, at the stage of evaluating active substances for inclusion into the Union list, both tonnage and consumption approaches are reasonable for assessing emissions if sales figures of the active and that specific purpose are available. Due to the lack of an appropriate model based on tonnages, at the stage of product authorisation in the first instance, an assessment based on consumption is proposed. Further research is necessary for adopting a sales based calculation as an option to assess emissions at the product authorisation stage.

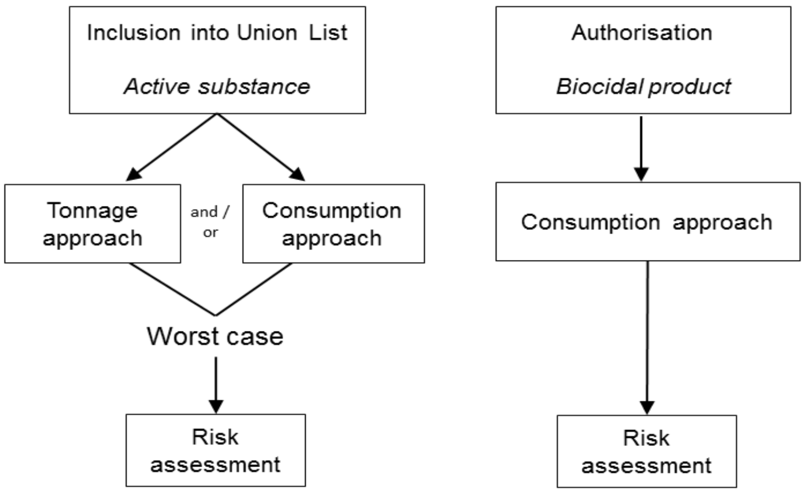

Figure 1: Tonnage and consumption-based approach for assessing environmental emissions at the stage of inclusion of an active substance into the Union list and at the product authorisation stage

1.5 Harmonised presentation

The emission scenarios for PT 19 are presented in text and tables within this report. In the tables, the input and output data and calculations are specified, and units according to (E)USES are used. The input and output data are divided into four groups:

S data Set	Parameter must be present in the input data set for the calculation to be executed (no method has been implemented in the system to estimate this parameter; no default value is set, data either needs to be supplied by the notifier or should be available in the literature).
D Default	Parameter has a standard value (most defaults can be changed by the user).
O Output	Parameter is the output from another calculation (most output parameters can be overwritten by the user with alternative data).
P Pick list	Parameter value can be chosen from a “pick list” of values.

Pick list values and default parameters are to be adapted, when specific data is available, instead of a mandatory use of these values as defaults.

2 General information about repellents and attractants

2.1 Target organisms

2.1.1 Arthropods

Most repellent products covered by PT 19 are used to prevent arthropods (i.e. insects and arachnids) from landing or climbing on the skin of exposed humans or animals, or on human clothing. Repellent products may also be used to prevent annoying organisms from entering designated areas such as housing etc. The aim of these products is thus to protect against bothersome and biting/sucking insects or arachnids which feed on blood or skin cells from living vertebrates, including humans. Some of the biters may cause unpleasant effects such as allergic reactions to insect saliva which may cause itching, redness, and swelling. Furthermore, many arthropod species are vectors, transmitting severe infectious diseases.

Undesired arthropods can also be controlled by means of attraction, i.e. the use of substances (attractants) in combination with non-chemical and non-biological means to kill the insect. Sex pheromones used as attractants control arthropod species by creating confusion among males, disrupting mating and preventing females from laying eggs.

2.1.1.1 Diptera

Biting *diptera* (flies and midges) attack humans and animals to obtain a blood meal. Whereas males mostly feed on nectar and other sugar containing plant juices, adult females also feed on blood for developing eggs. Species are often host-specific which is sometimes reflected in the common name for the species.

The most important group of biting *diptera* is the **mosquitoes** (family *Culicidae*, subfamilies: *Anophelinae*, *Culicinae*, and *Toxorhynchitinae*). Mosquitoes have a long slender body, long legs and long needle-shaped mouthparts. The adult insects measure between 2 mm and 12.5 mm in length. Some species bite in the morning or evening and at night; others feed during the day. Species bite in- and outdoors (Rozendaal, 1997). Mosquitoes transmit pathogens to more than 700 million people annually. Malaria is the most important disease caused by mosquito-transmitted pathogens. It is responsible for about three million deaths and 500 million episodes of illness each year (Govere & Durrheim, 2007). Besides malaria, mosquitoes are vectors of lymphatic filariasis, dengue fever, yellow fever and other diseases (*cf.* Table 2-1).

Black flies (family *Simuliidae*) have a worldwide distribution. There are about 200 species in 26 genera however only four genera (*Simulium*, *Prosimulium*, *Austrosimulium*, and *Cnephia*) contain species that bite humans. *Simulium* species act as vectors for the parasitic nematode *Onchocerca volvulus* which causes onchocerciasis (‘river blindness’). The fly serves as the larval host for the nematode which lives in humans and is transmitted to the black fly during feeding (Service, 2008).

Horse flies (family *Tabanidae*) are true flies with about 4 300 known species worldwide. Medically important are the species of *Tabanus*, *Chrysops* and *Haematopota*. Bites from female horse flies, also through clothing, are quite painful and may sometimes cause large itching swellings. Females of most species feed during the daytime and are active in bright sunshine. Horse flies can transmit lyme disease (usually transmitted by hard ticks), but their main medical importance is to act as vectors for the filarial worm *Loa Loa* in West and Central Africa, causing loiasis in humans (Service, 2008).

Tsetse flies (family *Glossinidae*) are medium sized (6-15 mm in length) flies with 23 known species. Both male and female tsetse-flies bite people (Service, 2008). The tsetse fly bites only in daytime (Rozendaal, 1997). It is the primary biological vector of trypanosomes, which cause the human sleeping sickness and animal trypanosomiasis (Service, 2008). The disease is limited to the African continent.

The **stable fly** (family *Muscidae*, *Stomoxys calcitrans*) has the size and appearance of a common house fly. Unlike other *diptera*, both sexes are blood-feeders of a variety of warm-blooded animals. Stable flies are primary day-active and tend to feed on the lower extremities of their hosts. Stable flies are no important vectors of animal and human diseases but they can serve as carriers for a variety of pathogens due to their tendency to probe the skin of more animals in their feeding. Transmitted pathogens may cause leishmaniasis, anthrax, brucellosis, equine infectious anemia, and bovine diarrhea virus. Stable flies also transmit *Trypanosoma evansi,* which causes the surra disease in horses, mules, camels and dogs (Talley, 2008).

Sandflies (family *Phlebotomidae*) are tiny insects (1.3-3.5 mm long) with up to 500 known species (WHO, 2013). Sandflies are occurring in different habits, ranging from semi-desert to rainforest. Most biting occurs outdoors, at dawn and during the night (Rozendaal, 1997). Sandflies are important vectors of leishmaniasis. The disease is caused by protozoa and transmitted by about 30 phlebotomine species (WHO, 2013). Species living in the Mediterranean region can transmit sandfly fever, also called pappataci fever (Rozendaal, 1997).

No-see-ums (family *Ceratopogonidae*) are small (about 1.5 mm long) bloodsucking midges. The important *Culicoides* genus is distributed worldwide and can cause serious biting problems. No-see-ums obtain blood from mammals, birds, reptiles and humans. For most species, biting activity peaks in the early evening. No-see-ums are transmitters for viral (e.g. bluetongue virus) and protozoa diseases, and filarial worms (Rozendaal, 1997).

Common houseflies (*Musca domestica*, family *Muscidae*) are 6-9 mm long non-metallic flies, which are almost endemic worldwide. Houseflies feed on any organic material, including almost all food of humans, rotting vegetables, carcasses, and excreta (Service, 2008). Due to their food prone to contain pathogens, their continuous deposition of faeces, and their contact with food intended to be consumed by animals and humans they can transfer pathogens that may cause serious diseases like typhoid fever, cholera, diarrhoea, dysentery, conjunctivitis, and mycosis (Rozendaal, 1997).

2.1.1.2 Siphonaptera

Siphonaptera (fleas) are wingless and tiny insects (1-8 mm long) with a characteristic jumping movement. They mainly feed on the blood of mammals and birds (Rozendaal, 1997; Durden & Traub, 2002). Both sexes take blood meals. Fleas breed close to the resting and sleeping places of their host, in dust, dirt, carpets, etc. (Rozendaal, 1997).

The human flea (*Pulex irritans*) feeds on humans and is capable of transmitting pathogens of medical importance. However, the species is commonly an ectoparasite of swine, domestic cats and dogs. The cat flea *Ctenocephalides felis* occurs worldwide. The flea species feeds on domestic and feral cats as well as on humans, dogs, and several livestock species. The cat flea is the most common flea on dogs and cats in most parts of the world. The dog flea *Ctenocephalides canis* is abundant worldwide and also parasitises wild canids such as foxes and wolves (Durden & Traub, 2002). Fleas can transmit flea-borne typhus (caused by *Rickettsia typhi*), tularaemia (caused by bacillus *Francisella tularensis*), and parasitic tapeworms that occur in cats and dogs. Fleas also transmit the *Yersinia pestis* bacteria which caused epidemic plague in past centuries and killed millions of people (Rozendaal, 1997).

2.1.1.3 Phthiraptera

Lice (*Phthiraptera*) are tiny, wingless insects that feed on the blood of mammals and birds. Three species of lice are adapted to humans, i.e. the head louse (*Pediculus humanus capitis*), the body louse (*Pediculus humanus humanus*) and the pubic louse (*Pthirus pubis)*. Only the body louse is a vector of human diseases, transmitting typhus fever, trench fever and relapsing fever (Rozendaal, 1997).

2.1.1.4 Trombiculidae

Trombiculidae, also called harvest mites, belong to the order of mites (*Acari*). The name 'chigger' refers to the larvae growth stage of the parasitic mite during which the larvae mite feeds on skin cells of their human or animal host. The affected skin areas may react with severe irritation, itching, swelling and rashes. Biting mites are vectors for the disease scrub typhus via transmission of *Rickettsia tsutsugamushi*, causing fever, headache and lymphadenopathy. The disease was common in troops during the Second World War and is still occurring in rural areas of Asia and Australia (Rozendaal, 1997).

2.1.1.5 Ixodida

Ixodida (ticks) are arachnids that suck blood from animals and humans. Both sexes feed on blood, the males less frequently than the females. Two families have to be distinguished, i.e. hard ticks (*Ixodidae*) with about 650 species, and soft ticks (*Argasidae*) with about 150 species. Hard ticks are between 3 and 23 mm long. Larvae as well as nymphs and adults feed on blood. Hard ticks attach to the host by sitting on leaf or branch ends and waiting for the host to pass by and brush against the leaves or branches. Because hard ticks remain attached to their hosts for some days, they are transported over certain distances. The combination of changing hosts and being carried over distances accounts for their importance as vectors for diseases. Soft ticks have one larva, five nymphal and the adult life cycle stages, all of them feeding on blood. Different from hard ticks, soft ticks leave their host after feeding, which lasts about 30 minutes. Species feeding on human blood are found around villages and inside houses. Ticks are vectors of a variety of diseases such as lyme disease, relapsing fever, tick-borne meningoencephalitis as well as the Rocky Mountain spotted fever and Q fever (Rozendaal, 1997).

2.1.1.6 Tineidae

The moths' family (*Tineidae*) contains more than 3 000 species. Most moths are small or medium-sized, with wings held like roofs over the rest of the body. Moths do not directly attack humans but affect them by their feeding habit, which also comprises human food as well as fabric.

The most widespread species feeding on fabric are the webbing clothes moth (*Tineola bisselliella*), the case-making clothes moth (*Tinea pellionella*) and the carpet moth (*Trichophaga tapetzella*). Solely the moth larvae can feed on natural fibres in clothing or fabrics. Infestation of the cloth moth is of concern for stored products.

As for cloth moths, also for foodstuff moths, the damaging stage is the caterpillar. Moth larvae may feed on all types of cereals, dried fruits or dehydrated vegetables, nuts, chocolate, candies and other confections. The most common species of meal moths found in home pantries is the Indian mealmoth (*Plodia interpunctella*). Other infesting species are the Mediterranian flour moth *Ephestia (Anagasta) kuehniella*, the tobacco moth *Ephestia elutella* and the almond moth *Ephestia cautella.*

Table 2-1: Summary of arthropod vectors for human vector-borne diseases (according to Rozendaal, 1997; Govere & Durrheim, 2007; Talley, 2008)

Vector	Disease or pathogen	Main geographic distribution of the disease
Mosquitoes *(Culicidae)*		
Anopheles	Malaria	Tropical and subtropical regions of all continents (except the Antarctic)
Culex	Japanese encephalitis	Southeast Asia, Far East
Aedes	Yellow fever	Tropical and subtropical regions of South America, Latin America and Africa
	Dengue fever	Globally in regions near the equator
Mansonia, Culex, Aedes, Anopheles	Lymphatic filariasis	Tropical and subtropical regions of Asia, Africa, Central and South America, and Pacific Island nations
Other biting diptera		
Tsetse flies	African sleeping sickness	Tropical Africa
Black flies	River blindness (onchocerciasis)	Africa, Central and South America
	Mansonellosis	Tropical Africa and America
Sandflies	Leishmaniasis	Tropical and subtropical regions of America, Africa and Asia
	Sandfly fever	Subtropical regions of the Eastern Hemisphere, i.e. Southern Europe, North Africa, Balkan region, North India
Horse flies	Loiasis	West and Central Africa
	Tularaemia	North America, parts of Europe and Asia
No-see-ums	Mansonellosis	America (Latin America to Northern Argentina), the Caribbean, Africa (from Senegal to Kenya and Angola to Zimbabwe)

Table 2-1 cont.:

Vector	Disease or pathogen	Main geographic distribution of the disease
Fleas (*Siphonaptera*)		
Fleas	Typhus, plague	Epidemic plague in past centuries; occurrence of flea-borne typhus and plague is possible in most parts of the world
Lice (*Phthiraptera*)		
Body louse	Trench fever	Serious infection of the armies during World War I and II; in recent times cases are reported form Bolivia, Burundi, Ethiopia, Mexico, Poland, former USSR and North Africa
	Louse-borne relapsing fever	Occurrence under poor living conditions, especially in developing countries (Africa, Asia, South America)
	Epidemic typhus	Epidemic infection during World War I and II; thereafter epidemics have occurred in Eastern Europe, Middle East and parts of Africa
Ticks (*Ixodida)*		
Hard ticks Soft ticks	Tick-born relapsing fever	Tropics and sub-tropics, Europe, North America
	Lyme disease	Northern temperate regions of the world, including China, Europe, USA and the former USSR
	Viral encephalitis	Far East and former USSR, Europe
	Rocky Mountain spotted fever	The Americas
Biting mites (*Trombiculidae*)		
Harvest mites	Scrub typhus	Asia, Australia

2.1.2 Vertebrates

Scent marking or territorial marking is a typical behaviour used by **cats** and **dogs** to identify their territory. This is achieved by depositing strong-smelling substances such as urine at prominent locations within the territory. Scent marking is preferably done on vertical surfaces like corners or walls of buildings, trees, fences, every kind of pole (e.g. lamp poles), stones, etc. It is also not unusual for cats and dogs to show territorial behaviour (urine-marking) indoors, e.g. on new objects in the household having an unfamiliar smell, or when having conflicts with other animals. Unwanted pollution of both urban and rural areas may also occur via the deposition of faeces/urine by cats and dogs in gardens, flower beds and playgrounds. Furthermore, dogs and cats can spoil indoor furniture, carpets, curtains, sofa cushions etc. by scratching, nibbling, and lacerating. In all these cases repellents are designed to keep pets away from these places or objects.

European **moles** (*Talpa Europea*, family *Talpidae*) are mammals that live in a system of subsurface tunnels. They feed on earthworms and insects. Moles are 15 to 20 cm long with grey to black velvety fur. They have powerful, shovel-like front limbs, used for burrowing underground. Molehills are small mounds of waste material, arising as an outcome from digging or repairing burrows. The activity of moles may cause damage to gardens, lawns or man-made constructions like pathways or terraces.

Martens (family *Mustelidae*) are slender, agile animals. They have bushy tails, and large paws, the fur varies from yellowish to dark brown. Martens are omnivorous animals, consuming squirrels, mice, rabbits, birds, fish, insects, and eggs, and they will also eat fruit and nuts when these are available. Repellents are used against martens to deter damage to vehicles caused by chewing/biting of car cables.

