

RIVM report 320202001/2003

**Environmental risk assessment for  
veterinary medicinal products**

Part 1. Non-immunological drug substances  
Second update

M.H.M.M. Montforts

This report replaces RIVM report 601300001/1999 (first update).

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National Institute of Public Health and the Environment, Expert Centre for Substances.  
PO BOX 1, 3720 BA Bilthoven, The Netherlands. Telephone +31 30 274 9111, fax +31 30 274 44 01



## Preface

This report was originally published in 1997 with report number 613310001. In 1999 the first update was released under report number 601300001. In the last four years, science and regulations have developed. The scientific base for the risk assessment in general, and veterinary medicinal products in particular, has been strengthened in the EU Energy, Environment and Sustainable Development programme of the Fifth Framework Programme, within the project Environmental Risk Assessment of Veterinary Medicines in Slurry, ERAVMIS, contract number EVK1-CT-1999-00003. A further harmonisation of risk assessment has been attempted by the European Commission through the development of a new Technical Guidance Document for new and existing substances and biocides, and the activities of the DG SANCO Task Force on Harmonisation of Risk Assessment.

Following changes in the Netherlands legislation on the spreading of manure and recent developments in European regulations, especially the guidance document development by the CVMP, this second update is released under report number 320202001. The guidance provided by CVMP/VICH on Phase I has been incorporated.

In case C-322/00 ECJ (October 2<sup>nd</sup>, 2003) the Netherlands have been convicted for the implementation of the Nitrate Directive 91/671/EEC. The conviction is based on –amongst others– the use of nitrate loss standards instead of nitrate immission standards, the neglect of some sources of nitrogen in the measures taken, and the derogation for nitrogen loads on grassland (250 kg N/ha/y). As a result, the nutrient accounting system (MINAS) and fertilising standards will be revised before January 1<sup>st</sup>, 2006. In response to these revisions, as well as the future adoption of the upcoming VICH/CVMP guidance on Phase II, a third update of this report is to be expected in 2005.

This is a guidance document in support of the environmental risk assessment for the Netherlands registration procedure of veterinary medicinal products.

The author welcomes all comments: [mark.montforts@rivm.nl](mailto:mark.montforts@rivm.nl)

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## **Abstract**

The environmental risk associated with the use of veterinary medicinal products is assessed at registration in the Netherlands. This report guides the applicants and the national registration authority through the evaluation scheme. It contains transparent exposure models that predict exposure concentrations, as well as uniform guidance to assess the potential effects of the product to exposed organisms in dung, soil and water.



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## Summary

The European Commission has issued in Directive 2001/82/EC, that with a request for registration of a veterinary medicinal product, information is to be provided to enable an assessment of the safety for the environment. The environmental risk associated with the use of veterinary medicinal products is assessed at registration in the Netherlands. This report guides the applicants and the national registration authority through the evaluation scheme.

According to the Netherlands law a veterinary medicinal product is a substance, whether or not after preparation or processing, with the intention:

- a. to cure, relieve or prevent any affection, illness, morbid symptom, pain, injury, or defect of an animal;
- b. to remedy, improve, or change the functioning of organs of an animal;
- c. to diagnose a disease or defect in animals at application in an animal.

This definition includes pure substances (organic and inorganic) and preparations (including homeopathic products, vaccines, and flea-belts), and excludes disinfectants (e.g. for udders and for cleaning stables).

It contains transparent exposure models that predict exposure concentrations, as well as uniform guidance to assess the potential effects of the product to exposed organisms in dung, soil and water. If reliable actual exposure data are available, these may replace the predicted values.

Directive 2001/82/EC describes the assessment process in two phases. The first phase (Phase I) shall assess the potential of exposure of the environment to the product. The first phase is thus limited to product identification and exposure assessment. Several exemptions for further testing are given, such as trigger values for predicted environmental concentrations (PECs). When these exemptions do not apply and trigger values are exceeded, one enters Phase II.

In the second phase (Phase II) the reviewer shall consider whether further specific investigation of the effects of the product on particular ecosystems is necessary. Phase II is also divided in two parts, Tier A and Tier B. Tier A begins with an elaborate evaluation of the possible fate and effects. If the applicant is unable to demonstrate that exposure is minimised to a level of no concern to the environment, then the effects in the relevant compartments must be adequately investigated in Tier B. The Tier B evaluation is subject to expert judgement and is beyond the scope of this document.



# 1. Introduction

## 1.1. Scope and objectives of the report

The fate and behaviour of pharmaceuticals in the environment has been studied since several decades [1-3], and the presence and effects of residues in the environment is a concern that has been identified not long after that [4-8]. More recently several reviews on use, emission, fate, occurrence and effects of pharmaceuticals have been published and at national and international regulatory levels the environmental risks of pharmaceuticals are on the agenda [9-15].

The EC has issued in Directive 2001/82/EC that with a request for registration of a veterinary medicinal product information is to be provided to enable an assessment of the safety for the environment. The methodology has not been finalised yet [16-18] and suggestions for risk assessment methodology are given in literature [9,19-23]. The proposed risk assessment procedure at registration of human medicines and veterinary medicines is discussed by several authors [24-27]. Considerations on the assessment of pharmaceutical feed additives are given by Jorgensen et al. and the Scientific Committee on Animal Nutrition in [28] and [29].

In this document a risk assessment methodology is presented. The different livestock categories have different characteristics in housing and manure production, but the emission and distribution routes are identical. To ensure an equal assessment of all products a uniform risk assessment methodology is required.

The goals of this document are threefold:

- to provide a tool for a uniform risk assessment of veterinary medicinal products;
- to provide a basis for the incorporation of the risk assessment into the Netherlands Uniform System for the Evaluation of Substances (USES);
- to inform interested parties and outsiders on the assumptions, default parameters, and model dimensions that are used to assess the risk for the Dutch environment.

## 1.2. Framework of the environmental assessment of veterinary medicinal products

According to the EU Directive 2001/82/EC on veterinary medicinal products an assessment of ecotoxicity shall be compulsory for any application for marketing authorisation for a veterinary medicinal product other than applications submitted in accordance with Articles 12(3)(j) and 13(1). This assessment shall normally be conducted in two phases.

In the first phase, the investigator shall assess the potential extent of exposure to the environment of the product, its active substances or relevant metabolites, taking into account:

- the target species, and the proposed pattern of use (for example, mass-medication or individual animal medication),
- the method of administration, in particular the likely extent to which the product will enter directly into environmental systems,
- the possible excretion of the product, its active substances or relevant metabolites into the environment by treated animals; persistence in such excreta,
- the disposal of unused or waste product.

In a second phase, having regard to the extent of exposure of the product to the environment, and the available information about the physical/chemical, pharmacological and/or toxicological properties of the compound which has been obtained during the conduct of the other tests and trials required by this Directive, the investigator shall then consider whether further specific investigation of the effects of the product on particular ecosystems is necessary. As appropriate, further investigation may be required of:

- fate and behaviour in soil,
- fate and behaviour in water and air,
- effects on aquatic organisms,
- effects on other non-target organisms.

