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Supplement to the methodology for risk evaluation of biocides (I)

Emission scenarios to be incorporated into the Uniform System for the Evaluation of Substances (USES)

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Abstract

This report documents the launch of the process to complete the whole range of emission scenarios for biocide applications to be incorporated in USES (Uniform System for the Evaluation of Substances). To date, a limited number of emission scenarios for various biocide applications have been covered. This report deals with two of the most urgently needed biocide applications, namely, disinfectants used for sanitary purposes and applications for use in the medical sector. Emission scenarios are presented for all relevant situations. Other biocide applications - not yet investigated - will be a subject for future studies.

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Samenvatting

In versie 1 en 2 van het Uniform System for the Evaluation of Substances (USES) is voor een beperkt aantal toepassingen van niet-landbouwbestrijdingsmiddelen een emissie scenario opgenomen. Voor de 23 product typen in de Europese richtlijn (Directive 98/8/EC) is nagegaan welke toepassingen als eerste in aanmerking moeten komen om uitgewerkt te worden. Dit rapport behandelt de eerste twee toepassingen, namelijk die voor biociden gebruikt voor ontsmetting van sanitair in woningen en openbare ruimten en voor biociden toegepast in de medische sector.

De toepassing van biociden voor sanitair betreft de industrial categories 5 (Personal/domestic) en 6 (Public domain). Het emissiescenario wordt gepresenteerd in Tabel 2.1.

Het gebruik van biociden in de medische sector - industrial category 6 (Public domain) - omvat meerdere toepassingen. Achtereenvolgens worden emissiescenario's gepresenteerd voor:

1. desinfectie van ruimten, meubilair en voorwerpen (Tabel 2.6);
2. desinfectie van instrumenten (scopes Tabel 2.7 en overige instrumenten Tabel 2.8);
3. wasgoed desinfectie (Tabel 2.9).

Summary

Only a limited number of emission scenarios for the application of biocides have been incorporated in the Uniform System for the Evaluation of Substances (USES) versions 1.0 and 2.0. Directive 98/8/EC on the placing of biocidal products on the market distinguishes 23 product types. A priority list has been made for research on emission scenarios and this report presents emission scenarios for the first two most urgently needed applications, the disinfectants used for sanitary purposes and disinfectants for use in the medical sector. The application of biocides for sanitary purposes belongs to industrial category 5 (Personal/domestic) and for different purposes in the medical sector to industrial category 6 (Public domain). Emission modules are presented for:

1. disinfection of rooms, furniture and objects (Table 2.6);
2. disinfection of instruments (scopes, Table 2.7 and other instruments Table 2.8);
3. laundry disinfection (Table 2.9).

1. Introduction

The government of the Netherlands developed the first version of the Uniform System for the Evaluation of Substances (USES 1.0) in the framework of their first National Environmental Policy Plan. USES 1.0, available since 1994, harmonised the risk assessment of new and existing substances, biocides and plant protection products. USES 1.0 was tailored to the corresponding EC and national legislation. USES 1.0 was subsequently used as one of the basic documents for the development of the EU Technical Guidance Document to assess risks of new and existing substances in support of the corresponding EC legislation and its computer implementation, the European Union System for the Evaluation of Substances (EUSES 1.00).

Simultaneously with the development of EUSES 1.0 a second version of USES was developed by VROM, mainly for use in the Netherlands. USES 2.0 comprises risk assessment methods for biocides and plant protection products, in addition to methods for new and existing substances. The risk assessment methods for biocides and plant protection products are in accordance with the corresponding national legislation and as much as possible with the corresponding EC legislation. In USES 2.0, the risk assessment methods for new and existing substances are fully equivalent to EUSES 1.00.

As part of USES 1.0 and USES 2.0 several emission scenarios for biocides (non-agricultural pesticides) have been developed at the RIVM within a period of approximately 10 years (Luttik *et al.*, 1993 and 1995; Montfoort *et al.*, 1996). These scenarios include:

DISINFECTANTS
- Acute discharge of swimming water by public pools to the sewage treatment plant (STP)
- Chronic discharge of swimming water by public pools to the STP
- Discharge of swimming water by pools into surface water
- Disinfectants in accommodations

INDUSTRIAL BIOCIDES
- Biocides in the textile industry
- Biocides in the paper and cardboard industry
- Biocides in process and cooling-water installations

PRESERVATIVES IN THE METALWORKING INDUSTRY

HOUSEHOLD PRODUCTS USED FOR FOGGING

WOOD PRESERVATIVES AND WOOD PROTECTORS

Creosote impregnation

Salt impregnation

Drenching and dipping

Remedial timber treatment in buildings

Leaching from impregnated wood to surface water

Leaching from impregnated wood to surface water

Leaching from impregnated wood to soil

ANTIFOULINGS

Most of these have already been implemented in USES.

Recently adopted has been Directive 98/8/EC of the European Parliament and he Council (EC, 1998) on the placing of biocidal products on the market. This Directive distinguishes 23 product types contributing to four main classes, (Table 1.1). Subgroups have been added to two product types. These subgroups are distinguished by the CTB (the Dutch Board for the Authorisation of Pesticides). In this table the status of emission scenarios is indicated as follows:

A. Emission scenarios present and incorporated in USES 1.0 and 2.0;
B. Emission scenarios developed and incorporated in USES 2.0;
C. Emission scenarios developed but not yet incorporated in USES;
D. Emission scenarios originally planned to be published in this report;
E. Emission scenarios to be developed in future.