The European wild **rabbit** *Oryctolagus cuniculus* (family *Leporidae*) is endemic in almost all parts of Europe. Wild rabbits feed on grass, forbs and weeds. Their fur is brown-grey to yellowish. Rabbits live underground in burrows and holes. Wild rabbits are undesired in human gardens because their burrowing activity may cause damage to man-made constructions like pathways or terraces.

2.2 Mode of action

2.2.1 Repellents

The English word repellent is derived from the Latin verb ‘repellere’, which means to drive back, to beat, to strike or to flash back. Repellents are furthermore defined as ‘any stimulus which elicits an avoiding reaction’ (White, 2007).

Host-location by hematophagous arthropods is regulated by stimuli generated by the host, like dark clothing, human emanations (e.g. CO_2, lactic acid and carboxylic acid), skin temperature, and moisture (Barnhard & Xue, 2007). Insects can detect odours due to changes in the electrical activity of olfactory receptors within the antenna and maxillary palpal sensillae. Vision is also important for host location (Butler, 2007).

There are two specific types of insect repellents: barrier repellents and olfactory repellents. Barrier repellents serve as a ‘barrier’ to the insect, preventing either landing or penetration of the skin. Barrier repellents lead to a change in the behavioural capability of the insect, e.g. the insect may land on the human skin but it is not able to bite (Gerberg & Novak, 2007).

Most insect repellents however are vapour or olfactory repellents, which are active in the vapour phase. These repellents have an impact on the insect’s olfactory sense, resulting in avoidance of the released substances or insects are no longer able to locate a potential host

(Govere & Durrheim, 2007). Hence, insect repellents have to have a minimum vapour pressure to be effective. In general, repellents with a high vapour pressure will have a repellent effect already at low concentrations whereas lower volatility of a repellent will result in a protection for longer time periods (Moore & Debboun, 2007).

According to Gupta & Bhattacharjee (2007), an ideal repellent must be volatile, must come in contact with the insects' olfactory organ, and must have a certain lipid solubility to trigger the olfactory sensation. There are also insect repellent products available based on sound production particularly ultrasound. These electronic devices are not dealt with in the context of this ESD.

Repellents against vertebrates are intended to keep away animals from objects, areas, potted plants, or other animals. Products release an odour which confuses or disturbs the sense of smell of the target animals and discourages them from visiting the treated areas so that they get trained over a period of time and learn to avoid the treated areas.

2.2.2 Attractants

Attractants used can be food (e.g. jam, honey, sugar, and apple juice) however, since the BPR does not apply to food and feed used as attractants, they will not be considered in the context of this ESD.

Pheromones used in attractants are chemicals that trigger a natural behaviour response in another member of the same species. The term 'pheromone' is based on the Greek words *pherein* (to transport) and *hormone* (to stimulate). There are different types of pheromones like alarm pheromones (released when being attacked by a predator), sex pheromones (released to indicate the availability of the female for breeding), or food trail pheromones (released by social insects for marking the trail to an attractive food source).

As with repellents, pheromones have an olfactory mode of action which requires a certain potential for transfer into the air phase and being transported there to reach the target organism. Pheromones used in biocidal products of PT 19 are generally sex pheromones. Many insect species release sex pheromones to attract males. Pheromone traps lure target organisms by releasing a synthetic pheromone in combination with a non-biological and non-chemical means (e.g. a sticky paper) catching the males, which will disrupt mating of the species.

Furthermore, substances present in human emanations, e.g. CO_2 and lactic acid may act as attractants, especially for mosquitoes.

3 Selected uses for repellents and attractants

Repellents and attractants can be assigned to the following categories, based on their intended use:

- Insect repellents applied on human skin and garments (see section 3.1)
- Insect repellents applied on animal coat (see section 3.2)
- Repellents applied in the environment of humans and animals (see section 3.3)
- Insect repellents used for factory-treated textiles (see section 3.4)
- Attractants (see section 3.5)

3.1 Insect repellents applied to human skin and garments

3.1.1 Description of use area

Insect repellents applied to human skin and garments aim to protect an individual from the bites of ectoparasites like mosquitoes, mites, ticks and lice (Peterson & Coats, 2001). Besides the prevention of nuisance from insects, insect repellents are used by humans as a personal protection measure against vectors of diseases.

Repellent products for human skin are generally available as ready-to-use formulations employed by the general public, like aerosol sprays or pump sprays, emulsions and lotions, gels and gel sprays, crèmes, towelettes, and roll-on sticks. For applications on clothes, sprays are most commonly employed. Formulations can have an influence on the effectiveness of an insect repellent. Additives used in the products like oils and fixatives may reduce the loss of repellent volatiles and enhance the time of efficacy when applied. A more recent development is slow release formulations utilising microcapsule and polymer systems to provide a long-term release of the active substance (Moore & Debboun, 2007; Xue et al., 2007).

Repellents applied on textile articles are sometimes preferred because of the limited contact with the human skin, reducing possible occurrences of allergic reactions. In addition, the strong adherence of the repellent substances to fabrics makes it possible to prolong the product effectiveness of the repellent products. Applying repellent formulations to garments is often used to complete the personal protective strategy against insect bites. Using repellent treated clothes together with applying specific repellents on human skin, provide the best known individual protection system to prevent biting from disease-carrying insects (Rozendaal, 1997; Young & Evans 1998; McCain & Leach, 2007).

3.1.2 Biocidal active substance typically applied in this area

The use of repellent substances against blood-sucking ectoparasites dates back to ancient times, when oils, vinegar, herbs, tars and smokes were used to repel insects. Dimethyl phthalate (DMP, patented in 1929 as a fly repellent) was one of the first synthetic repellents on the market. Subsequently, DMP was further implemented into a famous insect repellent after the second world war, which was also known as 6-2-2. This repellent mixture contained 6 parts DMP, 2 parts Indalone (butyl-3,3-dihydro-2,2-dimethyl-4-oxo-2H-pyran-6-carboxylate, patented in 1937), and 2 parts ethyl hexanedial (became available in 1939).

Due to the impact of vector-borne diseases on US military troops in endemic areas, the US military consequently initiated an extensive screening program, which aimed at finding other substances with insect repellent properties. In 1953, N,N-diethyl-*meta*-toluamide (DEET) was discovered. DEET is a broad spectrum repellent which is still a commonly used active substance in human skin repellent products (Moore & Debboun, 2007). DEET concentrations used in a multitude of formulations worldwide vary from 5% to 100% (Frances, 2007a). With respect to the European market, DEET products in most cases do not contain more than 50% active ingredient (Dr Knoell Consult, 2012a and Dr Knoell Consult, 2012b).

Since then, several other compounds have been found to also bear repellent activity. Today, commercially available insect repellents for human skin can be divided into two categories: synthetic chemicals and plant-based essential oils, extracts or fatty acids. Prominent substances belonging to the first group are DEET (see above), Icaridin (1-piperidinecarboxylic acid, 2-(2-hydroxyethyl)-1-methylpropylester, developed in the 1980'), and IR3535 (3-(N-acetyl-N-buthyl)aminopropionic acid ethyl ester, developed in 1975). Typical Icaridin and IR3535 concentrations in human skin repellent products vary from 5% to 30% and from 5% to 20%, respectively (Puccetti, 2007, Frances, 2007b, Dr Knoell Consult, 2012b). Referring to plant-based insect repellents, a variety of essential oils and extracts have repellent properties (Gerberg & Novak, 2007). Numerous plant-based repellents contain essential oils from the citronella group family (*Poaceae*), or even natural pyrethrins, geraniol, lavender oil, neem extract, and fatty acids like lauric acid and decanoic acid (Moore et al., 2007). The repellent PMD (p-menthane-3,8-diol) is found in small quantities in the essential oils of lemon eucalyptus leaves (*Corhymbia citriodora citriodora*) and may be isolated using a distillation process (Strickman, 2007). PMD formulations sold in the USA contain as much as approximately 26% PMD (Citrefine ®, 2013; Strickman, 2007) whereas formulations currently on the European market contain mostly less than 15% PMD (Dr Knoell Consult, 2012a; Dr Knoell Consult, 2012b).

For the treatment of clothing by the general public, any repellent considered for skin application can be used. In addition, the active substance permethrin ((3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate) is a commonly used repellent and insecticide compound for the treatment of clothing (McCain & Leach, 2007).

3.1.3 Environmental release pathway

The production of the active substance as well as the formulation of the skin/garment repellent product, and waste disposal are life cycle steps which will not be considered in the framework of this ESD. Recovery and disposal is not a matter of concern since recovery is not intended for this type of products. The packaging material with possible residual amounts of the product will be disposed of as municipal waste. In this case, the general risk management measures based on EU waste legislation apply.

Emissions to the environment can take place during the application of the product on human skin or garments. A fraction can be released to the floor when repellents are applied indoors or to paved or unpaved ground during outdoor applications. However, according to TM IV/2013, emissions resulting from the stage of application on human skin or garment are of minor importance since they take place non-repeatedly on a very limited area and are therefore not considered within this ESD.

The main emissions of this use to the environment occur during the removal phase of the insect repellent. Removal of the product from human skin and garments can either take place:

1. Through showering or bathing of humans who have used an insect repellent and/or washing of the clothes treated with the repellent formulation. Sewage treatment plants are the primary compartment for emissions whereas surface water bodies (including sediment) as well as the soil compartment (including groundwater) are secondary exposed compartments for remnants via sewage treatment plant effluents and sewage sludge applications, respectively.

2. Through direct release to surface water if people with treated skin go swimming in outdoor surface waters (only for human skin repellents).

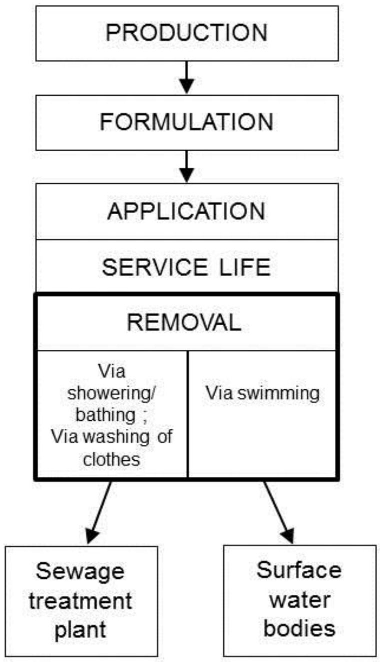

Figure 2: Relevant life-cycle stages to be considered for PT 19 products when assessing environmental emissions due to the use on human skin or clothes

3.1.4 Emission scenarios

3.1.4.1 Removal through showering and bathing of humans as well as washing of garments

The calculation of environmental emissions for products applied on human skin or garments following showering/bathing or washing is based on existing scenarios for the assessment of emissions from biocides used as private human hygiene biocidal products (ESD for PT 1, van der Aa & Balk, 2004). The ESD for PT 1 contains calculation methods using the annual tonnage applied, and the average consumption of a product (both approaches are based on Van der Poel & Backer, 2002). The existing scenarios have been modified to calculate emissions of repellents to the environment.

Referring to the tonnage approach, two parameters used for the calculation ($Fprodvol_{reg}$ and Fmainsource) are intended for scaling the tonnage of the active substance marketed in the EU for that specific purpose to local emissions into a municipal STP. For the remaining parameters, the following assumptions have been made:

F_{air}: Evaporation from treated skin and garments is considered negligible by default (F_{air} = 0). However, since olfactory repellents act through evaporation, a transfer of a fraction of the active substance to the air compartment during use of the product may take place. Therefore, the default value can be replaced if data are available justifying the quantification of this fraction.

F_{skin}: During the 'leave-on' phase of the product on human skin, a certain amount of product might be dermally absorbed and metabolised in human bodies, hence it is no longer available for release into the municipal wastewater system. By default, this fraction is set to 0. The value can be replaced if data are available justifying the quantification of this fraction. For treated garments, a limited contact of the repellent product with human skin is to be expected, and therefore no skin absorption is assumed.

F_{water}: The fraction entering wastewater is set to 1 by default. It can be modified, if data for the evaporation and dermal absorption are available. Repellent formulations specifically destined for textiles may be more resistant to laundry processes, resulting in a lower released fraction to the STP.

$T_{emission}$: The time period during which a repellent is released is related to the intended period of use for the product. Biting and sucking arthropods in Europe might plague humans from early spring to late autumn but not all insect repellents are thought to protect from all types of insects, but just from certain species. Therefore as a realistic worst case, 91 days (3 months of peak bug season) have been chosen. This value was agreed at TM IV/2010.

Table 3-1: Emission scenario for calculating the release of repellents used on human skin and garments based on the annual tonnage applied (according to van der Aa & Balk, 2004)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Relevant tonnage in the EU for this application	TONNAGE		[$t.yr^{-1}$]	S
Fraction for the region	$Fprodvol_{reg}$	0.1	[-]	D (van der Aa & Balk, 2004, Table 4.1)
Relevant tonnage in the region for this application	TONNAGEreg		[$t.yr^{-1}$]	S/O (eq. 3.1)
Fraction of the main source (local sewage treatment plant)	$Fmainsource_4$*	0.002	[-]	D (van der Aa & Balk, 2004, Table 4.1)
Fraction released to air	$F_{4,air}$	0	[-]	D
Fraction dermally absorbed	$F_{4,skin}$	0	[-]	D
Fraction released to wastewater	$F_{4,water}$	1	[-]	D/O (eq. 3.2)
Number of emission days for life-cycle stage 4	$T_{emission4}$	91	[$d.yr^{-1}$]	D
Output				
Local emission rate to wastewater	$Elocal_{4,water}$		[$kg.d^{-1}$]	O
Intermediate calculation				
Relevant tonnage in the region for this application: $TONNAGEreg = Fprodvol_{reg} \bullet TONNAGE$ (3.1)				
Fraction released to wastewater: $F_{4,water} = 1 - (F_{4,air} + F_{4,skin})$ (3.2)				
End calculation				
$Elocal_{4,water} = TONNAGEreg \bullet 1000 \bullet Fmainsource_4 \bullet F_{4,water} / T_{emission4}$ (3.3)				

* The subscript '4' refers to the life-cycle stage 'private use' according to van der Poel (2000)

The consumption-based approach for insect repellents applied on human skin and garment is based on the post-consumer release prediction model according to PT 1 (van der Aa & Balk, 2004) with some modifications that have been included.

$Qform_{appl}$: As a default value for the consumption of a repellent product on human skin or garments, a value of 0.6 mg/cm^2 skin/garment surface is proposed (see Appendix 6.1). This value must coincide with the efficacy of the product and must be adapted accordingly. The parameter can further be modified if differing application amounts are indicated due to product characteristics (e.g. with respect to the viscosity of the product).

N_{appl}: The number of applications per day on human skin is among other things dependent on the time a human spends outdoors, the occurrence and population size of annoying or harmful insects, the kind of active substance in the product, the concentration of the active substance in the product, as well as the type of formulation. These parameters and other factors (like host-specific characteristics) determine the duration of protection offered to humans, hence they will also determine the number of applications on skin that are required for successful insect repellency. Since the number of repellent applications per day is closely related to the effectiveness of the repellency action of an insect repellent, a pick-up list has been established for choosing the appropriate daily number of applications. A basic assumption is the maintenance of 12 hours of protection per day. The default values for the number of daily applications can be overruled if the product label gives advice on the maximum number of applications per day. For repellent spray applications to garments, a default value of one application per day is assumed, since stronger adhesion of the repellent to the fabrics of the garment is to be expected.

Table 3-2: Pick list for number of applications per day

Treatment	Efficacy of the product (h)	N_{appl}
Human skin	≥ 12 h	1
	≥ 6 h - < 12 h	2
	≥ 4 h - < 6 h	3
	< 4 h	4
Human clothes		1

$AREA_{skin}$: The consumption of repellents for applications on human skin is dependent on the surface area to be treated. In most cases repellents are intended to be applied on the head, arms, legs, hands and feet, omitting the trunk. Sometimes repellent sticks are used only locally, e.g. for the treatment of sensitive body parts like the face skin. The skin surface area of a standard adult person is defined by HEEG (Human Exposure Expert Group; EC, 2013c) and poses the basis for assessing the application amount for insect repellents when applied on human skin. The max. AREAskin relevant for the product should be calculated by adding up relevant body parts to be treated, based on the default values provided in the following Table 3-3.

Table 3-3: Default values for the surface area of a standard adult person (EC, 2013c)

Body parts	Surface area for a standard adult person			
	cm^2	%	cm^2	%
Trunk			5 710	34.4
Head	1 110	6.7	10 660	64.2
Arms	2 270	13.7		
Hands	820	4.9		
Legs	5 330	32.1		
Feet	1 130	6.8		
Total			16 600*	

* There is a slight difference between the total surface area given by HEEG (16600 cm^2; EC, 2013c) and the surface area when summing up single body parts.