These further investigations shall be carried out in accordance with the test protocols laid down in Annex V of Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, or where an end point is not adequately covered by these protocols, in accordance with other internationally recognised protocols on the veterinary medicinal product and/or the active substance(s) and/or the excreted metabolites as appropriate. The number and types of tests and the criteria for their evaluation shall depend upon the state of scientific knowledge at the time the application is submitted.

The European Agency for the Evaluation of Medicinal Products (EMA)<sup>1</sup> has published guidance on the environmental risk assessment (ERA) of VMPs, and this assessment was implemented in 1997 [16]. The assessment scheme takes the use of the product and the properties of the products into account in the assessment (phase I or II), the emission routes (slurry-soil; water; pasture) and the data requirements. After the final draft of the EMA (1997) guidance, an international harmonisation between the EU, USA and Japan was started by the International Co-operation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)<sup>2</sup> to which both the European Commission and the EMA are committed [30]. The guidance document on Phase I was completed and finalised (15 June 2000) for implementation by July 2001 in the European Union and United States [18] and replaces the EMA 1997 guidance on Phase I. This guidance document is at this moment leading for the registration procedure.

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<sup>1</sup> Commonly referred to as the European Medicines Evaluation Agency

Within the VICH guidance document a limited assessment is foreseen for substances with a generally accepted low hazard (vitamins, electrolytes), and with a presumed negligible emission and exposure level. The exposure level that is considered irrelevant for the total environment is quantified both for water (effluent) and soil for some groups of compounds and several routes of emission: 1 µg/L and 100 µg/kg, respectively (Phase I). These triggers are derived from a dataset of toxicity values of several antibiotics, although the determination of a safe level is criticised from an ecotoxicological point of view [24]. Not only these exposure trigger values define the desired level of quality for soil and effluent. Should these triggers be exceeded, a risk assessment based on the PEC/PNEC approach is warranted for soil, surface water, sediment and groundwater (Phase II), according to the EMEA guidance [31].

The EU Directive is included in the Dutch law on veterinary medicines (Diergeneesmiddelenwet 27 June 1985, Stb. 410, last amendment 10 July 1995). By the direction of the Directorate of Public Health (GZB) of the Ministry of Public Health, Welfare, and Sports (VWS), the Expert Centre for Substances (SEC) of the National Institute for Public Health and the Environment (RIVM) performs the environmental assessments under the charge of the Agency for the Registration of Veterinary Medicinal Products (BRD). The registration procedure of veterinary medicinal products in the Netherlands is as a whole divided in two rounds. After the first round the applicant has a limited period to respond to questions or calls for more information from the BRD. After the second round the application and evaluation reports are submitted to the Board for the Registration of Veterinary Medicinal Products (CRD). The CRD advises the responsible minister on the admittance of a veterinary product, based on assessment reports on the various fields of interest (e.g. ecotoxicology, residues, consumer exposure, and animal health). The minister decides then on registration.

### **1.3. The subject of the environmental risk assessment**

According to the Dutch law a veterinary medicinal product is a substance, whether or not after preparation or processing, with the intention:

- a. to cure, relieve or prevent any affection, illness, morbid symptom, pain, injury, or defect of an animal;
- b. to remedy, improve, or change the functioning of organs of an animal;
- c. to diagnose a disease or defect in animals at application in an animal.

This definition includes pure substances (organic and inorganic) and preparations (including homeopathic products, vaccines, and flea-belts), and excludes disinfectants not used on animals (e.g. for cleaning stables).

It is not clear whether or not the Dutch law includes all ingredients in a preparation to be taken into account in the environmental risk assessment. The words ‘substance’ and ‘product’

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<sup>2</sup> Commonly referred to as the Veterinary International Conference on Harmonisation

are used more or less arbitrarily, or at least interchangeable. However, the EMEA documents state explicitly: ‘... shall assess the potential of exposure of the environment to the product, its ingredients or relevant metabolites. Metabolites which represent less than 20% of the applied dose are not considered relevant...’[31]. ‘This assessment must address the risks arising from each of the components of the product, not just the risk from live organisms in vaccines’ [32]. All ingredients in a product are therefore taken into account,

Metabolites are not assessed in Phase I [33]. In Phase II metabolites formed in amounts  $\geq 20\%$  of the administered dose are separately assessed [31].

Insecticides intended for use on animals are dealt with as veterinary medicinal products, e.g. pour-on anthelmintics and anti-parasitic agents. Because of the division between the Pesticide act and the Veterinary Medicine act, the following uses of disinfectants and insecticides are **not** dealt with as veterinary medicinal products, but as biocides: disinfection (including fumigation), fish nurseries, footwear, milk extraction systems, means of transport, hatcheries [34,35]. Nevertheless, the models presented here may be applied equally for biocides. Immunological products (vaccines) are not dealt with in this report [36].

## 2. Model description

### 2.1. Structure of the environmental assessment

The risk assessment is an evaluation of the possible fate and effects of the product. As a whole, the risk assessment is structured around the hazard quotient approach [37]. Predicted environmental concentrations are compared with effect values established in toxicity studies. If reliable exposure data are available, these may replace the predicted values. This comparison is done using the hazard quotient approach. Hazard quotients indicate the likelihood of occurring of adverse effects.

The first phase (Phase I) shall assess the potential of exposure of the environment to the product and its ingredients. The first phase is thus limited to product identification and exposure assessment of the total residue [33]. Several exemptions for further testing are given, such as trigger values for predicted environmental concentrations (PECs). When these exemptions do not apply and trigger values are exceeded, one enters Phase II.

In the second phase (Phase II) the reviewer shall consider whether further specific investigation of the effects of the product on particular ecosystems is necessary. Phase II is also divided in two parts, Tier A and Tier B. Tier A begins with an elaborate evaluation of the possible fate and effects. If the applicant is unable to demonstrate that exposure is minimised to a level of no concern to the environment, then the effects in the relevant compartments must be adequately investigated in Tier B. The Tier B evaluation is subject to expert judgement and is beyond the scope of this document.

As told, in Phase I several exemptions from further testing are incorporated, but if adverse environmental effects are still anticipated from the use of such products, the further assessment of possible exposure to the environment can be performed.

### 2.2. Release estimation

Emission can take place at any step in the life cycle of the product. Dosage, route of application, type of target animals, excretion, route of entry into the environment, and agricultural practice determine the point of emission:

- at production;
- at application (external application);
- at removal of waste material containing the product (manure, dirty water, fish water);
- by excretion via faeces and urine (grazing animals);
- by contagion (immunological products);

- or at disposal of the containers (empty bottles and flee-belts).

The environmental assessment for veterinary non-immunological medicinal products is only concerned with emission at or after use of the product.

The Phase I assessment is based on a release of the 'total residue' into the environment (manure, dung, soil, water). See the VICH guidance on Phase I for detail [33].

Product type, target animal, route of administration, dosage, and excretion are critical for the selection of the emission scenario. The main categories are:

- removal of waste material containing the product (manure, dirty water, fish water);
- excretion via faeces and urine (grazing animals);
- spillage at external application or direct exposure outdoors.

The major routes for internal application of the product are:

- oral;
- intra-ruminal;
- by injection (intra-muscular, sub-cutane).