The following product types (PT) are covered in this report:

PT 2: Private-area and public-health area disinfectants and other biocidal products, for:
a) Sanitary sector
b) Medical sector

The development of the other emission scenarios - starting with those mentioned with a "D" not yet covered in this report - will be part of further work on biociode emissions.

The emission scenarios are presented in tables, with the input and output data, and calculations specified. USES units are used in the emission scenarios. The input and output data are divided into four groups:

S	data Set	a value for this parameter must be present in the data entry set (data either to be supplied by the notifier or available in the literature);
D	Default	a fixed value which can be changed by the user;
O	Output	the value being the result of a previous calculation;
P	Pick list	parameter values to be chosen from a pick list with values.

Table 1.1 Main classes of biocides and the accompanying product types as distinguished in Directive 98/8/EC; bulleted subgroups of product types as distinguished by the Dutch Board for the Authorisation of Pesticides (CTB)

No.	Class and product types	Status
I	Disinfectants and general biocides	
1	Human hygiene biocidal products	E
2	Private and public-health area disinfectants and other biocidal products:	
	• Swimming pools	A
	• Sanitary sector	D
	• Horticulture	E
	• Tiles and surfaces	E
	• Medical sector	D
3	Veterinary hygiene biocidal products	C, D [1)]
4	Food and feeding area disinfectants	(A [2)]), E
5	Drinking-water disinfectants	E
II	Preservatives	
6	In-can preservatives	E
7	Film preservatives	E
8	Wood preservatives	A, B
9	Fibre, leather, rubber and polymerised materials preservatives	(A), E [3)]
10	Masonry preservatives	E
11	Preservatives for liquid-cooling and processing systems	A
12	Slimicides	E [4)]
13	Metalworking-fluid preservatives	A
III	Pest control products	
14	Rodenticides	A[5)]
15	Avicides	A[5)]
16	Molluscicides	D
17	Piscicides	E
18	Insecticides, acaricides and products to control other anthropod species:	
	• Insecticides for manure	D [6)]
	• Insecticides for stables	D [6)]
	• Insecticides for refuse dumps	B [7)]
	• Insecticides for unoccupied interiors and stock rooms	B
19	Repellents and attractants	E
IV	Other biocides	
20	Preservatives for food or feedstocks	E
21	Antifouling products	A, D [8)]
22	Embalming and taxidermist fluids	E
23	Control of other vertebrates	E

1) The scenarios of a previous investigation (Montfoort *et al.*, 1996) have been adapted and will be published separately by RIVM/LBG in 1999.
2) Disinfectants used in the sugar industry have been studied previously (Luttik *et al.*, 1993); an emission scenario has not been introduced yet.
3) For the textile processing industry, an emission scenario has already been implemented.
4) A general emission scenario for the paper and cardboard industry has been implemented.
5) This has been partly filled in the ‘decision trees’ for agricultural pesticides. Secondary poisoning may be a problem; a possibility for assessment will be published soon (Luttik *et al.*)).
6) In combination with the emission scenario for product type 3 (class 1).
7) The same evaluation method as for pesticides is used in agriculture (application via sprays, field application).
8) An emission scenario for waterways has to be developed in addition.

2. Class I: Disinfectants and general biocides

2.1 Product type 2: Private and public-health area disinfectants and other biocidal products

This product type concerns a heterogeneous group of products used for disinfection, for example bathrooms, toilets, chemical closets, walls and floors in private homes and institutions such as offices, workshops, schools, hospitals and sport facilities (Van Dokkum *et al.*, 1998). All disinfectants not included in one of the other product types belong here. This report focuses on two subdivisions, namely "sanitary" and "medical".

2.2 Sanitary sector

The application of disinfectants for sanitary purposes as described above refers to nearly the same areas as the scenario "Disinfection in accommodations", described in Luttik *et al.* (1993) and incorporated in USES 2.0 (RIVM, VROM, VWS, 1998). The emission scenario for accommodations was designed for disinfectants used in accommodations for humans and for preparing food and drinks. This emission scenario assumes (default value) that 90% of the active substance is discharged into the sewer. Furthermore, the scenario uses the tonnage of the active substance applied per year in the region considered.

Scenario description

The sanitary purposes scenario for disinfectants described here uses the post-consumer release prediction and consumption data of the emission scenario document for soaps and detergents used in industrial categories 5 (Personal/domestic) and 6 (Public domain) (EC, 1996). This emission scenario document gives an estimate of a 100% release to waste water, and consumption of detergents for surface cleaning at 5 and 2 grams per capita per day for general purpose and lavatory cleaners, respectively, as used in the emission scenario document for (industrial category) IC-5 Personal/domestic and IC-6 Public domain (EC, 1996). The density of the detergents is assumed to be 1000 $kg.m^{-3}$.

Table 2.1 presents the emission scenario for disinfectants used for sanitary purposes. It should be noted that the standard STP of EUSES and USES is used, with 10,000 inhabitants feeding the system and waste water per inhabitant, at 0.2 m^3.

Table 2.1 Emission scenario for calculating the releases of disinfectants used for sanitary purposes

Variable/parameter (unit)	Symbol	Default	S/D/O/P
Input:			
Fraction released to waste water (-) [1)]	$F_{4, water}$	1	D
Active substance in product ($kg.l^{-1}$)	$C_{product}$		S
Consumption per capita ($l.cap^{-1}.d^{-1}$)			
General purpose (tiles, floors, sinks)	$Q_{product}$	0.005	D
Lavatory	$Q_{product}$	0.002	D
Output:			
$Elocal_{4,water}$ = Emission rate to waste water ($kg.d^{-1}$) [1)]			

[1)] The subscript "4" refers to the stage of private use in conformity with EUSES 1.0 and USES 2.0.