$AREA_{garment}$ The presence of repellents in garments will vary according to the article dimensions. A pick list for the surface area of different pieces of clothing is presented in

Table 3-4. The garment textile dimensions are based on the average area of skin that is meant to be protected. The garment surface area is increased by 10% with respect to human skin values. If no specific information is provided, the total area of an "outdoor garment set" (17 838 cm^2) can be assumed.

Table 3-4: Default values for the surface area of garments

Textile article	Surface area (cm^2)	Total surface area of an "outdoor garment set" (cm^2)
T-shirt/jacket	8 778	17 838
Trousers	5 863	
Socks*	3 197	

* Area estimation assumes that socks cover the feet and a third of the total leg surface area of an adult

F_{penetr}: As a default for the market share of a repellent active substance, a value of 50% (F_{penetr} = 0.5) is proposed (see Appendix 6.2). A refinement of this value can only be done by the evaluating Competent Authority (eCA), e.g. by taking into account information provided by the applicant, because only Member States have the knowledge about the market of all substances and products.

F_{inh}: As a default for the fraction of inhabitants using a skin repellent product, a value of 20% (F_{inh} = 0.2) is proposed (see Appendix 6.2). It is proposed to also apply this value to the fraction of inhabitants treating their garments with repellents also thought to be used for human skin.

A different value is considered for the fraction of inhabitants using a specific repellent product (e.g. a permethrin containing product), solely designed for the treatment of textiles by the general public. The target population that may use these specific formulations is expected to be tourists or excursionists that occasionally travel to areas with high densities of insects or regions with a known occurrence of carrying-diseases insects. As a means of reference, the number of reported long outbound holiday trips of the Dutch population to Caribbean areas (170 000 trips) in relation to the total national population in 2010 (16 574 989 inhabitants) is considered (CBS, 2011). This represents 1.02% of the population. F_{inh} = 0.01 is therefore suggested as the "best guess" value regarding the fraction of inhabitants using a specific repellent for clothes.

Table 3-5: Pick list for the fraction of inhabitants using repellent products for skin and garment application

Type and use of the repellent product	F_{inh} [-]
Skin repellent Human skin application	0.2
Skin repellent Garment application	0.2
Textile repellent Garment application	0.01

Table 3-6: Emission scenario for calculating the release of repellents used on human skin and garments based on the average consumption (according to van der Aa & Balk, 2004)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Number of inhabitants feeding one sewage treatment plant	Nlocal	10 000	[cap]	D (EC, 2003, Table 9)
Active substance in the product				
A)[2)]	$Cform_{volume}$		$[g.L^{-1}]$	S
B) [2)]	$Cform_{weight}$		$[g.kg^{-1}]$	S
Consumption per application				
D1)[2)]	$Vform_{appl}$		$[\mu L.cm^{-2}]$	D/S
D2)[2)]	$Qform_{appl}$	0.6	$[mg.cm^{-2}]$	D/S
Number of applications per day	N_{appl}		$[d^{-1}]$	P (*cf.* Table 3-2)
Treated area of human skin	$AREA_{skin}$		$[cm^2]$	P (*cf.* Table 3-3)
Treated area of garments	$AREA_{garments}$		$[cm^2]$	P (*cf.* Table 3-4)
Fraction released to air	F_{air}	0	[-]	D
Fraction dermally absorbed	F_{skin}	0	[-]	D
Fraction released to wastewater	F_{water}	1	[-]	D/O (eq. 3.4)
Fraction of inhabitants using a repellent product	F_{inh}		[-]	P (*cf.* Table 3-5)
Market share of repellent	F_{penetr}	0.5	[-]	D
Specific density of the product	RHOform	1000	$[kg.m^{-3}]$	D

Table 3-6 (cont.):

Output				
Local emission rate to wastewater	$Elocal_{water}$		$[kg.d^{-1}]$	O
Intermediate calculation Fraction released to wastewater $F_{water} = 1 - (F_{air} + F_{skin})$ (3.4)				
End calculation **A and D1*** $Elocal_{water} = Nlocal \bullet N_{appl} \bullet Vform_{appl} \bullet AREA_{skin/garment} \bullet Cform_{volume} \bullet F_{inh} \bullet F_{water} \bullet F_{penetr} \bullet 10^{-9}$ (3.5) **A and D2*** $Elocal_{water} = Nlocal \bullet N_{appl} \bullet Qform_{appl} \bullet AREA_{skin/garment} / RHOform \bullet Cform_{volume} \bullet F_{inh} \bullet F_{water} \bullet F_{penetr} \bullet 10^{-6}$ (3.6) **B and D1*** $Elocal_{water} = Nlocal \bullet N_{appl} \bullet Vform_{appl} \bullet AREA_{skin/garment} \bullet Cform_{weight} \bullet RHOform \bullet F_{inh} \bullet F_{water} \bullet F_{penetr} \bullet 10^{-12}$ (3.7) **B and D2*** $Elocal_{water} = Nlocal \bullet N_{appl} \bullet Qform_{appl} \bullet AREA_{skin/garment} \bullet Cform_{weight} \bullet F_{inh} \bullet F_{water} \bullet F_{penetr} \bullet 10^{-9}$ (3.8)				

* Active substance concentrations within the product and consumption amounts of the product per application can be given on a weight or volume basis. The end-calculations may therefore require the inclusion of the product density as appropriate and must include varying factors for converting units to gain an $Elocal_{water}$ in $kg.d^{-1}$. For transparency reasons, the parameters for the active substance in the product and the product application amount were assigned A, B, D1 and D2 – dependent on the unit in which they are available. This assignment has been done congruent to the ESD for PT 1 (van der Aa & Balk, 2004).

3.1.4.2 Release to surface water bodies through swimming

Humans treated with a repellent, can swim in coastal areas as well as in inland waters (rivers and lakes). To represent a realistic worst-case scenario, the release of repellents from the skin of treated humans into ponds, lakes or reservoirs during swimming is evaluated. Due to dilution effects, neither coastal areas nor rivers will be considered in the context of this ESD.

With entry into force of the revised Bathing Water Directive (2006/7/EC) (EU, 2006) concerning the management of bathing water quality, EU Member States are obliged to report to the Commission the number of bathing waters, i.e. the number of coastal waters, rivers and lakes, and to control the quality of the swimming waters according to standards defined in the directive.

In 2011, the EU Member States reported more than 21 000 bathing waters (coastal and inland), of which more than two thirds (69%) are coastal waters, the rest are inland waters (rivers and different types of lakes). Almost half of all EU inland bathing waters (approximately 6 850 lakes and rivers) are in Germany (30%) and France (20%). The EU average is 1.6 inland bathing waters per 1 000 km^2 (EEA, 2012). These results reveal the importance of inland surface waters for leisure activities such as swimming.

The term ‘surface water body’ refers hereafter to only ponds, lakes or reservoirs, and not flowing waters such as coastal waters and rivers.

The development of the 'swimming scenario' is based on a proposal made by the German competent authority at TM II/2011, and the comments made thereafter by other competent authorities and industry. A detailed description of the derivation of default parameters referring to the volume of the surface water body, the number of swimmers, and the swimming season is given in Appendix 6.3. Parameters already mentioned in the previous chapters will not be repeated here again.

$N_{swimmer}$: The average number of swimmers per day is set at 1 500 per default, please refer to Appendix 6.3.

F_{swim}: No information is available regarding the fraction of swimmers using an insect repellent. Surface water bodies are often located in forested areas where the occurrence of biting and sucking arthropods is likely. Furthermore, some surface water bodies have camping locations nearby and campers can be assumed to be equipped more often with an insect repellent than daily visitors of the lake. As a best guess it is assumed, that 2% of the swimmers use an insect repellent before entering the surface water body. This value of 0.02 for F_{swim} should be used as default value for active substance approval. However, for product authorisation a higher value (0.1) can be appropriate, to cover areas with higher insect infestation.

N_{appl}: According to Schets et al. (2011) visits of swimmers at Dutch fresh- and seawater sites lasted 41-79 minutes per occasion in 2007 and 2009. It can be expected that during this time period, treatment with a repellent will take place only once. The interlink between the number of applications and the efficacy of the product as proposed in Table 3-2 does not apply in this respect.

$F_{waterbody}$: The fraction released to the surface water body is set to 1 per default.

$V_{waterbody}$: The volume of the water body is 435 000 m^3 per default (please refer to Appendix 6.3).

$kdeg_{water}$: The rate constant for biodegradation in surface water for readily biodegradable substances can be taken from Table 7 of the Technical Guidance Document (k = 0.047 d^{-1}; EC, 2003). For not readily biodegradable substances, rate constants for biodegradation from simulation tests (aerobic aquatic degradation study or water/sediment degradation study) have to be used. Degradation rates obtained from the tests must be recalculated to 12°C.

$T_{emission}$: Concentrations of the repellent have to be calculated for emission periods of 1 day and 91 days.

Table 3-7: Emission scenario for calculating the release of repellents used on human skin due to swimming activities in surface water bodies

Parameters	Nomenclature	Value	Unit	Origin
Input				
Daily number of swimmers	$N_{swimmer}$	1500	[-]	D
Fraction of swimmers using the repellent product	F_{swim}	0.02/0.1[1)]	[-]	D
Number of applications per day	N_{appl}	1[2)]	[d^{-1}]	D
Fraction released to surface water body	$F_{waterbody}$	1	[-]	D
Active substance in the product				
A)	$Cform_{volume}$		[$g.L^{-1}$]	S
B)	$Cform_{weight}$		[$g.kg^{-1}$]	S
Consumption per application				
D1)	$Vform_{appl}$		[$\mu L.cm^{-2}$]	D/S
D2)	$Qform_{appl}$	0.6	[$mg.cm^{-2}$]	D/S
Treated area of human skin	$AREA_{skin}$		[cm^2]	P (*cf.* Table 3-3)
Specific density of the product	RHOform	1000	[$kg.m^{-3}$]	D
Output				
Local emission rate to surface water	$Elocal_{water}$		[$kg.d^{-1}$]	O

1) A value of 0.02 for F_{swim} should be used as the default value for active substance approval. For product authorisation, a higher value (0.1) can be appropriate to cover areas with higher insect infestation.

2) The interlink between the number of applications and the efficacy of the product as proposed in Table 3-2 does not apply in this respect (see explanation to parameter N_{appl}).

Table 3-7 (cont.):

Calculation		
A and D1		
$Elocal_{water}$ =	$N_{swimmer} \bullet N_{appl} \bullet Vform_{appl} \bullet AREA_{skin} \bullet Cform_{volume} \bullet F_{swim} \bullet F_{waterbody} \bullet 10^{-9}$	(3.9)
A and D2		
$Elocal_{water}$ =	$N_{swimmer} \bullet N_{appl} \bullet Qform_{appl} \bullet AREA_{skin} / RHOform \bullet Cform_{volume} \bullet F_{swim} \bullet F_{waterbody} \bullet 10^{-6}$	(3.10)
B and D1		
$Elocal_{water}$ =	$N_{swimmer} \bullet N_{appl} \bullet Vform_{appl} \bullet AREA_{skin} \bullet Cform_{weight} \bullet RHOform \bullet F_{swim} \bullet F_{waterbody} \bullet 10^{-12}$	(3.11)
B and D2		
$Elocal_{water}$ =	$N_{swimmer} \bullet N_{appl} \bullet Qform_{appl} \bullet AREA_{skin} \bullet Cform_{weight} \bullet F_{swim} \bullet F_{waterbody} \bullet 10^{-9}$	(3.12)

Table 3-8: Calculation of surface water concentrations following swimming of humans having used an insect repellent on their skin

Parameters	Nomenclature	Value	Unit	Origin
Input				
Local emission rate to surface water body	$Elocal_{water}$		$[kg.d^{-1}]$	O
Volume of water body	$V_{waterbody}$	435,000	$[m^3]$	D
First order rate constant for biodegradation in surface water	$kdeg_{water}$		$[d^{-1}]$	S
Number of emission days	$T_{emission,1d}$	1	[d]	D
Number of emission days	$T_{emission,91d}$	91	[d]	D
Number of emission events	$N_{emission,91d}$	91	[-]	D
Local concentration in water body after one day	$Clocal_{water,1d}$		$[mg.L^{-1}]$	O
Local concentration in water body over 91 days	$Clocal_{water,91d}$		$[mg.L^{-1}]$	O
Refined local concentration in water body over 91 days (including degradation)	$Clocal_{water,91d\text{-}ref}$		$[mg.L^{-1}]$	O
Calculation				

$$Clocal_{water,1d} = Elocal_{water} \bullet 10^3 \bullet T_{emission,1d} / V_{waterbody} \quad (3.13)$$

$$Clocal_{water,91d} = Elocal_{water} \bullet 10^3 \bullet T_{emission,91d} / V_{waterbody} \bullet 10^3 \quad (3.14)$$

$$Clocal_{water,91d-ref} = Clocal_{water,1d} * \frac{1-\left(e^{-kdeg_{water} * T_{emission,1d}}\right)^{N_{emission,91d}}}{1-e^{-kdeg_{water} * T_{emission,1d}}} \quad (3.15)$$

As a first tier approach, the $PEClocal_{water}$ corresponds to $Clocal_{water,91d}$ from equation 3.14 and should be used for the risk assessment, representing the worst-case situation.

Calculation of $PEClocal_{water}$ according to $Clocal_{water,91d\text{-}ref}$ (equation 3.15) provides a refinement option considering degradation processes in the water body. This approach is based on equations 4, 7 and 8 of the ESD for PT 18 (OECD ESD No. 14 (insecticides for stables and manure storage systems); OECD, 2006).

3.2 Insect repellents applied on animal skin

3.2.1 Description of use area

Insect repellents for application on animal coats are used mainly for horses, cats and dogs. As in the case for repellents applied on human skin, they too are intended to shield animals from the bites of ectoparasites and for protection against vectors of diseases (e.g. heartworms or west-nile-virus).

Horses are susceptible to summer eczema, when harassed by blackflies. Furthermore, horses often become nervous when being annoyed by insects, so the use of insect repellents on horses contributes to the safety of the rider.

Referring to cats and dogs, hygienic reasons play an important role for ectoparasites to be undesired. Furthermore, fleas on cats or dogs may change their host, so humans may be subsequently infested. Repellent products for animal coats are generally ready-to-use formulations employed by the general public.

For horses, mostly trigger sprays are used for repellent applications as some horses get frightened from the sibilant noise of spraying when using aerosol sprays. There are also lotions, emulsions or gels available which are distributed on the horse coat with a cloth or sponge. Roll-on sticks are designed especially for horse faces. Minor formulation types are available as concentrates, which have to be subsequently diluted in water prior to applying either by trigger spray bottles, sponges or cloths. Since hobby riders have a clear preference for applying ready-to-use formulations (according to an inquiry of products currently on the German market for being used on horses; Dr Knoell Consult, 2012b), the preparation of an application solution will not be considered here. Indirect application methods for horses are also available in the form of ribbons or patches which need to be fixed to the riding equipment.

Sprays or spot-on preparations are mainly used for direct applications of insect repellents on cats or dogs. Shampoos formulated with repellents are also available but they are not considered in the context of this ESD.

Indirect methods for repelling fleas, mites and ticks from cat and dog coats are very popular, the most abundant type of indirect application is by a formulation integrated into collars which are fixed around the neck of the targeted animals. Additional formulation types like impregnated neckties or patches are also available. Emissions arising from indirect application methods for horses and pets will not be considered in this context as such releases are diffuse and difficult to quantify. Furthermore, the main pathway for emissions is the one to solid waste, when collars, neckties or patches are discarded. As indicated before, the disposal to municipal waste is not included in this ESD.

Therefore, the direct application of insect repellents to a horse, cat or dog may be taken as a worst case scenario and is considered as the most relevant in this framework.

3.2.2 Biocidal active substance typically applied in this area

In principle, all active ingredients used for repelling insects from human skin are also employed for horses. With particular reference to cats and dogs, here the most abundant active ingredients used as repellents are lavender oil, neem extract, geraniol, and fatty acids (nonanoic acid, decanoic acid).

3.2.3 Environmental release pathway

Referring to the use of insect repellents for horses, the ESD focuses on the hobby sector of riding activities as it represents the worst-case situation for repellent emissions to the environment, compared to the professional sector.

Treatments of horses with an insect repellent are generally done before taking a ride (either as a leisure activity or participation in a horse riding tournament) or before the horses are brought out to pasture for grazing. Applications on dogs and cats are done before the animals enter the outdoor environment. Emissions to environmental compartments can take place during the application of products onto animals' skin. In this context, spray applications are deemed to be the only application mode with noteworthy emissions to the environment.