External applications are dermal: pour-on, sheep dips, fumigation, etcetera. Use of products with external application may result in the product being found in washings from dairy parlours and pig and poultry stables due to cleaning of the pens<sup>3</sup>. If there is no direct route to the manure (spilling, washing), but there is appreciable adsorption through the skin leading to systemic effects, the pathways for internal application should be followed. This applies especially for insecticides and anthelmintics.

Functions and uses not specified here are dealt with on a case by case basis. Based on the husbandry conditions described in Chapter 3.1, the following possible emission routes are identified (Table 1).

*Table 1 Possible emission routes of veterinary medicines.*

<b>Livestock category</b>	<b>slurry application</b>	<b>grazing animals</b>	<b>spillage at application and exposure outdoors</b>	<b>emission of waste water or direct entry into water</b>
<b>cattle</b>	X	X		X
<b>pigs</b>	X			X
<b>horses and ponies</b>	X	X		X
<b>sheep</b>	X	X	X	X
<b>chickens</b>	X			X
<b>fish farms</b>	X			X

## 2.3. Environmental distribution

The emitted product will be distributed in the environment. The route of distribution and the fate in the environment are important for the final predicted environmental concentration (PEC) and the severity of the effect.

For veterinary medicinal products, the routes of exposure for the terrestrial and aquatic environment are through the application of contaminated manure, dung and urine.

Distribution occurs within exposed compartments and through different compartments.

The terrestrial environment is reached via:

1. Direct excretion of dung and urine;
2. Direct spillage on the field;
3. Spreading of slurry and sludge.

The aquatic environment is reached via:

1. Leaching and drainage from manured land;
2. Direct defecating into water;
3. Direct application in water (fish);
4. Direct discharge of waste water into surface water (fish);
5. Release from Sewage Treatment Plant (fish).

Products used for external application (e.g. sheep dips):

1. Are directly accessible to birds;
2. Reach the soil (and surface-dwelling invertebrates) after disposal, and
3. Also insects in treated fleece are exposed directly.

*Table 2 Primary and secondary exposed compartments after emission and distribution.*

<b>Emission category</b>	<b>manure/ dung</b>	<b>soil</b>	<b>ground water</b>	<b>water sediment</b>	<b>biota</b>
<b>Manure application</b>	X	X	X	X	
<b>Grazing animals</b>	X	X	X	X	
<b>Spillage at application outside</b>		X	X		X
<b>Residues on fleece</b>					
<b>Waste water or direct entry into water</b>		X	X	X	

<sup>3</sup> These washings, called 'dirty water' generally contain <3% dry matter, and are made up of water contaminated by manure, urine, crop seepage, milk, other dairy products and cleaning materials.

## 2.4. Exposure module

In the exposure module the calculated concentrations in the relevant environmental compartments are gathered. These depend on the type of application and the type of target animals selected. See Table 2 for the exposed compartments.

Exposure of birds and mammals through application of veterinary medicinal product residues is possible. Because these non-target species are exposed to the products via their feed and water, calculations are performed to translate concentrations in compartments to

concentrations in the feed. Five exemplary food chains will be regarded:

- Birds and/or mammals with a diet consisting entirely of worms caught in polluted land or dung;
- Birds and/or mammals with a diet consisting entirely of fish caught in polluted water;
- Birds and/or mammals exposed through surface water;
- Birds and/or mammals exposed through feed (insects in grass and fleece);
- Birds exposed through feeding on exposed product (sheep dips and footbaths).

## 2.5. Effect assessment

In Phase I no effect studies are required. In Phase II the actual hazard quotient approach is carried out and here effect studies are compulsory. All delivered information shall be summarised and evaluated in order to establish the reliability and usefulness for the assessment. As pointed out in the EMEA (1997) document [31], studies should be performed according to international accepted guidelines for testing, and Good Laboratory Practices should apply whenever possible.

In the effect assessment a no-effect concentration is derived from experimental toxicity data (PNEC: predicted no-effect concentration) by dividing the experimental concentration (or dose) that causes 50% mortality or effect (LD50, LC50, or EC50) and/or the no-observed-effect-concentration (NOEC) by an extrapolation factor. This results in PNEC values for a compartment (e.g. soil or water) or ecosystem.

For (dung)-insects, the experimental toxicity result (% effect) is used, as is done in the risk assessment for the registration of pesticides. For birds exposed through sheep dips, the risk is assessed using acute LD50 data, as chronic exposure is not likely.

## 2.6. Risk characterisation

For veterinary medicines several risk and hazard quotients (RCR: risk characterisation ratio) are constructed to account for different types of dispersion. Most frequently the short-term time-scale is observed, and for secondary poisoning the long-term scale is taken into account. The species for which a risk evaluation is carried out are birds, mammals, (ground)water organisms, earthworms, beneficial arthropods, plants and micro-organisms.

For each compartment/ecosystem or species evaluated a separate RCR is calculated, based on the PEC/PNEC concept.

$$RCR_{comp} = \frac{PEC_{comp}}{PNEC_{comp}}$$

### input

$PEC_{comp}$	predicted environmental concentration in compartment	$[mg_c \cdot kg^{-1}]$ or $[mg_c \cdot l^{-1}]$	O
$PNEC_{comp}$	predicted no effect concentration for compartment	$[mg_c \cdot kg^{-1}]$ or $[mg_c \cdot l^{-1}]$	O

### output

$RCR_{comp}$	risk characterisation ratio for compartment	[-]	O
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For some species non-extrapolated effect data are used. This yields e.g. 'PEC/%effect'-ratios. These ratios are denoted as RCR as well.



### 3. Release estimation

In the next chapter the emission and distribution models are presented. In this chapter the routes of emission are introduced, as well as many parameter values. This means that a lot of modelling language will be used. Firstly we introduce conventions on the use of parameters and units. Parameters and variables are divided into four types :

S	data Set	a value for this parameter must be present in the data entry set.
D	Default	a fixed value. The user can change most default values.
O	Output	the value is the result of a previous calculation.
P	Pick-list	Parameter value can be chosen from a pick-list with values.
c	closed	Default or output parameter is closed and cannot be changed by the user.

For the parameter symbols, as far as possible, the following conventions are applied:

- Parameters are mainly denoted in capitals;
- Specification of the parameter is in lower case;
- Specification of the compartment for which the parameter is specified is shown as a subscript.

Example: the weight fraction of organic carbon in dung:  $F_{oc_{dung}}$ .

Most values are expressed in units of the SI system (Système International d'Unités). As a consequence, some parameters have an uncommon unit. Kilograms of chemical are indicated by  $[kg_c]$ . Other masses will usually be indicated as wet weight or dry weight ( $[kg_{wwt}]$  and  $[kg_{dwt}]$  respectively), or by compartment (bodyweight or feed:  $[kg_{bw}]$  and  $[kg_{fd}]$ , respectively) It should be noted that for the dimension 'time' the non-SI units 'day' [d] and 'year' [yr] are used, instead of second [s], since these are more relevant units in the framework of this assessment.

In contrast with industrial chemicals, the emission module for veterinary medicines does not usually result in emissions to waste water and air from point sources. Instead, emissions take place to a specific area directly (direct immission into surface water, spillage to soil) or indirectly (spreading with manure or dung).