Model calculations:

$$Elocal_{4,water} = 10{,}000 * Q_{product} * C_{product} * F_{4, water}$$

2.3 Medical sector

Annex II of (EC, 1998) does not specify the medical sector as a separate area. Several aspects of the use of product type 2 as disinfectant are related to this sector. Table 2.2 overviews the subdivision under product type and topics relevant for the medical sector. The topics as in Van Dokkum *et al.* (1998) which belong to product type 2, are also specified in this table.

Table 2.2 Subdivision of product type 2 for topics relevant to the medical sector according to Annex II (EC, 1998) and BIOEXPO[1] (Van Dokkum *et al.*, 1998)

Annex II	BIOEXPO
2.1 Medical equipment	Sterilisation of medical instruments in hospital
2.4 Accommodation for man	Disinfection in accommodations for man (bathrooms, toilets, chemical closets, walls and floors in institutions [amongst others hospitals])
2.7 Waste water	Sewage water from hospitals
2.8 Hospital waste	Infectious waste (including hospital waste)
2.10 Others	Laundry disinfectants (hospitals)

All topics relevant to the medical sector are described here. Subsection 2.2.1 deals with the definitions and requirements, as well as the processes and chemicals involved.

[1] Development of a concept for the environmental risk assessment of biocidal products for authorization purposes (BIOEXPO)

2.3.1 Sterilisation, disinfection and cleaning

This section deals with definitions and requirements, and processes and chemicals related to the particular topics and is derived from Dutch directives on disinfection and sterilisation (WIP, 1991; WIP, 1998).

Sterilisation

Sterilisation is a process in which all organisms are killed or eliminated. Disinfection is a chemical or physical process aimed at eliminating the risk of passing micro-organisms. Which method is chosen depends on a number of factors, such as the nature of the material, the possible organisms concerned and the risk of infection for patients and personnel.

Sterilisation, conducted by heating in most cases, is required for:

- medical aids and instruments for direct contact with sterile body tissue, the bloodstream, or the circulatory system,
- accessories for endoscopes (biopsy tongs, cutting instruments, etc.),
- scopes to be inserted in sterile body tissue or cavities.

Sterilisation methods that may be applied are:

1. dry heating,
2. moist heating with saturated steam (e.g. at a temperature of 120 degrees Celsius and a pressure of 200 kPa),
3. subatmospheric steam in combination with a disinfectant,
4. ethylene oxide (ETO),
5. gamma radiation,
6. plasma sterilisation,
7. sterilisation with fluids.

With reference to the sterilisation methods above, for methods 1, 2 and 5, emission scenarios for none of these sterilisation methods have been developed, since no biocides are involved. The third method (3) is no longer applied in the Netherlands since the use of the disinfectant, formaldehyde, is prohibited for medical purposes in conformance with the Netherlands Pesticide Act. Since the General Administrative Order on Medical Aids took effect (Stb., 1995) formaldehyde sterilisers may be marketed in The Netherlands. A European standard is being drawn up at the moment. As only one specific substance, in this case formaldehyde, is involved and European standards are applicable, no emission scenario has been developed. The fourth method (4), sterilisation with ETO, is only applied to a limited number of objects, such as electronics and instruments containing thermolabile plastics (providing they are not sensitive to ETO). Sterilisation with ETO is only applied with extreme care and is bound to strict statutory regulations. Therefore this process is not covered by an emission scenario in this report. Plasma sterilisation (5) is a fairly new method. A plasma is a gas in which so much energy is introduced by means of radiation of a radio frequency that molecules are split into atoms and electrons are released from the atoms. Therefore a plasma is very reactive, reacting within a short time with essential substances in the cells of micro-organisms. An advantage is that no hazardous residues will be formed. So far, most of the experience has been acquired using a hydrogen peroxide gas plasma; this method is not allowed on the Dutch market and no emission scenario document has been developed (the substance used is unlikely to be released as it decomposes completely). Besides plasma sterilisation, small-scale experiments are carried out at using sterilisation with fluids (7): peracetic acid with or without hydrogen peroxide. Since the status of the method is unclear, no emission scenario is presented. Furthermore, the substances involved are used as disinfectants and will be covered as such in this report. It should be noted that such equipment is designed specifically for the use of a certain chemical with unique containers and other provisions. The equipment put on the market meets the requirements of the European Union Medical Device Directive (MDD) (EEC, 1993). This means that the equipment can be placed anywhere within the EU market. It is not necessary, to ask for admission of disinfectants used in the equipment.

Disinfection

Disinfection has been replaced by cleaning in many cases nowadays, as disinfection is not always considered e necessary. Thermal disinfection is, if possible, always and in all places preferred. Disinfection is required for:

- medical aids coming into contact with mucous membranes (e.g. "scopes", respirators, hose systems for anaesthesia),
- medical aids usually cleaned after use but which have been used incidentally on an infected patient,
- medical aids used for large amounts of excretionary products (bedpans, urinals, sputum basins); cleaning and thermal disinfection are often carried out in one operation,
- surfaces with blood or blood-containing material, pus or infected secretions.

The way disinfectants affect micro-organisms can vary. Table 2.3 presents an overview of the action mechanisms, representative groups of chemicals and their antimicrobial activity.