Referring to horses, product applications are predominantly conducted outside stables, so a fraction may be released to the ground, either being paved or not. The first approach considers horses kept in loose barns which are groomed and prepared for riding on bare soil or grassland places. It is assumed that a spray application leads to spray drift, entering the soil beneath and around the treated horse. The second approach relates to an equestrian facility with a paved yard, where a number of horses are treated the same day with an insect repellent. Remains entering paved ground by spray drift are washed off with rainwater and are assumed to be discharged to the municipal wastewater treatment plant or directly to surface water bodies.

Horses may also be treated with an insect repellent when being brought to pasture for grazing. Since rolling of horses is a typical body care behavioural element (Matsui et al., 2009), it cannot be excluded that repellent product remnants on horse skin are transferred to soil.

A further conceivable route for repellent release after application on horses is through water hosing. The hosing of horses is a common practice (especially in summer) for cooling down horses after riding or any other activity, or just to relieve horses at elevated temperatures, making them feel more comfortable. Hence, a scenario has been developed, accounting for these potential emissions.

For cats and dogs, an outdoor spray application with emissions to bare soil is included. A further scenario deals with emissions arising from indoor product applications.

Emissions to the environment can also occur due to repellent treated cats and dogs by washing and bathing. However, a scenario has not been implemented in this ESD but is subject to further research (see section 4), if it is identified to be needed for product authorisation.

3.2.4 Emission scenarios

3.2.4.1 Emissions during application

A) Direct emissions to soil

This scenario considers horses kept in loose barns which are groomed and prepared for riding on bare soil or grassland places. Furthermore, applications of cats and dogs standing on bare soil or lawn are accounted for. It is assumed that a spray application leads to spray drift, entering the soil surrounding the treated animals.

The following parameter and default values are integrated in the calculation:

N_{appl}: Horse grooming or preparation of horses for riding is done once a day so a default number of one application per day is applied. As outlined above, indirect methods for protecting cats and dogs from arthropod attacks are more common than spray applications, hence also for cats and dogs one spray application per day is considered realistic.

$AREA_{skin}$, V_{soil}: According to the 'revised guideline on environmental impact assessment for veterinary medicinal products' (EMEA, 2008), the default bodyweight values for horses and ponies with respect to PEC_{soil} calculations for pasture animals are 600 kg and 250 kg, respectively. For this assessment, 450 kg body weight as a rounded-up mean value is taken. Referring to cats and dogs, body weights of 6 kg and of 40 kg, respectively, cover the body weight of typical breeds. The corresponding surface areas are calculated according to the DRAWAG draft proposal (EC, 2010b).

Table 3-9: Treated skin areas for horses, cats, and dogs as well as soil areas for emissions

Animal species	Body weight (BW) (kg)	Skin area ($AREA_{skin}$) (cm^2)[1)]	Soil area for emissions (m^2)	Soil volume (V_{soil})[2)] (m^3)
Horses	450	58 300	6	3
Dogs	40	12 100	1.5	0.75
Cats	6	3 500	0.8	0.4

1) Calculated according to DRAWAG proposal (EC, 2010b): $AREA_{skin}$ (cm^2) = $0.11 \bullet BW^{0.65} \bullet 10^4$, rounded values

2) For calculating soil volumes, a soil depth of 50 cm is taken, which was discussed at WG-V-2014 for PT 18 (and reconfirmed in WG-I-2015 for PT 19) and emissions to a limited soil area in the vicinity of houses or terraces. As discussions on relevant depth and critical distances are continuing and knowledge on the subject is just developing, the included calculations must be considered as examples only. Definitive decisions will be made at a later stage.

$Qform_{appl}$: A questionnaire (Dr Knoell Consult, 2013) has been distributed amongst riders, querying the practice of insect repellents use on horses, i.e. the mode of application, application amounts, number of applications per day, and months for applications. Product application amounts specified by the riders are highly variable, ranging from 3.5 mL to 50 mL product per horse and application. As a default value for the consumption of a repellent product on human skin, a value of 0.6 mg/cm^2 skin surface is proposed (see Appendix 6.1). Taking this value also for horses, an application amount of 35 g product per application is estimated, which is considered a reasonable worst-case value for emission assessments. This application amount covers the majority of application amounts indicated by the inquired riders. The same application amount (0.6 mg/cm^2) is proposed as a default for cats and dogs. This value must coincide with the efficacy of the product and must be adapted accordingly. The parameter can further be modified if differing application amounts are indicated due to product characteristics (e.g. with respect to the viscosity of the product).

F_{soil}: The fraction entering the soil by spray drift is set to 0.1 by default. This value is in agreement with the default values taken for spray drift in the ESDs for PTs 10 (Migné, 2002) and 18 (OECD ESD No. 18, OECD, 2008).

$kdeg_{soil}$: The rate constant for biodegradation in soil of readily biodegradable substances can be taken from Table 8 of the TGD (EC, 2003). For not readily biodegradable substances, rate constants for biodegradation from simulation tests have to be used. Degradation rates obtained from the tests must be recalculated to 12°C.

$T_{emission}$: Generally there are specific designated areas within a barn yard to tie horses for grooming and preparation for riding. Spray applications of repellents conducted over certain time periods might therefore affect the same soil areas repeatedly. It is assumed that an insect repellent is applied once daily at the same place during the peak bug season of 91 days. Although the yearly time span for the occurrence of annoying insects is longer than three months, the pressure exerted by populations is only temporarily high and horses will not be treated with an insect repellent every day. Therefore, 91 emission days are considered reasonable.

It is not realistic that applications on cats and dogs will always be conducted at the same place. Therefore, just a one-fold application is relevant. Concentrations of the repellent have to be calculated for 1 day (for horses, cats and dogs) and for 91 days (for horses).

Table 3-10: Emission scenario for calculating the release of repellents used on horses or pets due to spray drift: Emissions to bare soil

Parameters	**Nomenclature**	**Value**	**Unit**	**Origin**
Input				
Active substance in the product	$Cform_{weight}$*		[g.kg^{-1}]	S
Consumption per application	$Qform_{appl}$*	0.6	[mg.cm^{-2}]	D/S
Number of applications per day	N_{appl}	1	[d^{-1}]	D
Treated area of skin	$AREA_{skin}$		[cm^2]	P (*cf.* Table 3-9)
Fraction released to soil by spray drift	F_{soil}	0.1	[-]	D (Migné, 2002, Tables 9 and 10; OECD ESD No. 18, OECD, 2008, Table 4.3-7)
Output				
Local emission of the active substance during application due to spray drift	$Elocal_{soil}$		[kg.d^{-1}]	O
Calculation				
$Elocal_{soil} = N_{appl} \bullet Qform_{appl} \bullet AREA_{skin} \bullet Cform_{weight} \bullet F_{soil} \bullet 10^{-9}$ (3.16)				

* Please refer to the previous scenarios for volume-based application amounts and/or active ingredient contents.

Table 3-11: Calculation of the concentration in soil following emissions to bare soil from spray applications of repellents on horses, cats and dogs

Parameters	Nomenclature	Value	Unit	Origin
Input				
Local emission of the active substance during application due to spray drift	$Elocal_{soil}$		$[kg.d^{-1}]$	O
Soil volume	V_{soil}		$[m^3]$	P (*cf.* Table 3-9)
Bulk density of wet soil	RHO_{soil}	1700	$[kg_{wwt}.m^{-3}]$	D
First order rate constant for biodegradation in soil	$kdeg_{soil}$		$[d^{-1}]$	S
Number of emission days	$T_{emission,1d}$	1	[d]	D
Number of emission days	$T_{emission,91d}$	91	[d]	D
Number of emission events	$N_{emission,91d}$	91	[-]	D
Output				
Local concentration of active ingredient in soil resulting from one day	$Clocal_{soil,1d}$		$[mg.kg_{wwt}^{-1}]$	O
Local concentration in soil over 91 days	$Clocal_{soil,91d}$		$[mg.kg_{wwt}^{-1}]$	O
Refined local concentration in soil over 91 days (including degradation)	$Clocal_{soil,91d\text{-}ref}$		$[mg.kg_{wwt}^{-1}]$	O
Calculation				

$$Clocal_{soil,1d} = Elocal_{soil} \bullet T_{emission,1d} \bullet 10^6 / (V_{soil} \bullet RHO_{soil}) \quad (3.17)^*$$

$$Clocal_{soil,91d} = Elocal_{soil} \bullet T_{emission,91d} \bullet 10^6 / (V_{soil} \bullet RHO_{soil}) \quad (3.18)^*$$

$$Clocal_{soil,91d-ref} = Clocal_{soil,1d} * \frac{1-\left(e^{-kdeg_{soil}*T_{emission,1d}}\right)^{N_{emission,91d}}}{1-e^{-kdeg_{soil}*T_{emission,1d}}} \quad (3.19)^*$$

* Equation 3.17 applies to the treatments of horses, cats and dogs, whereas equations 3.18 and 3.19 only relate to the treatment of horses.

With respect to horses, as a first tier approach the $PEClocal_{soil}$ corresponds to $Clocal_{soil,91d}$ from equation 3.18 and should be used for the risk assessment, representing the worst-case situation.
Calculation of $PEClocal_{soil}$ according to $Clocal_{soil,91d\text{-}ref}$ (equation 3.19) provides a refinement option considering degradation processes in soil. This approach is a refinement and based on

equations 4, 7, and 8 of the OECD ESD for PT 18 (OECD ESD No. 14 (insecticides for stables and manure storage systems); OECD, 2006).

B) Emissions to paved ground and discharge to STPs or surface water bodies

Horse ranches or yards generally have paved areas outside the stables that are used by riders for horse grooming purposes. Spray drift due to spray applications may enter concrete or paving stones and can be washed-off by rainwater. There is no common practice in equestrian facilities with regard to the handling of this rainwater. According to the German Association for water, wastewater and waste (DWA) (2013), the rainwater from sealed areas is commonly not introduced into the manure/slurry system for practical reasons. Liquids entering the manure/slurry system have to be spread to arable or grassland. So farmers try to prevent the discharge of liquids not regulated by law into the manure/slurry system.

Further options for disposal include the discharge of rainwater to the wastewater treatment system, discharge into a storm water system, or discharge directly into surface water bodies. The importance of a release into the storm water systems is currently under evaluation by Member States and hence will not be contemplated at this stage of ESD preparation. This route for emissions has to be considered according to the procedure, which will be agreed upon in the near future. Nevertheless, emission scenarios have been defined below for the remaining two discharge options (STPs and surface water bodies). A further possibility would be the direct percolation of water into the soil area surrounding the paved yards. However, with reference to the size of paved yards and the corresponding significant volume of rainwater that is to be expected, this mode of discharge is not considered relevant.

The following parameter and default values are integrated in the calculation:

N_{horses}: Horse farms are prevalently located near cities and urban areas to provide an accommodation for horses owned by different riders. These horse farms often provide shelter for a considerable number of horses. In the context of this ESD, a horse farm is assumed, where 50 horses are kept.

F_{water}: The fraction entering paved ground by spray drift is set to 0.1 by default. This value is in agreement with the default values taken for spray drift in the ESDs for PTs 10 (Migné, 2002) and 18 (OECD ESD No. 18; OECD, 2008).

N_{appl}: The number of applications to horses per day is set to 1 per default.

F_{rider}: According to a questionnaire distributed amongst riders (Dr Knoell Consult, 2013), the practice of using insect repellents is highly variable. Dependent on the sensitivity of the horse and the practice of the riders, some riders treat the complete horse with a repellent, others only treat the legs and/or parts of the waist and other riders do not use an insect repellent for horses at all. Specific figures on the use of insect repellents by riders are not available. As a best guess it is assumed, that 20% of the riders of a horse farm treat the complete horse with the repellent.

Table 3-12: Emission scenario for calculating the release of repellents used on horse skin due to spray drift: Emissions to paved ground

Parameters	Nomenclature	Value	Unit	Origin
Input				
Number of horses	N_{horses}	50	[-]	D
Fraction released to water by spray drift	F_{water}	0.1	[-]	D (Migné, 2002, Tables 9 and 10; OECD ESD No. 18, OECD, 2008, Table 4.3-7)
Active substance in the product	$Cform_{weight}$*		[g.kg^{-1}]	S
Consumption per application	$Qform_{appl}$*	0.6	[mg.cm^{-2}]	D/S
Number of applications per day	N_{appl}	1	[d^{-1}]	D
Treated area of horse skin	$AREA_{skin}$	58300	[cm^{2}]	D (*cf.* Table 3-9)
Fraction of riders treating the complete horse	F_{rider}	0.2	[-]	D
Output				
Local emission rate to wastewater	$Elocal_{water}$		[kg.d^{-1}]	O
Calculation				
$Elocal_{water} = N_{horses} \bullet N_{appl} \bullet Qform_{appl} \bullet AREA_{skin} \bullet Cform_{weight} \bullet F_{rider} \bullet F_{water} \bullet 10^{-9}$ (3.20)				

* Please refer to the previous scenarios for volume-based application amounts and/or active ingredient contents

With reference to the discharge to STPs it is considered reasonable to assume, that only one farm with 50 horses is discharging wastewater to a STP. Environmental concentrations in secondary exposed compartments (surface water, sediment, soil and groundwater) can be calculated according to the procedure laid down in the EU TGD (EC, 2003). With reference to the direct release into surface water bodies, the same approach as for the wood preservatives for a flowing water body is proposed.

$FLOW_{surfacewater}$: Corresponding to the ESD for PT 8 (OECD ESD No. 2; OECD, 2013), a small creek with a flow rate of 0.3 m^3/s is proposed. This means that, during one day, 25 920 m^3 water will pass the point of discharge.

Table 3-13: Calculation of surface water concentrations (slow moving surface water body) due to emissions to paved ground following spray applications of repellents on horses

Parameters	Nomenclature	Value	Unit	Origin
Input				
Local emission rate to water	$Elocal_{water}$		$[kg.d^{-1}]$	O
Volume of receiving water body	$FLOW_{surfacewater}$	25,920	$[m^3.d^{-1}]$	D OECD ESD No. 2; OECD, 2013, Tables 4.3, 4.6 and 4.9)
Output				
Local concentration in surface water	$Clocal_{water}$		$[mg.L^{-1}]$	O
Calculation				
$Clocal_{water} = Elocal_{water} / FLOW_{surfacewater} \bullet 10^3$				(3.21)

C) Indoor applications on cats and dogs: Emissions to STPs

Spray repellents against ectoparasites on cats and dogs can also be applied indoors. During the application, fractions may reach the indoor air, the applicator, the treated surface (i.e. the pelt of cats and dogs), and the floor. Emissions to the applicator and the floor will be discharged to STPs, either by washing of clothes or by cleaning operations. The model for calculating these emissions is congruent with the approach for assessing emissions due to indoor surface spray repellent applications (see section 3.3.4.1, Table 3-16 and Table 3-18). The following parameter should be taken for the calculations:

$N_{appl,building}$: As outlined above, indirect methods for protecting cats and dogs from arthropod attacks are more common than spray applications, hence also for cats and dogs one spray application per day is considered realistic.

$AREA_{treated}$: This parameter corresponds to the parameter $AREA_{skin}$ of Table 3-9.

Emissions to the treated surface (the pelt of the animals) do not result in quantifiable emissions to the environment. Therefore, for assessing emissions to STPs, only those fractions emitted to the applicator and to the floor are relevant.

3.2.4.2 Emissions through rolling of horses

Rolling on pasture is a natural equine behaviour which may occur for numerous reasons. Rolling enables the stretching of muscles and maintains muscle flexibility. Rolling is also related to coat care and general comfort. Horses roll to allay the irritation of sweat by drying the sweat with dirt. This dirt layer acts as a protection against annoying insects (Matsui et al., 2009). Horses may also roll to help shed their winter coats or alleviate any irritation or itchiness of the skin.

The following parameter and default values are integrated in the calculation:

N_{appl}: One application per day is considered realistic since grooming usually takes place once a day. If horses react very sensitively to insects, riders use other options to protect their horses from insect bites (e.g. horse rugs).

$AREA_{skin}$: During rolling, only parts of the treated skin area come in contact with ground, i.e. parts of the neck, the buttocks, the flanks, and the spine. Therefore, abrasion will only pertain to these body parts, and only 30% of the whole surface area of a horse is used for assessing this route of intake into soil (17 490 cm^2). The default value of 30% is taken from the DRAWAG document and relates to the body surface of animals in contact with treated stable surfaces (EC, 2010b).

F_{soil}: No information is available on the abrasion of certain quantities of an insect repellent during rolling. Matsui, et al. (2009) have reported that one rolling event lasts for about half a minute (39 seconds at maximum). Owing to this short time period, only a minor fraction of the insect repellent will be rubbed off. Thus, 1% abrasion per rolling is considered a realistic worst-case guess (F_{soil} = 0.01).