The emission module that characterises the releases to the environment via manure requires parameters from the distribution module (degradation rates and application intervals), and is therefore incorporated in the distribution chapter (Chapter 5).

### 3.1. Animal husbandry

The emission routes vary with the target animal to be treated. The animals in the Netherlands can be divided into two major groups: pets and livestock, poultry and fish. Pets are kept on a small-scale basis, with a limited number of animals at one place. Because with pets no mass medication can be expected, products intended for this group are exempted from further assessment. Horses are part of the animal husbandry group (stock-breeding and -raising industry), but are considered to be individually treated.

The category livestock discerned, with their excreta production and the related phosphate production in the Netherlands, are based on the index in [38].

The faeces of grazing animals in the field are referred to as dung. As the dung is not collected and stored over time, for the hazard assessment the peak concentrations and the drug excretion pattern in time are important. In the field faeces and urine are dispersed separately, whereas in the stable they are mixed. The excreta obtained indoors, referred to as manure, are collected and stored for some time. Slurry is the mixture of faeces, urine, and materials from the housing of animals (e.g. spilled feed, straw, litter, sand, water, down).

The modelling starts with a pick-list of animal categories. Each animal category has its own list of animal-specific parameter values, which will be presented in the chapters below.

Table 3 Pick-list of main animal categories and emission routes.

Livestock main category	Animal category and defaults	Emission route			
		E			
	see pick list in chapter	spreading of slurry	grazing animals	spillage at application pasture	emission of waste water
		Eslurry	Edung	Edirect <sub>pasture</sub>	Elocal <sub>water</sub>
cattle	3.2	X	X		
pigs	3.3	X			
horses and ponies	3.4	X	X		
chickens	3.5	X			
sheep	3.6		X	X	
fish	3.7	X			X

#### input

- livestock main category [-] P

#### output

E emission routes [-] O

- picklist animal subcategories and values [-] O

Goats, fur-bearing animals, and rabbits are not assessed because of the modest scale of these branches. Also the numbers of turkey, duck, ostriche, emoe, nandoe, guinea-fowl, quail, and geese are relatively small compared to chickens, and they are not dealt with separately in this document.

The possible inputs and outputs for the environmental assessment of veterinary medicinal products are limited. The general parameters are given in Table 4.

*Table 4 General parameters for animal categories.*

<b>General application inputs</b>		
(averaged) body weight	$m_{\text{animal}}$	$[\text{kg}_{\text{bw}}.\text{animal}^{-1}]$
<b>input for spreading of slurry</b>		
number of cycles per year	$N_{\text{cycle}_{\text{animal}}}$	$[\text{animal}.\text{place}^{-1}.\text{yr}^{-1}]$
number of milking days	$T_{\text{milking}}$	$[\text{d}.\text{yr}^{-1}]$
number of housing days	$T_{\text{housing}_{\text{animal}}}$	$[\text{d}.\text{yr}^{-1}]$
phosphate production	$P_{\text{P2O5}}$	$[\text{kg}_{\text{P2O5}}.\text{place}^{-1}.\text{d}^{-1}]$
<b>input for grazing</b>		
dung production pasture	$P_{\text{dung}_{\text{animal}}}$	$[\text{kg}_{\text{wwt}}.\text{animal}^{-1}.\text{d}^{-1}]$
urine production pasture	$P_{\text{urine}_{\text{animal}}}$	$[\text{l}.\text{animal}^{-1}.\text{d}^{-1}]$
stocking density pasture	$N_{\text{animal}}_{\text{ha pasture}}$	$[\text{animal}.\text{ha}^{-1}]$
number of excretions per day	$N_{\text{excretion}}$	$[\text{d}^{-1}]$

Some animals are kept at their mature bodyweight, other are reared from a starting weight onwards. For animals in the latter situation the mean bodyweight is the most convenient value. For animals in the former group, the maximum body weight is used. The number of cycles per year is based on the production periods including the days the pens stand empty. For background information on dung production and partitioning see Appendix I. Notice the use of the word dung for the faeces in the field and the words manure and slurry for the mixture of excreta collected in the stable. The specific values for the different animal categories are given below.

## 3.2 Cattle

Dairy cows are housed in winter time (175 days) and graze during the rest of the year. During grazing they return to the stable for milking. In spring and autumn they also may return to the stable for the night. Dairy cows are kept on the farm together with yearlings (1-2 years old) and calves (0-1 year old) for replacement in the ratio 100:33:37.

A suckler cow is kept together with her calf (up to 6 months old) in the same way as dairy cows. Young bulls and heifers are kept for meat production. These animals also are grazed in summer time. These cattle are not used for milk production.

Veal calves are kept indoors: white veal calves live during 0-6 months and are fed milk powder; rose veal calves live during 0-7 months and are fed roughage and concentrate.

Breeding bulls are not assessed separately. There are a few artificial insemination farms, and as it concerns healthy full-grown animals, the combination of small-scale husbandry and low medicine use implies a relative low risk on environmental contamination.

The following categories of cattle are used in the risk evaluation:

- dairy and suckler cows;
- beef cattle;
- veal calves.

Table 5 Pick-list of animal subcategories and emission routes for cattle.

Livestock subcategory	Emission route				
	spreading of slurry	spreading of slurry	grazing animals	spillage and direct exposure at application pasture	emission of waste water
	Eslurry	Eslurry			
	grassland	arable land	Edung	Edirect <sub>pasture</sub>	Elocal <sub>water</sub>
beef cattle	X	X	X		
dairy cow	X	X	X		
veal calf	X	X			

Table 6 Default settings for cattle.

parameter	symbol	unit	value
(averaged) body weight	$m_{\text{dairy cow}}$	$[\text{kg}_{\text{bw}} \cdot \text{animal}^{-1}]$	600
	$m_{\text{veal calf}}$	$[\text{kg}_{\text{bw}} \cdot \text{animal}^{-1}]$	140
	$m_{\text{beef cattle}}$	$[\text{kg}_{\text{bw}} \cdot \text{animal}^{-1}]$	330
number of cycles per year	$N_{\text{cycle}_{\text{dairy cow}}}$	$[\text{animal} \cdot \text{place}^{-1} \cdot \text{yr}^{-1}]$	1
	$N_{\text{cycle}_{\text{veal calf}}}$	$[\text{animal} \cdot \text{place}^{-1} \cdot \text{yr}^{-1}]$	1.8
	$N_{\text{cycle}_{\text{beef cattle}}}$	$[\text{animal} \cdot \text{place}^{-1} \cdot \text{yr}^{-1}]$	1
number of housing days cattle excluding veal	$Th_{\text{housing}_{\text{non-veal}}}$	$[\text{d} \cdot \text{yr}^{-1}]$	175
number of housing days veal	$Th_{\text{housing}_{\text{veal calf}}}$	$[\text{d} \cdot \text{yr}^{-1}]$	365
phosphate production during housing	$P_{\text{P2O5}_{\text{dairy cow}}}$	$[\text{kg}_{\text{P2O5}} \cdot \text{place}^{-1} \cdot \text{d}^{-1}]$	0.11
	$P_{\text{P2O5}_{\text{veal calf}}}$	$[\text{kg}_{\text{P2O5}} \cdot \text{place}^{-1} \cdot \text{d}^{-1}]$	0.011
	$P_{\text{P2O5}_{\text{beef cattle}}}$	$[\text{kg}_{\text{P2O5}} \cdot \text{place}^{-1} \cdot \text{d}^{-1}]$	0.028
dung production pasture during grazing period	$P_{\text{dung}_{\text{dairy cow}}}$	$[\text{kg}_{\text{wwt}} \cdot \text{animal}^{-1} \cdot \text{d}^{-1}]$	52
	$P_{\text{dung}_{\text{beef cattle}}}$	$[\text{kg}_{\text{wwt}} \cdot \text{animal}^{-1} \cdot \text{d}^{-1}]$	11
stocking density pasture	$N_{\text{dairy}_{\text{ha pasture}}}$	$[\text{animal} \cdot \text{ha}^{-1}]$	3.5
	$N_{\text{beef}_{\text{ha pasture}}}$	$[\text{animal} \cdot \text{ha}^{-1}]$	9.5
number of excretions per day	$N_{\text{excretion}}$	$[\text{d}^{-1}]$	10.5