Table 2.3 Mechanisms of action on micro-organisms, representative categories of chemicals and antimicrobial activity (WIP, 1991)

Effect	Category	Antimicrobial activity *)						
		veg	myco	spor	fung	LF	HF	H/H
Dehydration and denaturation	**alcohols**							
	ethanol 70%	++	++	-	++	++	++	++
Oxidation, inactivation nucleic acids	**halogens**							
	chlorine **) 1000 ppm	++	++	++	++	++	++	++
	iodine(+alc) 1%/70%	++	++	±	++	++	++	++
	iodophore 10% aq.	++	+	±	±	+	+	++
Denaturation of cell proteins, destruction of cell walls	**phenols**							
	o-phenyl-phenol	++	++	-	+	+	-	-
Alkylation	**aldehydes**							
	glutaraldehyde 2%	++	++	+	++	++	+	++
	succinaldehyde 10%	++	++	-	++	++	-	++
Coagulation	**biguanides**							
	chlorhexidine 0.05-4%	++	-	-	-	+	-	+
	ditto (+alc) 0.5%/70%	++	++	-	++	++	++	++
Destruction of nucleic acid	**peroxides**							
	hydrogen peroxide	++	++	++	+	++	++	?

*) ++ very effective; + effective; ± effectiveness doubtful; - not effective; ? effectiveness unknown
veg = vegetative bacteria
myco = mycobacteria
spor = spores of bacteria
fung = fungi and yeasts
LF = lipophylic viruses
HF = hydrophylic viruses
H/H = (HBV) hepatitis B virus / (HIV) human immunodeficiency virus

**) sodium hypochlorite or sodium dichloroisocyanurate; ppm refers to free chlorine

This report only considers disinfectants from the Biocidal Products Directive (e.g. substances used for disinfection of the skin are therefore excluded). Indications from the Dutch directive on disinfection and sterilisation (WIP, 1991) of the substances for disinfection are presented in Table 2.4.

Table 2.4 Indications of substances for disinfection (WIP, 1991)

Category	Example	Choice
Objects resistant to chemicals	objects where risk for transfer after contamination with pathogenic micro-organisms is considerable:	
	- not containing blood	o-phenyl-phenol 2% chlorine 250 ppm
	- possibly containing blood	chlorine 1000 ppm alcohol 70%
Surfaces resistant to chemicals	operation room floor (as far as visibly contaminated)	chlorine 1000 ppm
	nursing patients in isolation quarters	chlorine 1000 ppm o-phenyl-phenol 2%
	kitchens (surfaces and equipment coming in contact with food)	chlorine 250 ppm thermal by preference
Objects and surfaces coming in direct contact with patient	thermometers, parts of anaesthesia equipment, transducers, etc.	alcohol 70% iodine 1% in alcohol 70%
Water-resistant instruments	after use and before sterilisation	sodium perborate 2%
Vulnerable temperature-sensitive, water-resistant instruments	endoscopes	glutaraldehyde 2%
Vulnerable temperature-sensitive, not water-resistant instruments	(purpose: sterilisation)	ethylene oxide

Furthermore, disinfectants are used as preservatives in the medical sector for media where development of micro-organisms may lead to infection of patients and personnel. Usually these are fluids which are not replaced frequently enough. Often disinfectants are used, however, at a low concentration. Table 2.5 - derived from the Dutch directive on disinfection and sterilisation (WIP, 1991) - gives some indications for the use of disinfectants as preservatives.

Table 2.5 Indications of the use of disinfectants as preservatives (WIP, 1991)

Type of fluid	Substance
Bath water for physiotherapy	tosylchloramide 20 $mg.m^{-3}$
Water mattresses	aldehydes *)
Water in flower vases	sodium dichloroisocyanurate 10 ppm free chlorine
Humidifier fluid for incubators	chlorhexidine 1:2000 in water
Water seal suction equipment	chlorhexidine 1:2000 in water

*) troublesome in practice, alternatives being investigated

Cleaning

Cleaning is the process of removing visible dirt and invisible organic material to prevent micro-organisms maintaining themselves, multiplying and spreading (WIP, 1993). The aim is to use cleaning as much as possible instead of disinfection. Hospitals use disinfectant-free normal household detergents and cleaning agents for cleaning.

Emission scenarios for disinfectant use

Disinfection of hospital rooms - i.e. product subtype 2.4 in Table 2.2: (Accommodation for man) - is presented in subsection 2.3.3. Sterilisation of medical instruments is not dealt with here, as this item is covered in the Medical Device Directive of the European Council, 93/42/EC. The disinfection of medical instruments, however, is presented in subsection 2.3.4. Disinfection of laundry - product subtype 2.10 in Table 2.2: (Others)" is discussed in subsection 2.3.5. The use of disinfectants for hospital waste is covered in subsection 2.3.6.

2.3.2 General assumptions

The scenarios presented in the subsections 2.3.3 to 2.3.6 assume that the model hospital considered is located at a site with an STP (sewage treatment plant) of the default size used in EUSES, i.e. 2000 m^3 waste water per day (10,000 inhabitants, 0.2 m^3 waste water $cap^{-1}.d^{-1}$). The contribution of the model hospital to the influent has been estimated to amount to 250 m^3 per day according to the data from CBS (1997) and CUWVO (1986) as follows:

Data

Number of hospitals	148	
Number of beds	60,489	
Number of patient-days per year	15,779,000	
Number of employees	137,478	
Amount of waste water	133 to 270	$l.d^{-1}.cap^{-1}$ (patients and personnel)

Estimations for the model hospital

1. Average number of patient-days per year	15,779,000 / 148	≅	107,000
2. Average number of employees	137,478 / 148	≅	1300
3. Estimated percentage of employees present per day			70
4. Average amount ($l.cap^{-1}.d^{-1}$) of waste water per person	(133 + 270) / 2	≅	200
Average amount of waste water from one hospital ($m^3.d^{-1}$)			
	(107,000 / 365 + 0.7 * 1300) * 0.2	=	250

For the emission scenario, the model hospital averages were used

2.3.3 Disinfection of rooms, furniture and objects

Before disinfection, normal domestic cleaning is always carried out. Furniture and objects are cleaned with disposable cloths and soap or synthetic detergents. The cleaning of floors can be carried out wet or dry. Sanitary fittings are divided into "clean" and "dirty". Clean sanitary fittings are e.g. sinks and tiles; dirty sanitary fittings are e.g. the inside of toilet bowls, toilet seats and the low tiles next to the toilet bowls.
The cleaned surfaces and objects are then treated with a disinfecting solution so that everything will remain wet for at least five minutes, i.e. the minimum exposure time required. The disinfected surfaces are allowed to air-dry. The dosage must be exact and the prescribed operating instructions must appear on the label of the disinfectant containers.