N_{horses}: According to EMEA (2008), the stocking density per hectare for pasture horses is 5 for ponies (<148 cm) and 3 for larger horses (> 148 cm). As a default, 4 horses per hectare are proposed.

$N_{rolling}$: A questionnaire distributed amongst riders contained questions referring to the rolling behaviour of horses on pasture. The outcome reveals that most horses are fond of rolling on pasture with a frequency of mostly between 1 to 3 times per day. Matsui et al. (2009) have reported an average rolling frequency of about 1 per day. As a default value, 2 times rolling of a single horse per day is proposed.

V_{soil}: Matsui et al. (2009) stated that horses are in favour of certain substrates for rolling. Bare soil is the preferred substrate, rather than sandy ground, grassland, or straw. Therefore, it is assumed that just 10% of the pasture area is used for rolling activities, accounting for 1 000 m^2. For calculating soil concentrations, a soil depth of 10 cm is taken, which is the default value for grassland soils (EC, 2003). The default soil volume therefore accounts for 100 m^3.

$T_{emission}$: Local concentrations of the repellent have to be calculated for emission periods of 1 day and 91 days (*cf.* section 3.2.4.1).

Table 3-14: Emission scenario for calculating the release of repellents used on horses due to abrasion when rolling on pasture

Parameters	Nomenclature	Value	Unit	Origin
Input				
Active substance in the product	$Cform_{weight}$*		[$g.kg^{-1}$]	S
Consumption per application	$Qform_{appl}$*	0.6	[$mg.cm^{-2}$]	D/S
Treated area of horse skin	$AREA_{skin}$	17490	[cm^2]	D
Number of horses kept per hectare	N_{horses}	4	[-]	D
Number of applications per day	N_{appl}	1	[d^{-1}]	D
Number of rollings per day	$N_{rolling}$	2	[-]	D
Fraction released to soil by rolling	F_{soil}	0.01	[-]	D
Output				
Local emission of the active substance due to rolling	$Elocal_{soil}$		[$kg.d^{-1}$]	O
Calculation				
$Elocal_{soil} = N_{appl} \bullet Qform_{appl} \bullet AREA_{skin} \bullet Cform_{weight} \bullet N_{horses} \bullet N_{rolling} \bullet F_{soil} \bullet 10^{-9}$ (3.22)				

* Please refer to the previous scenarios for volume-based application amounts and/or active ingredient contents

The calculation of soil concentrations can be performed according to equations 3.17, 3.18 and 3.19.

3.2.4.3 Emissions due to hosing of horses

Hosing of horses with water is practiced by riders and persons responsible for the care of horses, especially during summer months after having exercised or trained horses. Hosing facilitates not only a more efficient cooling down process, but also the removal of sweat.

According to information gained by riders (Dr Knoell Consult, 2013), washing areas for horses are predominantly located outdoors, mostly near stable or house walls, since close proximity to a water supply is essential. Only large and professional equestrian facilities have official designated washing facilities indoors, which may lead to potential emissions into the wastewater system. Nonetheless, a separate scenario will not be considered for that case, as the release into STPs is deemed to be covered by the 'application on paved ground' scenario (*cf.* section 3.2.4.1, scenario B). Outdoor areas designated or chosen for hosing areas are generally paved or covered with concrete. Sometimes, anti-slip rubber mats cover the ground. There is no common practice in equestrian facilities on the handling of water used for hosing. In principle, the same options as laid down for the 'application on paved ground' scenario exist. However, it is a common practice that the washing water from such washing areas would be drained into the surrounding soil. This route of emission should therefore be contemplated in this framework.

The following parameter and default values are integrated into the calculation:

F_{soil}: During outdoor activities, horses cool down their skin and blood by an enormous production of sweat. According to Hodgson et al. (1994) under most conditions of exercise, at least two thirds of the metabolic heat dissipates by sweat losses of more than 10 L per hour. Due to this high production of sweat, the bulk of insect repellent will enter the environment through volatilisation or through sweat droplets from horses. Therefore, the fraction of insect repellent leached by the hosing of horses after riding is considered to be minor, i.e. 1 % of the applied amount (F_{soil} = 0.01).

$F_{rider,hosing}$: It is assumed, that half of the riders using an insect repellent (20% of all riders use an insect repellent according to Table 3-12) will hose their horses per day. Hence, the fraction of riders hosing their horses is 10 % ($F_{rider,hosing}$ = 0.1).

V_{soil}: A hosing area of 3 x 4 m is assumed with one side (4 m) adjacent to a house wall. The receiving soil compartment is further defined by a depth of 50 cm. This soil depth was discussed at BPC-WG ENV Meeting V/2014 for PT 18 (and reconfirmed in WG-I-2015 for PT 19) and emissions to a limited soil area in the vicinity of houses or terraces. Since hosing of horses leads to a kind of 'spray drift situation', a soil width of 50 cm around the hosing area is considered appropriate. When employing each, 50 cm for soil width and depth the soil volume accounts for 2.75 m^3. As discussions on relevant depth and critical distances are continuing and knowledge on the subject is just developing, the included calculations must be considered as examples only. Definitive decisions will be made at a later stage.

Table 3-15: Emission scenario for calculating the release of repellents used on horse skin due to hosing: release to adjacent soil

Parameters	Nomenclature	Value	Unit	Origin
Input				
Number of horses	N_{horses}	50	[-]	D
Fraction released to soil	F_{soil}	0.01	[-]	D
Active substance in the product	$Cform_{weight}$*		[g.kg^{-1}]	S
Consumption per application	$Qform_{appl}$*	0.6	[mg.cm^{-2}]	D/S
Number of applications per day	N_{appl}	1	[d^{-1}]	D
Treated area of horse skin	$AREA_{skin}$	58300	[cm^2]	D
Fraction of riders hosing their horses	$F_{rider,hosing}$	0.1	[-]	D
Output				
Local emission rate to soil	$Elocal_{soil}$		[kg.d^{-1}]	O
Calculation				
$Elocal_{soil} = N_{horses} \bullet N_{appl} \bullet Qform_{appl} \bullet AREA_{skin} \bullet Cform_{weight} \bullet F_{rider,hosing} \bullet F_{soil} \bullet 10^{-9}$ (3.23)				

* Please refer to the previous scenarios for volume-based application amounts and/or active ingredient contents

Soil concentrations can be calculated according to equations 3.17, 3.18 and 3.19.

3.3 Application of repellents in the environment of humans and animals

3.3.1 Description of use area

3.3.1.1 Indoor use

Insect repellents are applied in the environment of humans and animals for the following purposes:

a) Repellency of arthropods:

- Insect repellents are mostly applied indoors to favoured places or housing of cats and dogs. The purpose of these applications is to repel bloodsucking ectoparasites (i.e. lice, fleas, mites, and ticks) which use cats and dogs as hosts. These products are applied to pet's baskets textiles, carpets, sofas, chairs, in and around bedding and other such surfaces, which can serve as resting places for both pets and the ectoparasites themselves. The repellent products are generally available as ready-to-use spray formulations.

- Repellents are also used for the prevention of cloth moths entering wardrobes, drawers, and other storage places for textiles. Repellent products designed for this intention are available as ready-to-use sachets containing flower compositions, gel diffusers, moth balls, impregnated papers, and/or sprays.

- Insect repellent products may be additionally used for the treatments of air spaces against flies and mosquitoes: The repellent formulations are similar to those for insecticide applications in households, i.e. spray formulations, and different types of diffusers like coils and electric vaporisers. Furthermore, candles containing a repellent (mostly citronella) which release the repellent while burning can be used to deter and repel arthropods.

b) Repellency of cats and dogs:

A further area of use for these products is the repellency of vertebrates (cats and dogs) by treating objects and places to prevent fouling and other damaging activities. Products intended for this purpose include ready-to-use sprays or sticks (which are inserted into the soil of potted plants) as well as cellulose cards which are saturated with the active substance. These types of repellent products can be applied onto carpets, curtains, furnishings, pieces of scenery and in potted plants.

3.3.1.2 Outdoor use

- Outdoor use of repellents aims to prevent cats and dogs from territorial scent marking at vertical surfaces like corners or walls of buildings, trees, fences, poles (e.g. lamp poles), and stones. Furthermore, repellents may be used to avoid the deposition of faeces/urine by cats and dogs in gardens, flower beds and playgrounds and also to suppress or prevent burrowing activities by moles and rabbits, which may cause damage to gardens, lawns, pathways and terraces.

  Martens may enter human housings since their preferred resting place is under the car bonnet where they can subsequently cause damage by biting through rubber and hose parts of the engine. Repellent applications for this purpose include spray formulations, saturated felt pads which are plugged into the soil, saturated (mineral) granules or lava stones, saturated cellulose balls, gels, and powders.

- Insect repellent products are used for outdoor air space treatment against flies and mosquitoes (mentioned in the section for indoor use). According to Rozendaal (1997), the efficiency of air space treatment products is determined by the air exchange rate, i.e. products are only effective at places with a limited ventilation rate. Even more than with insecticides, the efficacy of repellents for air space treatment is dependent on the maintenance of an effective concentration in order to repel annoying arthropods for certain time periods. According to OECD (2008), diffusers employed outdoors are not considered as critical with regard to environmental emissions.

3.3.2 Biocidal active substances typically applied in this area

Natural oils and extracts are often used as active substances for repellents. For prevention of arthropod settlement in houses (introduced by cats and dogs) plant-based repellents such as geraniol, citronella, and neem extract are employed. However the synthetic repellent IR3535 is also used in these types of products.

Repellency of cloth moths in wardrobes is again mainly done by products containing natural oils and extracts.

The most prominent repellent active substance which is used in products for preventing cats and dogs from fouling and damaging indoors is methyl-nonyl-ketone. Whereas air space repellents formulated as coils, sprays, and vaporiser contain either natural pyrethrins or synthetic pyrethroids. However, based on product information available so far it was not possible to assign to these products only repellent properties without any insecticidal effect.

There is the need for further information whether these types of products refer to PT 19 or if they belong to the insecticides (PT 18). If the efficacy of these products would correspond to the PT 19 definition, emissions could be calculated based on the scenarios established for PT 18.

Referring to the outdoor use of repellents against cats, dogs, rabbits, moles and martens, typical active substances include methyl-nonyl-ketone, geraniol, lavender oil, and nonanoic acid.

3.3.3 Environmental release pathway

3.3.3.1 Indoor use

Formulations applied indoors (not considering air-space treatments) against arthropods carried by cats and dogs, moths, or even against cats and dogs themselves are either available as surface spray formulations or as a type of diffuser, e.g. moth ball, sachets, impregnated paper or cardboard, or a gel that allows a slow evaporation of the repellent into the environment. The formulations are ready-to-use hence the mixing and loading steps are not relevant. Emissions to the environment can take place during the application of the product. Fractions may reach the indoor air space, the applicator, the treated surface and the floor. Emissions to the applicator, the floor and/or the treated surface will be discharged to STPs either by washing of clothes or through cleaning operations.

3.3.3.2 Outdoor use

Outdoor applications of products against vertebrates (e.g. cats, dogs, rabbits, moles, martens) can enter the environment by two different routes. Firstly, if the products are applied on paved ground, or on walls which are surrounded by paved ground, residues washed-off by rainwater are drained to the wastewater treatment system or to the storm water system. The importance of a release into the storm water system is currently under evaluation by Member States and hence will not be contemplated in this framework. This route for emissions has to be considered according to the procedure, which will be agreed upon in the near future. Secondly, for applications to unpaved ground, the primary receiving compartment is the soil. Products are intended to be used by the general public and as mentioned above since these formulations are ready-to-use the mixing/loading step is not relevant in terms of emissions to the environment.

3.3.4 Emission scenarios

3.3.4.1 Indoor use

The assessment of environmental emissions is based on the existing ESD for PT 18 (OECD ESD No. 18; OECD, 2008), which provides a consumption-based approach for assessing the release to environmental compartments. The scenarios for surface spray treatment and diffusers have been adopted and are explained further below. Since the pathway for emissions due to repellent applications in households is through sewage treatment plants, a tonnage-based scenario is also included.

Tonnage-based approach

Emissions based on tonnage are calculated according to Table 3-1 above. The two scaling parameter $Fprodvol_{reg}$ and Fmainsource remain almost the same. The parameter for dermal absorption to skin is not relevant. For the remaining parameter, the following defaults are proposed:

$T_{emission}$: The number of emission days is set to 365 days, since all products can be assumed to be used the whole year round.

F_{air}, F_{water}: For spray surface applications the ESD for PT 18 (OECD ESD No. 18; OECD, 2008) defines a fraction to be transferred to air of 0.02. All other fractions, i.e. those on the applicator’s clothes, the treated surface or the surrounding floor, will be discharged to STPs either by washing or by cleaning operations. Therefore, the fraction entering wastewater is set to 0.98 in the tonnage-based option.

For active substances being formulated in diffusers, the repellent active is released under a vapour form. Although the ESD for PT 18 (OECD ESD No. 18; OECD, 2008) proposes that a fraction could turn into liquid form and settle down on the floor, most of the remains will enter at least the outdoor air in vapour form. Hence, the fraction entering wastewater for substances formulated in or as diffusers will be much lower as for those formulated as spray. Anyway, as active substances can be formulated as both, within sprays or diffusers, for worst-case consideration a fraction entering wastewater of 0.98 is proposed. The parameter can be modified if a repellent substance is solely formulated in or as a diffuser.

The calculations can be performed according to equations 3.2 and 3.3 of Table 3-1:

$$F_{4,water} = 1 - F_{4,air}$$
$$Elocal_{4,water} = TONNAGEreg \bullet 1000 \bullet Fmainsource_4 \bullet F_{4,water} / T_{emission4}$$

Consumption-based approach

The consumption-based approach for repellents applied indoors (not considering air space treatments) is based on the models detailed in the ESD for PT 18 (OECD ESD No. 18; OECD, 2008), sections 3.3 and 3.4. The employment of repellents against cats and dogs, arthropods transmitted by cats and dogs, and cloth moths in larger buildings is not considered relevant. Since the products are used by the general public in ready-to-use formulations, the mixing and loading step is lapsed.

Table 3-16: Emission scenario for calculating the release to wastewater from surface spray repellents used indoors – application step (according to OECD ESD No. 18; OECD, 2008)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Quantity of product applied	Q_{prod}		[kg.m^{-2}]	S
Fraction of active substance in the commercial product	F_{AI}		[-]	S
Number of applications per day per building	$N_{appl,\ building}$	1	[d^{-1}]	D
Fraction emitted to air	$F_{application,air}$	0.02	[-]	D (OECD ESD No. 18, OECD, 2008, Table 3.3-5)
Fraction emitted to applicator	$F_{application,applicator}$	0.02	[-]	
Fraction emitted to floor	$F_{application,floor}$	0.11	[-]	
Fraction emitted to treated surfaces	$F_{application,treated}$	0.85	[-]	
Area treated with the product	$AREA_{treated}$	2/5.9*	[m^2]	D (OECD ESD No. 18, OECD, 2008, section 3.3.1.2; EC, 2013b, page 55, A5)
Output				
Emission to air during the application step	$E_{application,air}$		[kg.d^{-1}]	O
Emission to applicator during the application step	$E_{application,applicator}$		[kg.d^{-1}]	O
Emission to floor during the application step	$E_{application,floor}$		[kg.d^{-1}]	O
Emission to treated surfaces during the application step	$E_{application,treated}$		[kg.d^{-1}]	O
Calculation				

$$E_{application,air} = Q_{prod} \bullet F_{AI} \bullet AREA_{treated} \bullet N_{appl,\ building} \bullet F_{application,air} \quad (3.24)$$

$$E_{application,applicator} = Q_{prod} \bullet F_{AI} \bullet AREA_{treated} \bullet N_{appl,\ building} \bullet F_{application,applicator} \quad (3.25)$$

$$E_{application,floor} = Q_{prod} \bullet F_{AI} \bullet AREA_{treated} \bullet N_{appl,\ building} \bullet F_{application,floor} \quad (3.26)$$

$$E_{application,treated} = Q_{prod} \bullet F_{AI} \bullet AREA_{treated} \bullet N_{appl,\ building} \bullet F_{application,treated} \quad (3.27)$$

* Indoor surface spray treatments - either for repelling arthropods or for repelling cats and dogs - are targeted applications. Therefore, the default values for spot treatments (2 m^2) and barrier treatments (5.9 m^2) should both be taken into consideration (*cf.* OECD ESD No. 18; OECD, 2008 and EC, 2013b).

In the subsequent cleaning step, OECD (2008) distinguishes between emissions to solid waste and to wastewater. Since the treatment of solid waste is governed under national legislation, it is not be considered further in this context and only the discharge to wastewater is taken into account.