### 3.3 Pigs

Three types of pig-farming are present in the Netherlands: exclusively sows or exclusively fattening-pigs, or a combination of both. On a sow-farm one finds sows with and without piglets. An average 78% of the sows has suckling piglets and 22% has none. According to [39] the average number of young (with 9 kg<sub>bw</sub> per piglet ) is 20 per place per year. If suckling piglets are treated instead of the sow, a treated body weight of 180 kg can be used instead. Manure excretion figures remain unaltered.

Breeding-boars live approx. 18 months on the farm, but as they perform 130 services a year, they are a minority on the farm. There are a few artificial insemination farms, and as it concerns healthy full-grown animals, the combination of small-scale husbandry and low medicine use implies a relative low risk on environmental contamination.

Pigs may be kept outside, but in the Netherlands the British outdoor-system is not used. Currently there are few farms that breed pigs on pasture land, but on most farms for 'free-ranging pigs' the pigs have the possibility to go outside on a concrete paved floor. Inside straw is present, and both areas are cleaned regularly. This category is not assessed separately in this report.

The Netherlands authorities encourage the development of mixed farms to reduce transport of animals. As a sow drops approx. 20 young and there are 2.8 cycles of fattening pigs a year, one needs one sow on every seven fattening pigs. For the moment we take only the segregated farming into consideration. The following categories of pigs are used in the risk evaluation:

- fattening pigs;
- breeding sows including piglets up to 25 kg.

*Table 7 Pick-list of animal subcategories and emission routes for pigs.*

Livestock subcategory	Emission route				
	E				
	spreading of slurry	spreading of slurry	grazing animals	spillage and direct exposure at application pasture	emission of waste water
	Eslurry	Eslurry			
	grassland	arable land	Edung	Edirect <sub>pasture</sub>	Elocal <sub>water</sub>
fattening pig		X			
breeding sow		X			

Table 8 Default settings for pigs.

parameter	symbol	unit	value
(averaged) body weight	$m_{\text{sow}}$	$[\text{kg}_{\text{bw}} \cdot \text{animal}^{-1}]$	240
	$m_{\text{fattening pig}}$	$[\text{kg}_{\text{bw}} \cdot \text{animal}^{-1}]$	70
number of cycles per year	$N_{\text{cycle}_{\text{sow}}}$	$[\text{animal} \cdot \text{place}^{-1} \cdot \text{yr}^{-1}]$	1
	$N_{\text{cycle}_{\text{fattening pig}}}$	$[\text{animal} \cdot \text{place}^{-1} \cdot \text{yr}^{-1}]$	2.8
number of housing days	$T_{\text{housing}_{\text{pigs}}}$	$[\text{d} \cdot \text{yr}^{-1}]$	365
phosphate production during housing	$P_{\text{P2O5}_{\text{sow}}}$	$[\text{kg}_{\text{P2O5}} \cdot \text{place}^{-1} \cdot \text{d}^{-1}]$	0.030
	$P_{\text{P2O5}_{\text{fattening pig}}}$	$[\text{kg}_{\text{P2O5}} \cdot \text{place}^{-1} \cdot \text{d}^{-1}]$	0.012

### 3.4 Horses and ponies

Approximately half of the horses in the Netherlands are privately owned. Private persons and farmers keep some horses for hobby. Terrain-managing institutes keep ponies for grazing. Especially these private animals graze in fields. Donkeys are also kept in the Netherlands, but their number is relatively small compared to horses and ponies. The commercial sector is divers and consists of riding schools, dairy farming, racing centres and stud-farms. Horses for meat production are mainly imported. The commercial animals are stabled most of the time. The manure (slurry) from riding-schools is mostly collected and used for mushroom-cultivation and compost for allotments. The major emission routes are grazing animals, and spreading of manure on allotments and spreading of mushroom-substrate after cultivation. Given the small scale of the latter emission routes, they are not further considered. Ponies have a shoulder height <148 cm, horses >148 cm. Horses and ponies come in different sizes and body weights: a full-grown horse weighs approx. 600 kg; a Haflinger pony 400 kg; and a Shetland approx. 250 kg. Shetlands are kept outside most of the year. As there were no data available for grazing horses these were manufactured using the data for beef cattle, see Appendix I.

Table 9 Pick-list of animal subcategories and emission routes for horses and ponies.

Livestock subcategory	Emission route				
	E				
	spreading of slurry	spreading of slurry	grazing animals	spillage and direct exposure at application pasture	emission of waste water
	Eslurry	Eslurry			
	grassland	arable land	Edung	Edirect <sub>pasture</sub>	Elocal <sub>water</sub>
ponies 250 kg			X		

Table 10 Default settings for horses and ponies.

parameter	symbol	unit	value
body weight	$m_{\text{pony}}$	$[\text{kg}_{\text{bw}} \cdot \text{animal}^{-1}]$	250
dung production pasture during grazing period	$P_{\text{dung}_{\text{pony}}}$	$[\text{kg}_{\text{wwt}} \cdot \text{animal}^{-1} \cdot \text{d}^{-1}]$	4.0
stocking density pasture	$N_{\text{pony}_{\text{ha pasture}}}$	$[\text{animal} \cdot \text{ha}^{-1}]$	5
number of excretions per day	$N_{\text{excretion}}$	$[\text{d}^{-1}]$	10.5

### 3.5 Chickens

Most chickens are kept indoors in cages or on floors. The manure from laying hens in cages is collected on a conveyor-belt. In the broiler industry, after every cycle the manure and litter from the floor is cleaned from the poultry house. Over eighty percent of the manure collected from layers is dried, and this percentage will increase rapidly to 100% in the next few years. Dry chicken manure cannot be injected and is hence applied to arable land. The number of chickens kept outdoors is insignificant compared to the other methods of housing. The different stages in the life-cycle (chick, in rearing, parent animal) have different body weights and manure production figures. The following categories of chickens are used in the risk evaluation:

- Laying hens and other adults;
- Broilers and other categories in rearing.