The only place where obligatory disinfection is carried out is in isolation wards. Only in the case of strict isolation does disinfection have to be carried out daily, otherwise wards can be disinfected just after termination of the isolation. The disinfection applies to floors, furniture and objects in the room itself, the sanitary facilities and the sluice. Other rooms are only disinfected in situations where contamination occurs due to spilling of possible infectious material. If the disinfectant concerned is the same as for the disinfection of lavatories and surfaces in accommodations for humans (households, offices, public places, etc.), the scenario of section 2.2 is used. Otherwise the scenario described in this subsection has to be used.

In order to prevent spreading of contamination it is necessary that cleaning equipment is cleaned, disinfected and dried daily. Objects disinfected are buckets and (plastic) brushes. Buckets are disinfected in the bedpan-washer machines, where thermal disinfection is applied. Brushes are immersed in a disinfecting solution (e.g. 1000 ppm free chlorine or 2% o-phenyl-phenol), rinsed and dried. Cloths are of the disposable type. Mops are preferably disposable, otherwise will to be washed in the laundry. The text above is derived from the Dutch directive on disinfection and cleaning of rooms, furniture and objects (WIP, 1993).

Scenario description

If a disinfection has to be carried out the model hospital will be assumed to use 25 litres of water with 4% active substance, i.e. 1 kg (based on maximum chlorhexidin value in Table 2.3). For disinfection of brushes the same assumptions apply. If the disinfectant concerned is used for both applications, the releases from the emission scenario results have to be summed. Table 2.6 presents the emission scenario for disinfectants used for sanitary purposes and brushes.

Table 2.6 Emission scenario for calculating of the releases of disinfectants used for sanitary purposes in hospitals

Variable/parameter (unit)	Symbol	Default	S/D/O/P
Input:			
Fraction released to waste water [1)]	$F_{3,\ water}$	1	D
Concentration at which active substance is used ($kg.l^{-1}$)			
Sanitary purposes	$C_{disinf1}$	0.04	D
Brushes	$C_{disinf2}$	0.04	D
Amount of water with active substance ($l.d^{-1}$)			
Sanitary purposes	Q_{water1}	25	D
Brushes	Q_{water2}	25	D
Output:			
$Elocal_{3,water}$ = Emission rate to waste water ($kg.d^{-1}$) [1)]			

1) The subscript "3" refers to the stage of processing in conformance with EUSES 1.0 and USES 2.0.

Model calculations:

$Elocal_{3,water} = Q_{water1} * C_{disinf1} * 0.1 * F_{3,\ water}$ (sanitary purposes)

$Elocal_{3,water} = Q_{water2} * C_{disinf2} * 0.1 * F_{3,\ water}$ (brushes)

$Elocal_{3,water} = Q_{water1} * C_{disinf1} * 0.1 * F_{3,\ water} + Q_{water2} * C_{disinf2} * 0.1 * F_{3,\ water}$ (sanitary purposes + brushes)

2.3.4 Disinfection of instruments

Disinfection of instruments like scopes should be done in automated washers/disinfectors (BSG, 1998). The majority of the hospitals with endoscopy units performing several thousands procedures per year use these washers nowadays (Van Gossum *et al.*, 1989). Where patient turnover is low, manual disinfection is still carried out. The washers are connected to the sewer for removal of the waste water (including the spent disinfectant). As disinfectants such as aldehydes are fairly volatile, washers/disinfectors are supplied with air-exchange equipment, e.g. exhaust hood, ventilation system, etc.) (WIP, 1998; APIC, 1994). The contents of (ultrasonic) baths used for manual disinfection will also be discarded into the sewer. For the emission scenario, use of automated washers/disinfectors is considered as these will penetrate almost completely, manual disinfection being unacceptable in the light of the working conditions. Other instruments are disinfected in solutions (or suspensions) of disinfectants to prevent adhesion of blood, pus, etc. These baths are discarded into the sewer after use.

If a biocide is notified for both disinfection of scopes and other instruments, the emission for a single point source (one hospital) should be calculated by summing the results of both emission scenarios (Tables 2.7 and 2.8).

Scenario description

a) Scopes

The most widely used disinfectant is glutaraldehyde at a concentration of 2% (WIP, 1998; RIVM, 1996; APIC, 1994). The emission scenario assumes that the model hospital has all possible units for performing endoscopy procedures as the enquiry (RIVM, 1996) shows that relatively small hospitals may have washers/disinfectors for every speciality related to endoscopy. Therefore the model takes the hospitals in the enquiry with the highest glutaraldehyde consumption as the basic institution since these hospitals can be considered to be average-sized hospitals. These hospitals use 150 kg glutaraldehyde per year in three machines.