$F_{simultaneity}$: Referring to the simultaneity factor there is no data available on the indoor use of repellent products at the scale of households. The ESD for PT 18 (OECD ESD No. 18; OECD, 2008) provides a methodology for calculating a simultaneity factor according to a French survey, dependent on the frequency of insecticide use in private households. This methodology is also recommended to be applied for indoor repellent treatments.

Table 3-17: Frequency of use of insecticides in households (taken from the OECD ESD No. 18; OECD, 2008, section 2.7)

Frequency of use	Number of positive answers (%)	% of houses treated per day
One time per day	2.77	100
One time per week	9.51	14.3
One time per month	17.74	3.22
Three to eleven times per year	32.15	1.9
One to two times per year	37.82	0.54

If all use frequencies apply to the use of a product, the simultaneity factor can be calculated as follows (example calculation):

$$F_{simultaneity} = \frac{100 \bullet 2.77 + 14.3 \bullet 9.51 + 3.22 \bullet 17.74 + 1.9 \bullet 32.15 + 0.54 \bullet 37.82}{100} = 5.52\%$$

A detailed description is provided in the ESD for PT 18 (OECD ESD No. 18; OECD, 2008, section 2.7).

N_{houses}: For indoor use of repellents it is assumed that 4 000 private houses are connected to the same STP (OECD, 2008).

F_{CE}: According to OECD (2008), the cleaning efficacy corresponds to the fraction of applied repellent that might be exposed to cleaning. This fraction is dependent on the formulation/application type. For surface spray applications a 50% exposure of the applied amount to cleaning activities is proposed whereas for diffusers it is assumed as a worst case that the entire fraction of residue deposited to the floor during use could be exposed to cleaning operations.

Table 3-18: Emission scenario for calculating the release to wastewater from surface spray repellents used indoors – cleaning step (according to OECD ESD No. 18; OECD, 2008)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Emission to applicator during the application step	$E_{application,applicator}$		[kg.d^{-1}]	O
Emission to floor during the application step	$E_{application,floor}$		[kg.d^{-1}]	O
Emission to treated surfaces during the application step	$E_{application,treated}$		[kg.d^{-1}]	O
Fraction emitted to wastewater from applicator after the application	$F_{applicator,ww}$	1	[-]	D (OECD ESD No. 18, OECD, 2008, section 3.3.7)D
Fraction emitted to wastewater during the cleaning step	F_{ww}	1	[-]	
Cleaning efficacy	F_{CE}	0.5	[-]	D (OECD ESD No. 18, OECD, 2008, Table 3.3-8)
Number of houses contributing to the same sewage treatment plant	N_{houses}	4000	[-]	D EC, 2013b, page 54, A4)
Simultaneity factor	$F_{simultaneity}$		[-]	D/S (OECD ESD No. 18, OECD, 2008, section 2.7)
Output				
Emission from applicator to wastewater during cleaning step	$E_{applicator,ww}$		[kg.d^{-1}]	O
Emission from floor/treated to wastewater during the cleaning step	$E_{treated,ww}$		[kg.d^{-1}]	O
Combined emission from floor/treated and applicator to wastewater during the cleaning step for one house	E_{ww}		[kg.d^{-1}]	O
Local emission rate to wastewater	$Elocal_{water}$		[kg.d^{-1}]	O

Table 3-18 cont.:

Calculation		
$E_{applicator,ww}$ =	$E_{application,applicator} \bullet F_{applicator,ww}$	(3.28)
$E_{treated,ww}$ =	$(E_{application,floor} + E_{application,treated}) \bullet F_{ww} \bullet F_{CE}$	(3.29)
E_{ww} =	$E_{applicator,ww} + E_{treated,ww}$	(3.30)
$Elocal_{water}$ =	$E_{ww} \bullet N_{houses} \bullet F_{simultaneity}$	(3.31)

Table 3-19: Emission scenario for calculating the release to wastewater from diffuser repellents used indoors – application step (according to OECD ESD No. 18; OECD, 2008)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Quantity of product contained in the diffuser	Q_{prod}		[g]	S
Fraction of active substance in the commercial product	F_{AI}		[-]	S
Number of diffusers	$N_{diffuser}$		[-]	S
Maximum duration of use of the diffuser	T_{MAX}		[h]	S
Duration of use per day electrical passive	T_{Day}	 8 24	[h.d^{-1}]	D (OECD ESD No. 18, OECD, 2008, section 3.3.6)
Fraction emitted to air during use	$F_{application,air}$	0.9	[-]	
Fraction emitted to floor during use	$F_{application,floor}$	0.1	[-]	
Output				
Emission to air during the use of the diffuser	$E_{application,air}$		[kg.d^{-1}]	O
Emission to floor during the application step	$E_{application,floor}$		[kg.d^{-1}]	O

Calculation

$E_{application,air} = Q_{prod} \bullet F_{AI} \bullet N_{diffuser} \bullet (T_{Day} / T_{MAX}) \bullet F_{application,air} \bullet 10^{-3}$ (3.32)

$E_{application,floor} = Q_{prod} \bullet F_{AI} \bullet N_{diffuser} \bullet (T_{Day} / T_{MAX}) \bullet F_{application,floor} \bullet 10^{-3}$ (3.33)

Table 3-20: Emission scenario for calculating the release to wastewater from diffuser repellents used indoors – cleaning step (according to OECD ESD No. 18; OECD, 2008)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Emission to floor during the application step	$E_{application,floor}$		$[kg.d^{-1}]$	O
Fraction emitted to wastewater during the cleaning step	F_{ww}	1	[-]	D (OECD ESD No. 18, OECD, 2008, section 3.3.7)
Cleaning efficacy	F_{CE}	1	[-]	D (OECD ESD No. 18, OECD, 2008, table 3.3-8)
Number of houses contributing to the same sewage treatment plant	N_{houses}	4 000	[-]	D EC, 2013b, page 54, A4)
Simultaneity factor	$F_{simultaneity}$		[-]	D/S (OECD ESD No. 18, OECD, 2008, section 2.7)
Output				
Emission from floor to wastewater during the cleaning step for one house	$E_{treated,ww}$		$[kg.d^{-1}]$	O
Local emission rate to wastewater	$Elocal_{water}$		$[kg.d^{-1}]$	O
Calculation				
$E_{treated,ww}$ (corresponding to E_{ww}) $= E_{application,floor} \bullet F_{ww} \bullet F_{CE}$ (3.34)				
$Elocal_{water} = E_{treated,ww} \bullet N_{houses} \bullet F_{simultaneity}$ (3.35)				

3.3.4.2 Outdoor applications

Application on paved ground

The emission assessment for use on paved ground is based on the ESD for PT 18 (OECD ESD No. 18; OECD, 2008). A distinction between releases occurring during the application of the products and due to run-off leaching from treated surfaces has not been made.

$AREA_{treated}$: A typically treated surface covers 25 m^2. This area is consistent with the default value for the area of foundations treated per day (private houses) with an insecticide against crawling insects (OECD, 2008).

F_{water}: A consumption of repellent products applied outdoors by animals does not take place. In line with the ESD for PT 18 for products directly applied to surfaces as sprays, granules, powder, gels, etc. it is assumed that 50 % is washed off the treated area during the first rainfall event after application to wastewater (F_{water} = 0.5). Products being applied in reservoirs/diffusers are protected from rain and can be assumed to only enter the wastewater/storm water stream to a limited extent. For these products, a default of F_{water} = 0.2 should be taken (corresponding to the default for outdoor bait stations in the ESD for PT 18).

$F_{simultaneity}$: Referring to the simultaneity factor, there is no data available on the outdoor use of repellent products at the scale of households. The ESD for PT 18 (OECD ESD No. 18; OECD, 2008) provides a methodology for calculating a simultaneity factor according to a French survey, dependent on the frequency of use. This methodology is therefore recommended to be also applied for outdoor repellent treatments (Table 3-17 and example calculation).

N_{houses}: For outdoor use of repellents, it is assumed that 2 500 private houses are connected to the same STP (according to the Manual of Technical Agreements of the Biocides Technical Meeting (MOTA) (EC, 2013b).

Table 3-21: Emission scenario for calculating the releases of repellents used outdoors for dispelling vertebrates – emission to paved ground

Parameters	Nomenclature	Value	Unit	Origin
Input				
Quantity of product applied per day	Q_{prod}		$[kg.m^{-2}]$	S
Fraction of active substance in the commercial product	F_{AI}		[-]	S
Outdoor surface area treated per day	$AREA_{treated}$	25	$[m^2.d^{-1}]$	D (OECD ESD No. 18, OECD, 2008, Table 4.3-3)
Fraction released to wastewater	F_{water}	1 / 0.2*	[-]	D (value of 0.2: OECD ESD No. 18, OECD, 2008, section 4.3.4.1)
Number of houses contributing to the same sewage treatment plant	N_{houses}	2500	[-]	D EC, 2013b, page 54, A4)
Simultaneity factor	$F_{simultaneity}$		[-]	D/S (OECD ESD No. 18, OECD, 2008, section 2.7)
Output				
Local emission rate to wastewater from one private house	E_{ww}		$[kg.d^{-1}]$	O
Local emission rate to wastewater	$Elocal_{water}$		$[kg.d^{-1}]$	O
Calculation				
$E_{ww} =$	$Q_{prod} \bullet F_{AI} \bullet AREA_{treated} \bullet F_{water}$			(3.36)
$Elocal_{water} =$	$E_{ww} \bullet N_{houses} \bullet F_{simultaneity}$			(3.37)

* For products directly applied to surfaces $F_{water} = 1$ should be taken, whereas for products being applied in reservoirs/diffusers a default of $F_{water} = 0.2$ should be employed.

Application on unpaved ground

Repellent products which are intended for preventing cats and dogs from territorial scent marking or defecation, and/or rabbits and martens entering the human environment, are applied onto/at certain areas, like pathways or flower beds. Surface applications may encompass an enlarged area, e.g. exposed larger flower beds, or just small but frequently visited places, like areas around a tree or a sand pit.

Heavy rainfall terminates the efficacy of repellents applied outdoors on surfaces so applications have to be done repeatedly, especially at the beginning of a campaign to train cats and dogs to visit alternative places. Research on repellent products currently on the German market for such purposes (Dr Knoell Consult, 2012b) indicated that initially at least a daily application is proposed. Once animals are trained to avoid the treated areas, the frequency of applications can be reduced. Two scenarios are considered for repellents, applied on soil surfaces:

1. A 'campaign', consisting of a preventive one-fold application to an area of 50 m^2.
2. A 'campaign', consisting of 'curative' daily applications over 5 days to a frequently visited area of 10 m^2.

For dispelling moles, repellents are buried into soil holes or into mole tunnels. The exposed soil compartment is the soil surrounding the repellent in the man-made hole or in the mole tunnel where the repellent has been placed. Emissions are assessed for applications in mole tunnels, congruent to the procedure outlined in the ESD for PT 14 (Larsen, 2003).

Table 3-22: Emission scenario for calculating the release of repellents used outdoors for dispelling vertebrates – application on unpaved ground/in soils (according to Larsen, 2003)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Quantity of product applied	Q_{prod}			
Surface treatments			[$kg.m^{-2}$]	S
Buried in holes			[$kg.hole^{-1}$]	S
Fraction of active substance in the commercial product	F_{AI}		[-]	S
Outdoor surface area treated per day	$AREA_{treated}$		[$m^2.d^{-1}$]	
preventive		50		D
curative		10		D
Fraction released to soil	F_{soil}	1	[-]	D
Output				
Local emission rate to soil after one application	$Elocal_{soil}$			O
Surface treatments			[$kg.d^{-1}$]	
Buried in holes			[$kg.hole^{-1}$]	

Calculation

$$Elocal_{soil,preventive} = Q_{prod,surface} \bullet F_{AI} \bullet AREA_{treated,preventive} \bullet F_{soil} \quad (3.38)$$

$$Elocal_{soil,curative} = Q_{prod,surface} \bullet F_{AI} \bullet AREA_{treated,curative} \bullet F_{soil} \quad (3.39)$$

$$Elocal_{soil,hole} = Q_{prod,hole} \bullet F_{AI} \bullet F_{soil} \quad (3.40)$$

Soil concentrations are assessed according to equations 3.17 to 3.19. For all scenarios (preventive, curative and hole), soil concentrations for one day must be assessed (equation 3.17). For the curative scenario, the concentrations also have to be calculated after five emission days (equations 3.18 and 3.19 have to be adapted accordingly). For equations 3.17 to 3.19, the following soil volume should be used:

V_{soil}: The default mixing soil depth for surface applications is 50 cm, yielding a soil volume of 5 m^3 for the curative use (10 m^2 treated area) and 25 m^3 for the preventive use (50 m^2 treated area). The soil depth of 50 cm was discussed at BPC-WG ENV Meeting V/2014 for PT 18 and emissions to a limited soil area in the vicinity of houses or terraces. As discussions on relevant depth and critical distances are continuing and knowledge on the subject is just developing, the included calculations must be considered as examples only. Definitive decisions will be made at a later stage. For repellents used in mole tunnels, a soil volume of 0.0085 m^3 should be taken. Soil exposure takes place in the lower half of an 8 cm diameter tunnel, with a mixing depth of 10 cm and up to 30 cm from the entrance hole.

3.4 Insect repellents used for factory-treated textiles

3.4.1 Description of use area

Research on the treatment of textiles or fibres and their subsequent effectiveness for insect protection began in 1942. Field and laboratory tests demonstrated that mosquitoes avoid some repellent treated fabrics for several days, while protection through skin applied repellents failed after a few hours (Travis & Morton, 1946). These findings started a new research area for military purposes that further developed in public health protection measures against insect-carrying diseases (McCain & Leach, 2007).

Textiles or fibres treated with insect repellents offer personal protection against biting insects by preventing the insect landing on the textile article, or the entry into the protected space. Repellent treated textile articles offer protection against blackflies, ticks, mites, mosquitoes, sand flies, fleas and body lice (Rozendaal, 1997; McCain & Leach, 2007).

Industrial treatment of the textile or fibre with the repellent active substances takes place during the fabrication (Tissier et al., 2001). It provides a better fixation of the repellent formulation to the fabrics, guaranteeing longer protection for humans. Examples of repellent factory-treated articles are garments, bed nets and tents.

Textile material differs according to the final use of the article. Open-mesh material is often use for bed nets and some garments. Polyester, nylon and cotton are common fabric materials for repellent treatment.

3.4.2 Biocidal active substances typically applied in this area

Synthetic pyrethroids are the preferred active substances for repellent factory-treated textile articles. The combination of strong sorption capacity, sunlight resistance and odourless properties make them the most suitable candidates for the targeted applications.

As is the case for general public preparations, permethrin is the most commonly used active substance for the treatment of textile articles, mainly for outer garments (no undergarments, hats, or socks).

A wide range of active ingredients can be used for treatment of bed netting, since they have limited contact with the skin. This limited skin exposure opens the possibility to use other active substances (mainly synthetic pyrethroids) such as lambda-cyhalothrin (3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyano(3-phenoxyphenyl)methyl cyclopropanecarboxylate), alpha-cypermethrin (cyclopropanecarboxylic acid, 3-(2,2-

dichloroethenyl)-2,2-dimethyl-, cyano(3-phenoxyphenyl)methyl ester), deltamethrin ((1*R*,3*R*)-[(*S*)-α-Cyano-3-phenoxybenzyl- 3-(2,2-dibromvinyl)]-2,2-dimethylcyclopropan-carboxylat, and permethrin (Rozendaal, 1997). However, most of these ingredients will not only function as a repellent but also attempt to kill the insects entering or landing on the particular textile/article. Therefore, they are not solely acting as repellents.

The dosage of the active substances in textiles will vary depending on the type of compound and nature of the fabric. These amounts are usually reported as the quantity of active substance per unit area (e.g. g/m^2).

3.4.3 Environmental release pathway

Releases to the environment during treatment of textiles or fibres with repellents relate to the discharges of the industrial residues after finishing steps. Active substances are normally used in aqueous solutions with chemical agents (mainly surfactants) that enhance the fixation to the textile material (Tissier et al., 2001). Emissions to the environment are thus related to the amount of active substance needed for the textile treatment and the waste water fraction resulting from the chemical treatment (residual fraction).

The additional route of emission of insect repellents from factory-treated articles occurs during the service life and washing processes of the articles. Two main removal processes are responsible for environmental emissions of biocidal active substances from insect repellent factory-treated textiles:

1. Cleaning or washing of the treated textiles: Releases may occur due to the cleaning and/or washing steps. Sewage treatment plants are the primary compartment for these emissions. The fraction released by this step depends on the fixation degree of the substance in the textile material.
2. Wash-off by rainfall: After application, direct product releases may occur due to the leaching of the substances from impregnated gear by rainfall. As a realistic worst-case model, the following section presents a scenario that contemplates the leaching of active substances from the treated textile of a camping tent.