Animals in rearing and broilers are non-oviparous. Laying hens and free hens are oviparous.

Table 11 Pick-list of animal subcategories and emission routes for chickens.

Livestock subcategory	Emission route				
	E				
	spreading of slurry	spreading of slurry	grazing animals	spillage and direct exposure at application pasture	emission of waste water
	Eslurry	Eslurry			
	grassland	arable land	Edung	Edirect <sub>pasture</sub>	Elocal <sub>water</sub>
hen		X			
broiler		X			

Table 12 Default settings for chickens.

parameter	symbol	unit	value
averaged body weight broilers	$m_{\text{chicken broiler}}$	$[\text{kg}_{\text{bw}}.\text{animal}^{-1}]$	1
body weight adult chickens	$m_{\text{chicken hen}}$	$[\text{kg}_{\text{bw}}.\text{animal}^{-1}]$	2
number of cycles per year	$N_{\text{cycle}_{\text{hen}}}$	$[\text{animal}.\text{place}^{-1}.\text{yr}^{-1}]$	1
	$N_{\text{cycle}_{\text{broiler}}}$	$[\text{animal}.\text{place}^{-1}.\text{yr}^{-1}]$	7
number of housing days	$T_{\text{housing}_{\text{chicken}}}$	$[\text{d}.\text{yr}^{-1}]$	365
phosphate production during housing	$P_{\text{P2O5 hen}}$	$[\text{kg}_{\text{P2O5}}.\text{place}^{-1}.\text{d}^{-1}]$	0.0011
	$P_{\text{P2O5 broiler}}$	$[\text{kg}_{\text{P2O5}}.\text{place}^{-1}.\text{d}^{-1}]$	0.00055

### 3.6 Sheep

Most sheep are only put up between mid-February and mid-April to lamb. Over the year they spend 10.5 months in field and 1.5 months indoors. One ewe raises an average 1.7 lamb (range 1.33-2.80 [40]). The lamb and ewe are turned out approx. three weeks after giving birth, and the lamb is slaughtered after 6 months when it reached a weight of 40-45 kg. A mature ewe weighs an average 82 kg [41]. The ewes may be treated for diseases when they are put up, and approximately one week after giving birth the animals are treated with anthelmintics. This latter treatment is repeated in May-June and September-October. The body weight and dung production of the lambs is therefore chosen at 32 calendar weeks (end of May) and averaged for ewes and rams, single and twins.

Sheep can also be dipped or substances can be applied topically in high volumes. The following categories of sheep are used in the risk evaluation:

- sheep on pasture, >1 year old, including lambs  $\leq 45$  kg.

Table 13 Pick-list of animal subcategories and emission routes for sheep.

Livestock subcategory	Emission route				
	E				
	spreading of slurry	spreading of slurry	grazing animals	spillage and direct exposure at application pasture	emission of waste water
	Eslurry	Eslurry			
	grassland	arable land	Edung	Edirect <sub>pasture</sub>	Elocal <sub>water</sub>
sheep			X	X	

Table 14 Default settings for sheep.

parameter	symbol	unit	value
body weight ewe	$m_{ewe}$	$[kg_{bw} \cdot animal^{-1}]$	82
body weight lamb	$m_{lamb}$	$[kg_{bw} \cdot animal^{-1}]$	36
dung production pasture during grazing period ewe	$P_{dung_{ewe}}$	$[kg_{wwt} \cdot animal^{-1} \cdot d^{-1}]$	1.025
dung production pasture during grazing period lamb	$P_{dung_{lamb}}$	$[kg_{wwt} \cdot animal^{-1} \cdot d^{-1}]$	1.758
stocking density pasture ewe	$N_{ewe_{ha\ pasture}}$	$[animal \cdot ha^{-1}]$	15
stocking density pasture lamb	$N_{lamb_{ha\ pasture}}$	$[animal \cdot ha^{-1}]$	25
number of excretions per day	$N_{excretion}$	$[d^{-1}]$	10.5

### 3.7 Fish

Fish medicines are mostly added to the water, after which the circulation is stopped. Some antibiotics can be added to the feed.

The scale of fish cultivation for commercial purposes is limited in the Netherlands [42]. In 1994 in total 26 and 10 companies were involved in cultivating eel and catfish, respectively. Rainbow trout is cultivated on a small scale in flow-through and in landbased systems, in which the water body fulfils a role in water treatment. Several trout nurseries use flow-through systems: surface water is lead through the fish basin over a settling tank back into the surface water system. There is one place in the province Zeeland where Salmonidae are kept in cages in the estuary. There are no cage systems in fresh surface water. Finally, there are occasional projects in the cultivation of turbot, tilapia, and sturgeon.

Most nurseries use recirculation systems that recycle the water after a (biological) water treatment (filtration). Catfish nurseries discharge on the Sewage Treatment Plants (STP), but 40% of the eel nurseries discharge directly on surface water. The number of companies that discharge the fish water untreated is negligible, as most have some way of water treatment (filters, settlement basins, ponds) before the water is discharged. The recycling systems and the settlement tanks before discharge remove virtually all particles. Many nurseries collect the sludge from this treatment and sell or use it as fertiliser.

The following scenarios are proposed, based on information given in [42]. The scenarios are based on a fish farm that breeds 50 tonnes eel a year, the median production.

- a) Continuous treatment; with recirculation/filtration, followed by settlement tank and STP;
- b) Continuous treatment; without recirculation/filtration, followed by settlement tank;
- c) Occasional treatment (up to 4 times a year), without recirculation/filtration before discharge on the settlement tank and STP;
- d) Occasional treatment (up to 4 times a year), without recirculation/filtration before discharge on the settlement tank.

On a yearly basis an eel farm discharges 200-1900 m<sup>3</sup> water per tonne fish, depending on the water use. An average 250 m<sup>3</sup> per tonne fish is used here, which results in a turnover rate of 35 m<sup>3</sup>.d<sup>-1</sup>. It is assumed that the total water volume of the nursery<sup>4</sup> is 70 m<sup>3</sup>. After the settlement tank the water fraction is discharged, while the sludge (2% dry matter) in the tank (and filters) is used as soil fertiliser. Per tonne fish 13 kg P (equivalent to 60 kg P<sub>2</sub>O<sub>5</sub>) is removed in the sludge. The load from the settlement tank and recirculation system will be expressed in terms of kg chemical per day, and it is assumed that this load is equally spread over 25 days in case of occasional treatment.

Table 15 Pick-list of animal subcategories and emission routes for fish.