Replacement of the disinfectant solution can be done at regular intervals or at a certain measured minimum concentration. Many hospitals contacted recently state that replacement is carried out every two weeks; however, it is not known what concentration glutaraldehyde has then. The disinfectant concentration declines during use because of:

1. dilution due to the carry-over of water (APIC, 1996; Bradley, 1994),
2. carry-over of disinfectant onto the scopes going to the rinsing phase,
3. volatilisation from the solution,
4. probable decomposition.

In a guideline from the United States (APIC, 1996) results of several investigations are given on glutaraldehyde declines, e.g. from 2.4% to 1.5% after 10 days in manual and automatic baths used for endoscopes (Mbithi *et al.*, 1993). The report mentions one investigator establishing a minimum effective concentration of 1.5%. Test strips constructed to indicate concentrations above 1.5% are available. The model assumes by default that replacement is carried out at regular intervals, with those replacements carried out the same day once every two weeks in the case of more than one washer/disinfector. This is expressed in the model as a replacement frequency of 25 times per year (with 150 kg in three machines and a concentration of 2% glutaraldehyde in the fresh solution, i.e. an amount of 100 l per machine per event).

Water emissions due to rinsing treated scopes are not considered in the model as the (daily) discharges to the sewer are negligible compared to the discharges at replacement of the disinfectant solution. The emission scenario has a default value of 0.25 for the so-called concentration reduction factor at replacement, which means that the concentration of the bath at replacement is reduced by 25%, leaving 0.75 times the start concentration. It is assumed here that the amount "lost" due to this concentration reduction factor is related to the 'drag over' of the liquid, volatilisation and decomposition.

The emission of the disinfectant into the air because of volatilisation from the solution will decrease when the concentration in the solution decreases. The maximum emission on the first day after refreshing the bath is of interest for the assessment

.

The method described by R.G. Thomas in Lyman *et al.* (1990) is used for the calculation of this volatilisation. This method follows the two-film concept for estimating the flux of volatiles across the air-water interface. For this method the following data are needed:

- Chemical properties: vapour pressure, water solubility, molecular weight,
- Environmental characteristics: wind speed, current speed and depth of water body.

The model is designed for calculating the volatilisation from water bodies such as rivers. For the emission scenario the wind speed is replaced by estimates for the air speed in the disinfector, a comparable flow of the solution and the depth in the disinfector. The defaults for these estimates are:

- air speed: WINDSPEED = 1 $m.sec^{-1}$ (air speeds >5 $m.sec^{-1}$ are not expected)
- liquid flow velocity: WATERSPEED = 1 $m.sec^{-1}$
- depth of bath: $DEPTH_{water}$ = 0.5 m

The basic steps of calculation according to Thomas (Lyman *et al.*, 1990) are (steps 1 to 6):

(1) Determination of Henry's law constant HENRY *(this is a standard calculation in EUSES/USES).*

(2) If HENRY < 3, then $Elocal_{3,air} = 0$ (end of calculation).

(3) If HENRY ≥ 3, the substance is considered to be volatile; determination of the nondimensional Henry's law constant (air-water partition coefficient) $K_{air\text{-}water}$ *(this is a standard calculation in EUSES/USES).*

(4) Calculation of the liquid-phase exchange coefficient k_l (MOLW = molecular weight):

MOLW ≤ 65: $k_l = 5.55*10^{-5} * (44 / MOLW)^{1/2}$

MOLW > 65 & WINDSPEED < 1.9 $m.sec^{-1}$:

$k_l = 6.53*10^{-5} * (WATERSPEED^{0.969} / DEPTH_{water}^{0.673}) * (32 / MOLW)^{1/2}$

MOLW > 65 & 1.9 < WINDSPEED < 5 $m.sec^{-1}$:

$k_l = 6.53*10^{-5} * (WATERSPEED^{0.969} / DEPTH_{water}^{0.673}) * (32 / MOLW)^{1/2} * e^{0.526(WINDSPEED - 1.9)}$

(5) Calculation of the gas-phase exchange coefficient k_g:

MOLW < 65: $k_g = 8.33*10^{-3} * (18 / MOLW)^{1/2}$

MOLW > 65: $k_g = 3.16*10^{-3}$ (WINDSPEED + WATERSPEED) * $(18 / MOLW)^{1/2}$

(6) Calculation of the overall liquid-phase mass transfer coefficient K_L:

$K_L = (K_{air\text{-}water} * k_g * k_l) / (K_{air\text{-}water} * k_g + k_l)$ m.sec^{-1}

The following steps for the emission model according to Lyman *et al.* (1990) for the concentration at any time (step 7) and for the emission scenario are specifically:

(7) Calculation of the concentration after 24 hours (maximum emission on the first day):

$$C_{day2} = C_{day1} * e^{-K_L * T_{day2} / (100 * DEPTH_{water})} \text{ mg./l}^{-1},$$

where C_{day2} = disinfectant concentration a certain time (T_{day2} in hours),

C_{day1} = disinfectant start concentration in refreshed bath,

T_{day2} = time in hours

(8) Calculation of the emission from the difference in concentrations (day 1 - day 2).

Model calculations have been carried out for the most commonly used disinfectant, namely glutaraldehyde. For the vapour pressure, only WHO/IPCS/ILO (1998) gave a value at 20°C: 2.3 kPa. For the solubility, glutaraldehyde could only be found to either "reacts with water" or "be miscible". For the calculation of Henry's law constant 950,000 mg.l^{-1} was used. The calculations using values for the depth of the bath of 0.5 m or more, wind speeds of 0.5 m.sec^{-1} or lower and water speeds of 0.5 m.sec^{-1} result in glutaraldehyde emissions due to volatilisation of 25% or less (i.e. a concentration decline from 2% to about 1.5%). This is in line with the data discussed earlier.