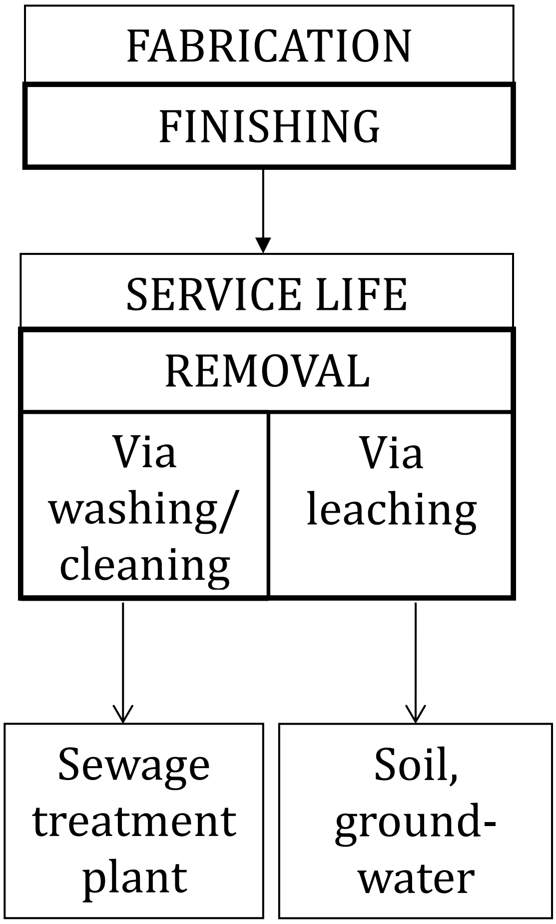

Figure 3: Relevant life-cycle stages to be considered when assessing environmental emissions due to industrially repellent-treated garments and gear

3.4.4 Emission scenarios

3.4.4.1 Emissions during industrial application of the repellent to textiles/fibres

Three sources of information on emission scenarios have been considered for the estimation of the releases during the industrial application of insect repellents to textiles or fibres: The EU – TGD, IC-13, textile processing industry (EC, 2003), the ESD for biocides used as preservatives in textile processing industry, product types 9 & 18 (Tissier et al., 2001), and OECD (2004; OECD ESD No. 7).

The proposed tonnage approach follows the default values reported for the formulation step of products under Industry Category 13 (textile processing industry) of the TGD (Tables A2.1 and B2.10).

Table 3-23: Emission scenario for calculating the release during the industrial application of insect repellents to textiles/fibres based on the annual tonnage applied (based on TGD, IC=13; EC, 2003)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Annual tonnage of active ingredient sold for insect repellent textiles in the EU	TONNAGE		$[t.yr^{-1}]$	S
Fraction for the region	$Fprodvol_{reg}$	0.1	[-]	D
Relevant tonnage in the region for this application	TONNAGEreg		$[t.yr^{-1}]$	S/O
Fraction of the main source	$Fmainsource_2$*	1	[-]	D (EC, 2003, Table B 2.10)
Fraction released to waste water	$F_{2,water}$	0.02	[-]	D (EC, 2003, Table A 2.1, worst-case value)
Number of emission days	$T_{emission2}$	300	$[d.yr^{-1}]$	D (EC, 2003, Table B 2.10)
Output				
Local emission rate to wastewater	$Elocal_{2,water}$		$[kg.d^{-1}]$	O
Intermediate calculation				
Relevant tonnage in the region for this application				
$TONNAGEreg = Fprodvol_{reg} \bullet TONNAGE$ (3.41)				
End calculation				
$Elocal_{2,water} = TONNAGEreg \bullet 1000 \bullet Fmainsource_2 \bullet F_{2,water} / T_{emission2}$ (3.42)				

* The subscript '2' refers to the life-cycle stage 'formulation' according to van der Poel (2000)

Furthermore, a consumption-based approach is proposed according to Tissier et al. (2001) and OECD (2004). The following parameter and default values are integrated into the calculation:

$Q_{textile}$: The quantity of daily treated textile is set to 13 tonnes per day. This value is in line with the OECD scenario as a worst case value. The use of other values regarding the quantity of textile processed for insect repellent purposes can be considered case-by-case.

$Q_{a.i.}$: The quantity of active substance applied per tonne of fibres or textile is a specific value that can be obtained from the efficacy data, the mass of the biocidal product preparation and the content of the active substance in the preparation.

$F_{fixation}$: According to the Tissier et al. (2001) scenario, the degree of fixation of biocides during finishing processes is approx. 70-80%. A fixation factor of 0.7 is therefore suggested, unless specific data is provided.

$F_{residual\ liquor}$: According to OECD (2004), a realistic worst case estimation of the fraction of residual liquor during the coating process is set to 0.01.

Table 3-24: Emission scenario for calculating the release during the industrial application of insect-repellents to textiles/fibres - consumption approach

Parameters	Nomenclature	Value	Unit	Origin
Input				
Mass of textile processed per day	$Q_{textile}$	13	$[t.d^{-1}]$	D (OECD, 2004, section 9.1)
Quantity of active ingredient applied per tonne of textile	$Q_{a.i.}$		$[kg.t^{-1}]$	S
Degree of fixation	$F_{fixation}$	0.7	[-]	D (Tissier et al., 2001, section 3.2.2)
Amount of residual liquors	$F_{residual\ liquor}$	0.01	[-]	D (OECD, 2004, section 9.4.5.4)
Output				
Local emission rate to wastewater	$Elocal_{water}$		$[kg.d^{-1}]$	O
Calculation				
$Elocal_{water} = Q_{textile} \bullet Q_{a.i.} \bullet (1 - F_{fixation}) + Q_{textile} \bullet Q_{a.i.} \bullet F_{residual\ liquor}$ (3.43)				

3.4.4.2 Emissions during the service life of repellent factory-treated textiles

A) Emissions due to washing of factory-treated garments and gear

Both documents, OECD (2004) and Tissier et al. (2001) propose a tonnage approach for calculating the release from treated textile articles during their service life. The tonnage-based calculation can be done according to OECD (2004), paragraph 197.

Since repellent-treated apparel and gear are worn/used during the whole year, when people are visiting regions with high mosquito population density, the emission period should be set to 365 days. The fraction of the substance entering wastewater should be fixed to 0.7. A service life of the factory treated garments/gear of one year is proposed.

The consumption-based calculation of emissions to the environment due to the washing of repellent factory-treated garments and other textile articles (i.e. bed nets), can be performed according the model calculations reported in section 3.1.4.1 (Table 3-6) for human skin and garment repellent products. In the following, special considerations and changes for repellent factory-treated articles are described.

$AREA_{garments}$: Surface area values for treated garments are reported in Table 3-4. For bed nets, a standard family size bed net of 12.5 m^2 can be assumed (Rozendaal, 1997).

F_{inh}: As a default for the fraction of inhabitants using one specific repellent impregnated textile, a value of 1% (F_{inh}= 0.01) is proposed (*cf.* Table 3-5).

F_{water}: The fraction of the active substance entering wastewater is set to 0.2 by default. Results from washing studies with factory-treated long-lasting insecticidal bed nets indicate a higher resistance against washings compared to mosquito nets that are treated traditionally in the field with an insecticide formulation (Hill, 2008; Nehring, 2012). However, there is a high variation regarding washing resistance, especially for the first washing. Hill (2008) and Nehring (2012) reported retention of insecticides in bed nets made from synthetic as well as cotton material of 26.3% to 124.8% of the applied active substance. In 10 of 15 cases, the retention was > 80% after the first washing. Average values for each follow-up washing of the impregnated bed nets remained below 10% of the inventory. Therefore, a value of 0.2 for F_{water} is proposed as a realistic worst-case. The default value can be modified by the applicant if reliable data from washing studies are available.

Table 3-25: Emission scenario for calculating the release of repellent factory-treated garment through washing based on the average consumption

Parameters	Nomenclature	Value	Unit	Origin
Input				
Number of inhabitants feeding one sewage treatment plant	Nlocal	10,000	[cap]	D (EC, 2003, Table 9)
Fraction released to wastewater	F_{water}	0.2	[-]	D
Quantity of active ingredient in the garment related to surface area	$Q_{a.i.,garment}$		[mg.cm^{-2}]	S
Treated area of garments washed per day	$AREA_{garment}$		[cm^{2}.d^{-1}]	P (*cf.* Table 3-4)
Fraction of inhabitants using the product	F_{inh}	0.01	[-]	P (*cf.* Table 3-5)
Market share of repellent	F_{penetr}	0.5	[-]	D
Output				
Local emission rate to wastewater	$Elocal_{water}$		[kg.d^{-1}]	O
End calculation				
$Elocal_{water} = Nlocal \bullet Q_{a.i.,garment} \bullet AREA_{garment} \bullet F_{inh} \bullet F_{water} \bullet F_{penetr} \bullet 10^{-6}$ (3.44)				

Note: as a worst case assumption for the above calculation, it is assumed that all inhabitants using the treated garments wash it on the same day.

B) Emissions during the service life of tents

The following parameters and default values are integrated in the calculation:

$Q_{a.i.,tent}$: The quantity of active ingredient in the tent textile is a specific value for each active substance.

$Q^*_{leach,camping}$: Information on the leaching of the active substance from the tent material is required for the model calculations. In the absence of leaching data and as a worst-case assumption, 100% release is assumed for the first camping season (independent from the service life of a tent).

$TIME_{camping}$: The time a tent is situated at the same camping location is fixed to 120 days per year. Although the camping season may last longer (from April to September/October), 120 days for emission per year are considered to represent a realistic worst-case situation since a camping place will not always be occupied, and tents have different sizes, so they will not always be built up at identical places.

$AREA_{tent}$: A square tent (family size) is assumed to have a width and length of 4 m and a height of 2 m, resulting in a total textile surface area of 48 m^2 (the bottom of the tent is excluded).

V_{soil}: A soil depth of 0.1 m and a distance for the surrounding soil affected by the leaching of the active ingredient from the tent of 0.5 m is proposed, resulting in a total soil volume of 0.9 m^3. The soil depth of 10 cm is considered appropriate since tents are situated in a more natural environment compared to houses, where a 50 cm soil depth might be suitable.

Table 3-26: Emission scenario for calculating the release of repellents leached out of tent textile

Parameters	Nomenclature	Value	Unit	Origin
Input				
Quantity of active substance on the tent textile	$Q_{a.i.,tent}$		[$mg.m^{-2}$]	S
Tent surface area	$AREA_{tent}$	48	[m^2]	D
Duration of camping season	$TIME_{camping}$	120	[d]	D
Number of emission events	$N_{emission,120d}$	120	[-]	D
Emission interval	$T_{emission,1d}$	1	[d]	D
Cumulative quantity of active ingredient leached out of 1 m^2 of treated tent over the first camping season	$Q*_{leach,camping}$		[$mg.m^{-2}$]	D/S
First order rate constant for removal from soil	$kdeg_{soil}$		[d^{-1}]	S
Soil volume	V_{soil}	0.9	[m^3]	D
Bulk density of wet soil	RHO_{soil}	1 700	[$kg_{wwt}.m^{-3}$]	D
Output				
Average daily emission due to leaching over first camping season for one tent	$E_{soil,leach,campig}$		[$mg.d^{-1}$]	O
Concentration in local soil after the first camping season	$Clocal_{soil,camping}$		[$mg.kg_{wwt}^{-1}$]	O

End calculations:

$$E_{soil,leach,camping} = Q*_{leach,camping} \bullet AREA_{tent} / TIME_{camping} \quad (3.45)$$

$$Clocal_{soil,camping} = \frac{E_{soil,leach,camping} * Time_{camping}}{(V_{soil} * RHO_{soil})} \quad (3.46)$$

$$Clocal_{soil,camping-ref} = \frac{E_{soil,leach,camping} * T_{emission,1d}}{(V_{soil} * RHO_{soil})} * \frac{1 - \left(e^{-kdeg_{soil} * T_{emission,1d}}\right)^{N_{emission,120d}}}{1 - e^{-kdeg_{soil} * T_{emission,1d}}}$$

As a first tier approach, the $PEClocal_{soil}$ can be calculated according to equation 3.46, representing the worst-case situation.

Calculating $PEClocal_{soil}$ according to equation 3.47 provides a refinement option considering degradation processes in the soil compartment. This approach of a refinement is based on equations 4, 7, and 8 of the ESD for PT 18 (OECD ESD No. 14 (insecticides for stables and manure storage systems); OECD, 2006).

3.5 Attractants

Article 2(5) of the BPRexcludes food and feed which is used as repellent or attractant from the scope of the regulation. However, products consisting entirely of food or feed or containing food or feed which are placed on the market as repellents or attractants are within the scope.

Host location of bloodsucking mosquitoes is among other things regulated by human emanations like CO_2 and lactic acid. Therefore, these substances are used in certain devices for luring mosquitoes and trapping them.

Pheromones are semiochemical substances produced by individuals of a species to modify the behaviour of other individuals within the same species, consequently having a target intraspecific effect (EC, 2008b). Due to the specific mode of action, pheromones are employed for sexual confusion or for trapping. A variety of pheromones used for the control of arthropods belong to the family of straight-chained lepidopteran pheromones (SCLPs). SCLPs are a group of pheromones consisting of unbranched aliphatics with a chain of nine to eighteen carbons, containing up to three double bonds, ending in an alcohol, acetate or aldehyde functional group. This definition includes the majority of known pheromones produced by insects of the order Lepidoptera (butterflies and moths) (OECD, 2002b; EC, 2005b).

SCLPs are naturally occurring chemicals and are known for their target-specificity, mode of action (modification of a behaviour instead of killing), their effectiveness at low application rates, their high volatility and rapid dissipation in the environment (EC, 2008b). Based on these properties, as well as their low toxicity towards humans and animals, data requirements for authorising SCLPs as plant protection products have been reduced and a simplified procedure for authorising new substances as SCLPs has been implemented (OECD, 2002b; US-EPA, 2008; EC, 2010c).

The applicability of this conclusion drawn for SCLPs in plant protection products with respect to pheromones used for biocidal purposes has been reconsidered in EC (2005b). The draft guidance considers that the conclusions drawn for SCLPs in plant protection products can be applied to the data requirements for pheromones according to the BPD (now the BPR). However, due to the different use and exposure pattern of biocides (e.g. indoor use and the use of dipteran pheromones which differ in properties from SCLPs), fewer generalisations can be made and each data requirement has to be accounted for and evaluated on a case-by-case basis.

3.5.1 Description of use area

According to the Manual of Decisions (EU, 2011), products containing an attractant substance and a substance that is an insecticide are considered to be PT 18 products (insecticidal products). If however a product contains an attractant as well as a non-chemical and non-biological means to kill an insect, the product is considered to be a PT 19 product.

Furthermore, traps containing an attractant, which are used for insect monitoring only, are not within the scope of the BPR according to the definition of a biocidal product (EU, 2011). Therefore, products containing an attractant should be regarded as PT 19 when:

- They contain only the attractant as the active ingredient. These kinds of products could not be identified to be relevant.
- The formulated product contains the attractant and a device for killing organisms, which has neither a chemical nor biological effect. Insects can be killed by drowning, electrocution or sticking on glue stripes.

Attracting products are mainly formulated as dispensers/diffusers, i.e. they slowly release the active substances into the air.

For luring mosquitoes outdoors, trap/diffuser systems are available, which release a stream of CO_2, simulating human exudation. Mosquitoes follow the CO_2 plume to the trap and there they are drawn into a net inside the device by a counterflow system. Trapped mosquitoes die from dehydration inside the nets. For enhancing catch rates, oct-1-en-3-ol or lactic acid can be added to the CO_2 stream.

Diffusers containing pheromones for moth control are typically applied indoors whereas pheromone diffuser products attracting mosquitoes and flies are also applied outdoors. The products can be employed by professionals and the general public in stables, restaurants, shops, official buildings, in the food processing industry and in private houses.

3.5.2 Biocidal active substances typically applied in this area

Biocidal active substances used in attractants are either substances being present in human exudations like CO_2 (included into Annex I to the BPR) and lactic acid, or pheromones. A mixture of the webbing cloth moth (*T. biselliella)* pheromone constituents is included in Annex I to the BPR following a simplified authorisation procedure. The same applies to oct-1-en-3-ol, which has the function of an attractant for mosquitoes and tsetse flies. For the foodstuff moths *P. interpuctella* and some *Ephestia* species, the compound (Z,E)-tetradeca-9,12-dienyl acetate (ZE-TDA) is a primary component of their sex pheromone. ZE-TDA is also included in Annex I to the BPR. Cis-trans-9-ene (muscalure), a sex pheromone produced by female house flies (*Musca domestica*) is used in PT 19 products to attract males.