Livestock subcategory	Emission route				
	E				
	spreading of slurry	spreading of slurry	grazing animals	spillage and direct exposure at application pasture	emission of waste water
	Eslurry	Eslurry			
	grassland	arable land	Edung	Edirect <sub>pasture</sub>	Elocal <sub>water</sub>
fish		X			X

Table 16 Default settings for fish.

parameter	symbol	unit	value
phosphate production per day	P <sub>P2O5 fish</sub>	[kg <sub>P2O5</sub> .d <sup>-1</sup> ]	8.22
fraction retention in sludge with filtration	F <sub>ret, filtration</sub>	[-]	0.5
fraction retention in sludge without filtration	F <sub>ret</sub>	[-]	0
number of application continuous treatment	Nappl <sub>con.</sub>	[yr <sup>-1</sup> ]	365
number of application occasional treatment	Nappl <sub>occ.</sub>	[yr <sup>-1</sup> ]	4
volume of waste water continuous treatment	Vwaste water <sub>con.</sub>	[l]	35000
volume of waste water occasional treatment	Vwaste water <sub>occ.</sub>	[l]	70000
dilution factor receiving water continuous treatment	DILUTION <sub>fish,con.</sub>	[-]	5
dilution factor receiving water occasional treatment	DILUTION <sub>fish,occ.</sub>	[-]	3
emission period for discharge to STP	Temission <sub>stp</sub>	[d]	25

<sup>4</sup> Based on a feed/growth factor of 1.7, a growth of 50 tonnes per year, and 0.3 m<sup>3</sup> system water per kg feed.

### 3.8 Agricultural manuring practice in the Netherlands

The Dutch agricultural practice is characterised by:

- restricted manure spreading periods for grassland and arable land;
- annual phosphate immission standards for animal fertiliser;
- annual nitrate immission standards for both artificial and animal fertiliser;
- injection of slurry into the grassland, ranging from just below the turf up to 30 cm depth;
- spreading of slurry onto arable land, immediately followed by a tillage operation;
- different fertiliser loads on sand, clay and peat soils, with variation in solid/liquid fractions depending on the season;
- different fertiliser recommendations depending on fertiliser type, soil type and crop.

The periods in which the spreading of manure (i.e. stable manure, slurry and sludge) is allowed are different for indicated and non-indicated areas. For indicated areas this period is February 1 - August 31 for grassland and arable land. For non-indicated areas this period is February 1 - September 15 for grassland and the whole year for arable land.

Cattle manure is used on grasslands and arable lands. Other manure types are predominantly used on arable land. Manure quality has been defined for administrative purpose [38], and these data reveal that manure application is limited by phosphate load for all animal categories. We assume that the phosphate immission standard is filled in one event, as this is practice in most fields [38]. During winter the manure is stored for 152 days. The amount of manure produced in this period determines the dilution of the excreted dosage. We need to take into account the number of treatments per place per year. A treatment that is repeated every cycle is given twice a year to veal, but seven times to broilers. We therefore calculate a maximum concentration in the manure, based on the intervals between spreading.

Degradation in the manure tank is not taken into account in the Phase I total residue approach. Manure tank conditions are variable and not standardised in the risk model, hence at the moment the incorporation of experimental results in the risk calculations is ambiguous [43].

*Table 17 Default settings for spreading of manure on grassland and arable land.*

Parameter	Symbol	unit	Value
mixing depth with soil	DEPTH <sub>field</sub>	[m]	0.20
phosphate immission standard	Q <sub>P2O5</sub>	[kg <sub>P2O5</sub> .ha <sup>-1</sup> ]	85
storage time slurry before spreading	T <sub>storage</sub>	[d]	152
number of spreading events	N <sub>spreading</sub>	[yr <sup>-1</sup> ]	1
reaction rate for biodegradation in slurry	kdeg <sub>slurry</sub>	[d <sup>-1</sup> ]	0



## 4. Emission and distribution models

### 4.1. Concentrations in dung

Treated animals that graze in the field excrete drug residues in the urine and faeces. Relevant environmental compartments that are exposed directly are the dung, the soil, and the surface water.

We assume that in the event the herd need a remedy that takes several treatments over a few days, the animals are housed or stabled. Therefore the model has to take only single-application products into account. We need a reasonable maximum concentration in dung, which preferably is determined in controlled experiments.

When this information is not delivered, we calculate a worst-case maximum. If useful information on excretion is available, this can be used to calculate a better estimation of the concentration in the dung.

Use the factors in Table 24 to adjust the dosage of products with external application. In addition, sheep are supposed to rub off 20% of the dosage they receive from dipping.

Table 18 Default settings for the module for the calculation of the maximum concentration in dung.

parameter	symbol	unit	value
duration of treatment	$T_{\text{treatment}}$	[d]	1
highest fraction excreted in dung in one day	$F_{\text{max. excreted dung}}$	[-]	1
number of dung excretion events per day	$N_{\text{excretion}}$	[d <sup>-1</sup> ]	10.5

Model for the calculation of the maximum concentration in dung if  $PEC_{\text{dung}}$  is not available from the dossier:

$$PEC_{\text{dung}} = \frac{Q_{\text{product}} \cdot C_c \cdot m_{\text{animal}} \cdot T_{\text{treatment}} \cdot F_{\text{max. excreted. dung}} \cdot N_{\text{excretion}}}{Pd_{\text{dung}}_{\text{animal}}}$$

#### input

$Q_{\text{product}}$	dosage product used	[kg.kg <sub>bw</sub> <sup>-1</sup> .d <sup>-1</sup> ]	S
$C_c$	concentration a.i. in product	[mg <sub>c</sub> .kg <sup>-1</sup> ]	S
$m_{\text{animal}}$	(averaged) body weight	[kg <sub>bw</sub> .animal <sup>-1</sup> ]	S/D
$T_{\text{treatment}}$	duration of treatment	[d]	D
$F_{\text{max. excreted dung}}$	highest fraction excreted in dung in one day	[-]	S/D
$Pd_{\text{dung}}_{\text{animal}}$	dung production animal in field	[kg <sub>wwt</sub> .animal <sup>-1</sup> .d <sup>-1</sup> ]	O
$N_{\text{excretion}}$	number of dung excretion events per day	[d <sup>-1</sup> ]	D

#### output

$PEC_{\text{dung}}$	predicted (maximum) concentration in dung	[mg <sub>c</sub> .kg <sub>wwt</sub> <sup>-1</sup> ]	O/S
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## 4.2. Concentrations in soil

The soil can be reached by direct and indirect exposure:

- spreading of slurry and sludge;
- leaching from dung on the pasture;
- direct excretion with urine on the pasture;
- emission of (high volume) topical application fluids.

### 4.2.1. The concentration in soil after spreading of slurry

The concentration in the soil depends on a number of factors. One has to consider the relation between the moments the substance is excreted into the slurry and the moments the slurry is removed from the basin, thus the time the substance is in the slurry. The effective time degradation can take place in slurry cannot be calculated mathematically. Therefore arbitrary values will be given to simulate an average situation. The amount of slurry spread depends on the immission standard and the phosphate content of the slurry. For the model calculations it is assumed that the excretion of residues into slurry takes place in one single event (in reality the excretion could takes several days).

The immission standard is filled in one spreading event. Given  $T_{\text{storage}}$  the maximum number of applications ( $N_{\text{application}}$ ) within the winter storage period is:

Table 19 Pick list for the calculation of the PECsoil.