Table 2.7 presents the emission scenario using the assumptions stated above.

Table 2.7 Emission scenario for calculating the release of disinfectants used in hospitals for disinfection of scopes and other articles in washers/disinfectors

Variable/parameter (unit)	Symbol	Default	S/D/O/P
Input:			
(a) Amount of active substance ($kg.y^{-1}$)	Q_{disinf}	150	D
or			
(b) Amount of product (l or kg)	$Q_{product}$	750	D
Active substance in product ($g.l^{-1}$)	$C_{product}$		S
Working concentration (%)	C_{disinf}	2	S
Concentration reduction at replacement	f_{red}	0.25	D
Number of washers/disinfectors	$N_{machines}$	3	D
Replacement frequency (y^{-1})	$Freq_{repl}$	25	D
Maximum number of washers/disinfectors with simultaneous replacements	$N_{rep\text{-}max}$	3	D
Depth of bath (solution in machine) (m)	$DEPTH_{water}$	0.5	D
Air speed above liquid in machine ($m.s^{-1}$)	WINDSPEED	0.25	D
Liquid flow velocity in machine ($m.s^{-1}$)	WATERSPEED	0.25	D
Volume of solution in machine (m^3)	$Q_{machine}$	100	D

Output:

$Elocal_{3,water}$ = Maximum emission rate to water on the day of a replacement ($kg.d^{-1}$)

$Elocal_{3,air}$ = Maximum emission rate to air after replacement ($kg.d^{-1}$)

Model calculations:

(b) $Q_{disinf} = Q_{product} * C_{product} * 10^{-3}$

$Elocal_{3,water} = Q_{disinf} / N_{machines} * N_{rep\text{-}max} / Freq_{repl} * (1 - f_{red}) * C_{disinf} / 2$

If:	*Then:*
HENRY < 3	$Elocal_{3,air} = 0$
HENRY ≥ 3 and:	
MOLW < 65	$k_l = 5.55*10^{-5} * (44 / MOLW)^{1/2}$
MOLW ≥ 65 & WINDSPEED < 1.9 $m.s^{-1}$	$k_l = 6.53*10^{-5} * (WATERSPEED^{0.969} / DEPTH_{water}{}^{0.673}) * (32 / MOLW)^{1/2}$
MOLW ≥ 65 & 1.9 < WINDSPEED < 5 $m.s^{-1}$	$k_l = 6.53*10^{-5} * (WATERSPEED^{0.969} / DEPTH_{water}{}^{0.673}) * (32 / MOLW)^{1/2} * e^{0.526(WINDSPEED - 1.9)}$
MOLW < 65	$k_g = 8.33*10^{-3} * (18 / MOLW)^{1/2}$
MOLW ≥ 65	$k_g = 3.16*10^{-3}\ (WINDSPEED + WATERSPEED) * (18 / MOLW)^{1/2}$

$K_L = (K_{air\text{-}water} * k_g * k_l) / (K_{air\text{-}water} * k_g + k_l)$

$C_{day2} = C_{day1} * e^{-K_L * T_{day2} / (100 * DEPTH_{water})}$

$Elocal_{3,air} = Q_{machine} * (C_{day1} - C_{day2}) * 0.001$

b) Other instruments

In all out-patient departments instruments are disinfected locally in baths which are regularly disposed of into the sewer. From the enquiry (RIVM, 1996), it was not quite clear which amount of disinfectant was released per day when a bath is replaced. The amounts of active substance used per year varied between 5 and 125 kg for average-sized hospitals (in most cases disinfectants with two active substances are used whereas both active substances have almost the same concentration). The emission scenario applies a default of 250 kg of active substance per year and a number of 100 replacements per year. The substances applied are supposed to have negligible volatilisation losses and a stability such that no concentration reduction occurs. Table 2.8 presents the emission scenario using the assumptions stated above.

Table 2.8 Emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of contaminated instruments

Variable/parameter (unit)	Symbol	Default	S/D/O/P
Input:			
Amount of active substance ($kg.y^{-1}$)	$Qyear_{disinf}$	250	D
Emission days, i.e. replacements (y^{-1})	$Temission_3$ [1)]	100	D
Concentration reduction at replacement	f_{red}	0	D
Output:			
$Elocal_{3,water}$ = Maximum emission rate at the day of a replacement ($kg.d^{-1}$) [1)]			

[1)] The subscript "3" refers to the stage of processing in conformance with EUSES 1.0 and USES 2.0

Model calculations:

(b) $Elocal_{3,water} = Qyear_{disinf} / Temission_3 * (1 - f_{red})$

2.3.5 Laundry disinfectants

Most Dutch hospitals nowadays do not have their own laundry but send the laundry out to specialised laundries (WIP, 1993) (personal communication with A. Sprenger, Hilversum hospital, 1998). At the moment about 100 large laundries are in operation for the catering industry and health care (Rozenburg, 1998). One large company, active in 8 EU countries with 25 establishments in the Netherlands and 35 in Germany, offers so-called re-usable OR systems to hospitals. These consist of a complete supply of patient-covers and clothing for the OR staff (Rentex, 1998). The Directive for linen (WIP, 1993) has no guidelines for hygiene in laundries but refers to the handbook of the Certex Foundation, which certifies laundries

according to ISO 9002. It has 46 certified members with a market share of about 80% in The Netherlands (Certex, 1998).
In the certification, the means for disinfection described is a time-temperature formula. It is possible, however, that disinfectants are used in laundries at present (personal communication with A. Sprenger, Hilversum hospital, 1998 and with P.G.M. Valk, Foundation Certex, Tilburg, 1998). The use of disinfectants in laundries is mentioned in the literature (Van Dokkum *et al.*, 1998; Van Kasteren, 1998). At some (large) laundries approached, it turned out that in the case of contaminated clothing, disinfectants are commonly used, especially hydrogen peroxide and hypochlorite.