3.5.3 Environmental release pathway

Attractants used in diffusers act by slowly releasing into the air compartment with only a limited fraction if at all being transformed into the liquid form.

According to OECD (2008), diffusers employed outdoors for killing insects (PT 18) are not critical with reference to environmental emissions. This conclusion can also be transferred to diffuser containing attractants.

With reference to the indoor use, emissions to indoor air are completely released to the outdoor air compartment during e.g. venting of the room (OECD, 2008). The fraction being transformed into a liquid form might be a target for cleaning operations and remains being washed off can either be discharged to wastewater (applicable for use in private houses and larger buildings), or the manure/slurry system for of employment in stables.

3.5.4 Emission scenarios

Emissions arising from indoor attractant use in diffusers can be calculated according to section 3.3.4.1, equations 3.32 and 3.33. Concentrations in wastewater should be calculated according to equations 3.34 and 3.35. According to OECD (2008), diffusers employed outdoors are not considered as critical with regard to environmental emissions. Concentrations in the manure/slurry system should be calculated according to the ESD for PT 18 (OECD ESD No. 14; OECD, 2006).

4 Further research

The scope of the project was, among other things, to identify knowledge gaps and areas for further research. The following has been identified for PT 19:

- At the stage of product authorisation, there is currently no model available for assessing emissions based on sales figures. Further research is needed to implement such an option.
- Repellents against martens are also used in cars, i.e. repellents are directly applied in cars to prevent martens from spoiling electric cables. Further research is needed on the relevance of environmental emissions occurring due to this product end-use.
- Emissions to the environment can occur due to repellent treated cats and dogs by washing and bathing. If such a scenario is identified as necessary for product authorisation, the development will be initiated by the Ad hoc Environmental Exposure WG.
- The default values for $F_{simultanity}$ provided in the ESD for PT 18 are also used for PT 19. According to the ESD for PT 18 the $F_{simultaneity}$ is based on a French survey conducted by the Conservatoire National des Arts et Métiers (CNAM)[1] in 2006. Since this survey considered both biocidal/non-biocidal and indoor/outdoor consumer uses of pesticides, further research on a new database more specific to PT 19 is needed.

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6 Appendix

6.1 Application amounts of repellent products for use on human skin

The following table contains a compilation of application amounts of repellent products currently on the market, information on application amounts gained by eCAs on repellent product dossiers being under evaluation, and literature data on application amounts of repellents and related products.

If the application amounts are given per cm^2 body surface, an application amount per person has been calculated, assuming treatment of head, arms, hands, legs, and feet (10 660 cm^2 body surface). Likewise, application rates given per person are assumed to only relate to a body surface of 10 660 cm^2.

Table 6-1: Application amounts for repellents and cosmetic products applied onto human skin

Product	Formulation	Application amount (mL or g product/ person)	Body surface treated (cm^2)	Application amount (µL or mg product/ cm^2 body surface	Reference
Standard dose of insect repellents	n.r.	16.4 mL[1]	10 660	1.54 µL	Caroll, 2007
DEET formulations	Sprays (aerosol spray or pump spray)	3 and 6 g	10 660	0.28 and 0.56 mg[2]	Dr Knoell Consult, 2012a
	Aerosol sprays	3.49[3], 5.24[3], 9.69[3], 5.65[4]	8 730 and 8 195	0.4, 0.6, 0.69 and 1.1 mg	
	Aerosol spray	112 mL[1]	10 660	10.5 µL	
	Towelettes	6 g	10 660	0.56 mg[2]	
	Liquids in flasks	3 and 6 g	10 660	0.28 and 0.56 mg[2]	
	Roll-on stick	3 and 6 g	10 660	0.28 and 0.56 mg[2]	
	Generally DEET products	1.2 g active ingredient (corresponding to 8.0 g product, assuming a DEET concentration of 15%)	10 660	0.75 mg[2]	US-EPA, 1998
p-methane-3,8-diol products	Spray	2.9 and 4.3 mL	10 660	0.27 and 0.40 µL[2]	Dr Knoell Consult, 2012b
	Aerosol spray	337 mL[1]	10 660	31.6 µL	Dr Knoell Consult, 2012a
Sunscreen	Lotion	6.4 g[1]	10 660	0.60 mg	Bremmer et al., 2006
Skin care	Body lotion	5.1 g[1]	10 660	0.48 mg	Bremmer et al., 2006

n.r. = not reported

[1] Value is calculated based on the application amount per cm^2 for a body surface of 10660 cm^2

[2] Value is calculated based on the application amount per person, assuming a body surface to be treated of 10660 cm^2

[3] Value is calculated based on the application amount given per cm^2 for a body surface of 8730 cm^2 (product specific information)

[4] Value is calculated based on the application amount given per cm^2 for a body surface of 8195 cm^2 (product specific information)

Application amounts (in cm^2 body surface) given for repellent products are, in most cases, close to or below the default value, which is defined in ConsExpo for the application of suntan or body lotions (0.60 and 0.48 mg/cm^2 body surface, respectively). For one DEET product, an approximately two-fold higher application amount is reported (1.1 mg/cm^2).

Carroll (2007) states a three-fold higher application amount to be generally representative of a standard dose of an insect repellent applied on human skin (1.54 µL/cm^2). Remarkably high product application amounts are recommended by the producers of one DEET and one p-methane-3,8-diol aerosol spray, with 10.5 µL/cm^2 and 31.6 µL/cm^2 body surface, respectively. A difference between different types of formulations in terms of application amounts did not become obvious.

As a default value for the consumption of a repellent product on human skin, a value of 0.6 mg/cm2 skin surface is proposed. This value is congruent with the value taken for the human risk assessment of cosmetic products.

6.2 Market share of repellents for use on human skin/garments and fraction of inhabitants using a repellent product for human skin/garments

The market share is generally defined as the percentage of total sales (either given as volume/amount or value) in a market, captured by a brand, product, substance, or company. In this case, the parameter defines the proportion of a single active ingredient used as an insect repellent applied on human skin in relation to other active ingredients used for that purpose. Figures on the market share of an active substance are not generally available for risk assessment purposes.

DEET is one of the most common active ingredients in repellents available in the majority of countries (Frances, 2007a). The U.S. EPA estimated that more than 38% of the US population uses a DEET-based insect repellent every year. Approximately, 15 million people in the U.K. (corresponding to 24% of the population of about 63 million UK inhabitants) employ DEET each year (Moore & Debboun, 2007; Frances and Debboun, 2007). Nevertheless there is no information available about the remaining population of the U.S. or the UK, and their practice of using an insect repellent at all, or of applying repellent products containing non-DEET active ingredients. Hence, a relation of people using DEET products and people using other insect repellents containing no DEET cannot be established. Besides, no information is available about DEET volumes consumed. In summary, the interpretation of the consumption figures for DEET products cited above in terms of market share is problematic.

At the time of drafting this ESD, DEET had already been included into the Union List of approved active substances of the Biocidal Products Regulation (BPR) ((EU) 528/2012). Further biocidal active substances reviewed for PT 19 purposes under the BPR are intended to be applied as a repellent on human skin (Icaridin, IR3535, decanoic acid, and lauric acid, PMD). Even when considering DEET as an important active ingredient for insect repellents applied on human skin, a variety of other actives might also be available in the future for the European market. Therefore, and in accordance with default market share factors that are proposed for assessing environmental emissions for other product types (e.g. PTs 1 and 2), a default of 50 % market share for an active substance (F_{penetr} = 0.5) is judged as a reasonable worst case.

In this context, the parameter F_{inh} describes the fraction of inhabitants using a repellent product for skin or garments.

Van der Aa & Balk (2004) have compiled fractions of inhabitants using human hygiene biocidal products, like antiperspirants (aerosols and roll-on sticks), and creams. For aerosols used as deodorant the percentage of inhabitants using a specific product is set to 20%. Although this figure cannot be transferred per se to the use of a human skin insect repellent product, in the absence of further data it is considered a ‘best guess’.

6.3 Development of parameter for the ‘swimming scenario’

Inland water bodies (in the following, this term excludes rivers) may differ with reference to their origin (natural or anthropogenic), the existence of thermal layering, the water chemistry, and their use. According to DWA (2006), a classification of surface water bodies can be made according their origin and the existence of stratification during the summer season (see Table 6-2).

Table 6-2: Classification of inland surface waters (according to DWA, 2006)

Origin	Seasonal stratification	
	No	Yes
Natural	Ponds, shallow lakes (> 10 ha)	Lakes
Artificial (with or without drawdown)	Quarry ponds, surface mine lakes, dam reservoirs, artificial ponds	Surface mine lakes, quarry ponds, dam reservoirs

The transport and distribution of substances in surface water bodies is essentially dependent on the existence of a seasonal stratification of the water body.

At the end of winter and beginning of spring, surface waters are generally completely mixed and constituents evenly distributed, due to the influence of wind. Rising temperatures during late spring and summer lead to warming of the upper water layers and a gradient in water temperatures, which cannot be influenced significantly by wind. This thermal layering of the deeper surface water body can be stable during summer and prevents blending of the whole water body and complete distribution of its constituents. The stability of thermal layering is dependent on the depth of the surface water body, and the exposition to wind. Surface water bodies sheltered from wind can already be thermal layered at water depths of less than 5 metres (DWA, 2006). According to HLUG (2013a), thermal layering is to be expected at a water depth below 10 metres. Shallow surface water bodies may also develop a short-term thermal layering during early summer, however, due to the influence of wind a complete circulation of the water body during summer takes place and hence, a complete distribution of its constituents (DWA, 2006).

Due to the entry into force of the revised Bathing Water Directive (2006/7/EC) (EU, 2006), there is plenty of information available on inland bathing water profiles in Europe, however, the number of bathing people is in most cases not reported. The German Federal Land Hesse has included this parameter into its bathing water profiles in addition to parameter dealing with the characteristics of the surface waters and swimming locations (HLUG, 2013b). This information on 65 inland surface water swimming locations (there is sometimes more than one swimming location at the same surface water body) together with a survey conducted by Ctgb in the Netherlands (Ctgb, 2013) on 72 Dutch inland surface water swimming locations (including the number of swimmers) have been used for defining a standard surface water, and the corresponding number of swimmers used for assessment purposes.

The data of Hesse in Germany revealed 25 surface water bodies to be layered during summer. These surface waters have an average depth of 3 – 14.3 metres, but only four of them have an average depth of less than 5 metres. Surface water bodies not being layered during summer (n = 36) have an average water depth between 1.52 and 8.64 metres with only three of them having a water depth of more than 5 metres. Based on these data, it is defined that surface water bodies reveal a stratification during summer below an average water depth of 5 metres. A distribution of substances entering surface waters will therefore only be considered for a water depth up to 5 metres.

Sometimes, swimming areas are bordered by surface marker buoys or swimming chains. These bordered water areas will initially be more affected by the emission of repellents than other water areas of the surface water body.

The influence of seasonal temperature changes on the mixing of water has already been pointed out above, as this phenomenon may lead to a complete mixed surface water body in spring and autumn as well as a stable thermal stratification of surface water bodies during summer. The latter phenomenon results in mixing of water only in the upper layers of the water body.

Besides, convection due to day/night temperature differences is a driving force for mixing. Due to lower air temperatures during night, the upper layers of the water body will cool down. The consequence is an enhanced density of the upper layers of the water which results in downwelling of this cooler water and upwelling of warmer water from the deeper layers of the water body. Hence, water temperature determines water density which accounts for turnover.

Mixing of surface water bodies is also facilitated by wind. Due to friction at the water surface, wind induces a water current which at the bank descends downwards and moves into the opposite direction in deeper water layers. The following table contains information on the dependency of wind speed and the resulting speed of the water current which is transported by the wind.

Table 6-3: Wind speed and resulting speed of transported water layer (according to Schwoerbel and Brendelberger, 2013)

Wind speed (km/h)	Beaufort scale	Estimated mixing depth (m)	Speed of the mixed water current (km/d)
7.2	2 (light breeze)	1 - 2	5.7
18	3 (gentle breeze)	4 - 7	10
36	5 (fresh breeze)	6 - 12	16

As can be seen from Table 6-3, already low wind speeds result in a considerable velocity of the water current and as a consequence, a considerable transport of substances being present in the water.

Besides seasonal and daily temperature differences and wind, driving forces for water mixing are groundwater influx, tributary surface waters, precipitation as well as human and animal activities.

In summary, there are valid arguments available, which lead to the conclusion, that the mixing of water within a surface water body is a fast rather than a slow process. However, it is not to be expected, that complete mixing of water in a water body will occur within one or a few days. It can be anticipated that there will be a temporary gradient in repellent concentration between the swimming zone and the rest of the surface water body, which is considered to be negligible due to the time limitation.

Evaluation of the surface water data has been done by calculating the quotient between the water volume of the entire lake and the average daily number of swimmers during summer. The water depth for assessing the water volume was cut-off at 5 metres if applicable, considering thermal stratification during summer.

For defining a realistic worst-case situation, only surface water bodies with a volume of water per swimmer of less than 5 000 m^3 have been evaluated as being representative. Hence, very large surface water bodies or those being visited by swimmers less frequently have not been contemplated. The suitable surface water bodies account for 54 in the Netherlands and 45 in Hesse. The following table summarises the average and 90^{th} percentile values of the surface water volumes and the average number of swimmers for each country as well as combined for both countries.

Table 6-4: Surface water volumes and number of swimmers: average and 90th percentile

Country	Number of surface water bodies	Volume of surface water[1] (m^3)		Number of swimmers[2]	
		average	90th percentile	average	90th percentile
NL	54	398 405	1 398 750	570	1 500
DE	45	479 265	1 178 654	828	1 106
NL + DE	99	435 160	1 210 000	687	1 500

[1)] Up to 5 metres water depth
[2)] Basis is the daily average number of swimmers during summer

For risk assessment purposes the average water body volume (435 000 m^3) and the 90th percentiles of the number of swimmers (1 500) are considered a realistic worst case scenario.

In the framework of the revised Bathing Water Directive, European Member States have to report the bathing seasons to the Commission. The following table contains bathing seasons of selected European countries, as published by the European Environment Agency.

Table 6-5: Bathing seasons of selected European countries

Country	Year of reporting	Start of bathing season	End of bathing season	Duration of bathing season (d)	Reference
Croatia	2011	1 or 25 June	21 August or 15 September	Min: 57 Max: 107	EEA, 2011a
Denmark	2011	1 June	1 September	92	EEA, 2011b
Finland	2011	15 or 25 June	15 or 31 August	Min: 51 Max: 77	EEA, 2011c
France	2011	29 April – 19 July	24 July – 2 October	Min: 75 Max: 164	EEA, 2011d
Germany	2011	2 April – 20 July	7 August – 10 October	Min: 74 Max: 191	EEA, 2011e
Greece	2011	1 June	31 October	152	EEA, 2011f
Hungary	2011	30 April – 4 July	15 August – 30 September	Min: 42 Max: 153	EEA, 2011g
Ireland	2011	1 June	15 September	106	EEA, 2011h
Italy	2010	1 Mai	30 September	152	EEA, 2011i
The Netherlands	2010	1 May	1 October	153	EEA, 2011j
Spain	2011	15 May – 11 July	27 August – 2 October	Min: 47 Max: 140	EEA, 2011k
Sweden	2011	21 June or 15 July	15 or 20 August	Min: 30 Max: 60	EEA, 2011l
Switzerland	2011	1 May – 1 July	15 August – 30 September	Min: 45 Max: 152	EEA, 2011m
UK	2011	15 May or 1 June	15 or 30 September	Min: 106 Max: 138	EEA, 2011n

Min = minimum; Max = maximum

The maximum duration of the bathing season is lowest in the northern European countries Denmark (92 d), Finland (77 d), and Sweden (60 d), whereas all other countries have maximum bathing seasons of more than 100 days. Germany has the longest maximum bathing season with more than 190 days. According to HLUG (2013a), noteworthy swimming in Hesse is to be expected from the beginning to the middle of May until the end of August/middle of September. This time period would comprise less than 140 maximum swimming days.

For determining the bathing season relevant for assessment purposes, the following considerations have been made. Swimming in surface water bodies is highest during July and August due to suitable water and air temperatures and the fact that there is holiday season.

Extensive swimming in surface water bodies during April and May is not to be expected since water temperatures and air temperatures (under moderate climate conditions) are in most cases not high enough. Swimming outside the holiday season is limited to weekends due to employment of adults and children going to school. Therefore, it is considered a realistic worst case to take 91 swimming days (3 months) for emission calculations.

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