Biologically contaminated laundry is packed in special (coloured) bags to distinguish it from ordinary laundry. The contaminated laundry is then not sorted but put directly into the machine where the bag is opened automatically. Some laundries treat the contaminated laundry in a separate washing machine (like hospitals with their own laundries); others put it into the 'washing street' (a series of one or more washing "tubes", i.e. continuously operating machines where the laundry enters dirty at one end and leaves clean at the other between the normal laundry). A number of certified laundries was approached by telephone; from the information gathered it turns out that in the case of the 'washing street' some laundries always use hydrogen peroxide or hypochlorite, while others use tumbler washing machines (10 - 25 kg laundry per batch) and rely on the temperature-time formula. In the latter method the temperature may be raised from 80-85° C to 90-95° C or a detergent-like peracetic acid may be used at a lower temperature (60° C) for temperature-sensitive fabrics.

Scenario description

The size of commercial laundries can vary considerably but large laundries may have three or more washing tubes with a capacity of 8000 $kg.day^{-1}$ per tube, producing 48 $m^3.day^{-1}$ of waste water (Van Kasteren, 1998) (personal communication with Dr.ir. P. Brasser of the Technical University of Delft, 1998). It is assumed here that a commercial laundry connected to the standard STP of EUSES/USES (2000 m^3 waste water per day) can have three washing tubes ($3 * 48 = 144$ m^3 waste water per day). On the other hand, the situation is considered where a hospital is doing its own laundry or where the contaminated laundry is done at a commercial laundry using a tumbler washing machine. It is estimated that per kg of dirty laundry 6 g of detergent ("soap") is used, 4 g for soaking and 2 g for the washing cycle (Van Kasteren, 1998). In the case of disinfection, it is estimated that about 10% of the amount of soap is disinfectant.

Table 2.9 presents the emission scenario using the assumptions stated above.

Table 2.9 Emission scenario for the calculating the release of disinfectants used for doing biologically contaminated laundry from hospitals

Variable/parameter (unit)	Symbol	Default	S/D/O/P
Input:			
a) Washing street			
Number of washing tubes (with disinfectant) (-)	Nm	3	D
Capacity of washing tube ($kg.d^{-1}$) *(laundry)*	Cap	8000	D
Amount of disinfectant for laundry ($l.kg^{-1}$)	$V_{product}$		S
Concentration active substance in disinfectant ($kg.l^{-1}$)	$C_{disinf1}$		S
Concentration reduction in washing process	f_{red}	0	D
b) Tumbler washing machine			
Capacity of machine (kg)	Cap	25	D
Number of batches (d^{-1})	Nb	3	D
Amount of disinfectant for laundry ($l.kg^{-1}$)	$V_{product}$		S
Concentration active substance in disinfectant ($kg.l^{-1}$)	$C_{disinf2}$		S
Concentration reduction in washing process	f_{red}	0	D
Output:			
$Elocal_{3,water}$ = Maximum emission rate at the day of a replacement ($kg.d^{-1}$) [1)]			

1) The subscript "3" refers to the stage of processing in conformance with EUSES 1.0 and USES 2.0.

Model calculations:

a) Washing street

a.1) $Elocal_{3,water} = Nm * Cap * V_{product} * C_{disinf1} * (1 - f_{red})$

b) Tumbler washing machine

$Elocal_{3,water} = Nb * Cap * V_{product} * C_{disinf2} * (1 - f_{red})$

2.3.6 Hospital waste disinfectants

In the General Administrative Order Decree Hazardous Waste (Stb., 1993) of the Environmental Protection Act a definition is given for the waste streams which are regarded as hazardous waste (see Table 2.10). This category of potentially infectious hazardous waste is usually called ‘hospital waste’. According to the Act hospital waste may only be delivered to a competent firm for collection or processing.

Table 2.10 Waste streams originating from medical treatment in intramural and extramural health care according to the General Administrative Order, Decree Hazardous Waste (Stb., 1993)

No.	Waste stream
46.1	Human anatomical remains and parts of organs released in operative and obstetrical surgery, in obduction and in scientific research/education
46.2	Laboratory animals and parts of laboratory animals (if not presented for destruction)
46.3	Waste from accommodations for laboratory animals as far as it is contaminated with pathogens
46.4	Waste from wards/rooms where patients are nursed in isolation because of danger of infecting hospital personnel
46.5	Waste from microbiological laboratories contaminated with bacteria, viruses or yeasts
46.6	Sharp objects such as (hypodermic) needles, capillaries snipped off, scalpels, unserviceable instruments and blood tubes
46.7	Larger amounts of blood, plasma and other paste-like and liquid waste materials
46.8	Cytostatica

Hospital waste has to be incinerated at ZAVIN in Dordrecht. ZAVIN is the only competent processor for hospital waste in the Netherlands (in cases of peaks, the kiln oven of AVR at Rotterdam is allowed to function as a "catch"). The waste is packed in sealed containers immediately after creation, so no disinfectants are used. In some cases hospital waste is sterilised in an autoclave at the source. After this sterilisation the remaining waste can be treated as normal waste. However, it is known that in one case the remaining waste is still sent for incineration to ZAVIN after removal of components suitable for recycling, e.g. glass. At the moment pilot projects are planned for three places in the Netherlands in which a combined shredder / disinfection system, as mentioned in the BIOEXPO report (Van Dokkum, 1998), will be used.

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