$N_{\text{cycle}_{\text{animal}}}$	$T_{\text{cycle}_{\text{animal}}}$	$N_{\text{application}}$
$\leq 2.4$	$\geq 152$	1
2.5-4.7	77-151	2
4.8-7.2	51-76	3

#### Input

$N_{\text{cycle}_{\text{animal}}}$  Number of cycles per year [animal.place<sup>-1</sup>.yr<sup>-1</sup>] D

#### Output

$T_{\text{cycle}_{\text{animal}}}$  Duration of cycle [d] O

$N_{\text{application}}$  Number of applications per storage period [animal.place<sup>-1</sup>] O

In case degradation is not considered (Phase I total residue approach):

$$Q_{\text{excreted}} = Q_{\text{product}} \cdot C_c \cdot T_{\text{treatment}} \cdot F_{\text{excreted}} \cdot m_{\text{animal}}$$

$$C_{P205} = \frac{Q_{\text{excreted}} \cdot N_{\text{application}}}{T_{\text{storage}} \cdot P_{P205}}$$

$$PEC_{soil} = \frac{C_{P2O5} \cdot Q_{P2O5}}{RHO_{soil} \cdot CONV_{area\ field} \cdot DEPTH_{field}}$$

Substances used for topical application (spraying or pour-on) on animals may reach the slurry directly due to spillage (drift from spraying). For pour-on this emission is considered negligible. Sprays and dips are supposed to spill 20% of the dosage.

Table 20 Default settings for the calculation of the concentration in slurry by direct exposure.

product type	symbol	unit	value
spray	Fslurry <sub>spillage</sub>	[-]	0.2
pour-on	Fslurry <sub>spillage</sub>	[-]	0

The  $F_{excreted}$  in the formula is corrected with  $(1 - F_{slurry_{spillage}})$  and finally the concentration in slurry caused by the  $F_{slurry_{spillage}}$  is added.

$$Q_{excreted} = Q_{product} \cdot C_c \cdot T_{treatment} \cdot m_{animal} \cdot ((1 - F_{slurry_{spillage}}) \cdot F_{excreted} + F_{slurry_{spillage}})$$

In case degradation is considered in Phase II, for every substance of concern, the following equations can be applied. Manure tank conditions are variable and not standardised in the risk model, hence at the moment the incorporation of experimental results in the risk calculations is ambiguous [43].

$$Q_{excreted} = Q_{product} \cdot C_c \cdot T_{treatment} \cdot F_{excreted} \cdot m_{animal}$$

$$k_{deg_{slurry}} = \frac{\ln 2}{DT50_{deg_{slurry}}}$$

$$C_{P2O5} = \frac{Q_{excreted}}{T_{storage} \cdot P_{P2O5}} \cdot \frac{1 - F_{rsl}^{N_{application}}}{1 - F_{rsl}} \cdot e^{-k_{deg_{slurry}} \cdot T_{rest} / 2}$$

$$F_{rsl} = e^{-k_{deg_{slurry}} \cdot T_{cyclus_{animal}}}$$

$$T_{rest} = T_{storage} - (N_{application} - 1) \cdot T_{cyclus}$$

$$T_{cyclus} = 365 / N_{cyclus_{animal}}$$

$$PEC_{soil} = \frac{C_{P2O5} \cdot Q_{P2O5}}{RHO_{soil} \cdot CONV_{area\ field} \cdot DEPTH_{field}}$$

Input-output list of the models for the calculation of the concentration in soil after uptake and excretion into slurry.

<b>input</b>			
$Q_{\text{product}}$	Dosage product used	$[\text{kg} \cdot \text{kg}_{\text{bw}}^{-1} \cdot \text{d}^{-1}]$	S
$C_{\text{c}}$	Concentration a.i. in product	$[\text{mg}_{\text{c}} \cdot \text{kg}^{-1}]$	S
$T_{\text{treatment}}$	Duration of treatment	[d]	S
$m_{\text{animal}}$	(averaged) body weight	$[\text{kg}_{\text{bw}} \cdot \text{animal}^{-1}]$	O
$F_{\text{excreted}}$	Fraction excreted in faeces and urine	[-]	S/D
$N_{\text{cycle}_{\text{animal}}}$	Number of cycles per year	$[\text{animal} \cdot \text{place}^{-1} \cdot \text{yr}^{-1}]$	O
$P_{\text{P2O5}}$	Phosphate production animal in stable	$[\text{kg}_{\text{P2O5}} \cdot \text{place}^{-1} \cdot \text{d}^{-1}]$	O
$DT50_{\text{deg}_{\text{slurry}}}$	Half-life time in slurry	[d]	S/D
$T_{\text{storage}}$	Average storage time slurry grassland/arable land	[d]	O
$N_{\text{spreading}}$	Number of slurry spreading events in a year	$[\text{yr}^{-1}]$	O
$Q_{\text{P2O5}}$	Phosphate immission standard	$[\text{kg}_{\text{P2O5}} \cdot \text{ha}^{-1}]$	D
$RHO_{\text{soil}}$	Dry bulk density of soil	$[\text{kg} \cdot \text{m}^{-3}]$	D <sup>c</sup>
$DEPTH_{\text{field}}$	Mixing depth with soil	[m]	O
$CONV_{\text{area field}}$	Conversion factor for the area of the agricultural field	$[\text{m}^2 \cdot \text{ha}^{-1}]$	D <sup>c</sup>
$N_{\text{application}}$	Number of applications per storage period	$[\text{animal} \cdot \text{place}^{-1}]$	O
<b>intermediate results</b>			
$k_{\text{deg}_{\text{slurry}}}$	Reaction rate for transformation in slurry	$[\text{d}^{-1}]$	O
$F_{\text{rsl}}$	Fraction remaining in slurry after time $T_{\text{interval}}$	[-]	O
$Q_{\text{excreted}}$	Amount substance excreted	$[\text{mg}_{\text{c}} \cdot \text{animal}^{-1}]$	O
$C_{\text{P2O5}}$	Concentration in phosphate	$[\text{mg}_{\text{c}} \cdot \text{kg}_{\text{P2O5}}^{-1}]$	O
$T_{\text{cycle}}$	Duration of cycle	[d]	O
$T_{\text{rest}}$	Duration of storage after last treatment	[d]	O
<b>output</b>			
$PEC_{\text{soil}}$	Concentration in the soil	$[\text{mg}_{\text{c}} \cdot \text{kg}_{\text{soil}}^{-1}]$	O

#### 4.2.2. The concentration in soil by spreading of urine and leaching from dung

Substances that are taken up and are excreted by grazing animals reach the soil. Urine is spread in several events per day and penetrates the soil. Residues might leach from dung into the soil. We assume that the water fraction in the dung is transferred to the soil (e.g. when raining) and that the residues are evenly distributed in the top 5 cm throughout the field (Table 21).

Substances with external application on grazing animals have a fraction of the dosage that is spilled ( $F_{\text{soil}_{\text{spillage}}}$ ). See § 4.2.4 and Appendix I for more information.

Model for calculation of the concentration in soil after spreading of urine and leaching from dung.

$$Q_{\text{excreted urine}} = Q_{\text{product}} \cdot C_c \cdot m_{\text{animal}} \cdot F_{\text{excreted urine}} \cdot T_{\text{treatment}}$$

$$Q_{\text{leached.dung}} = Q_{\text{product}} \cdot C_c \cdot m_{\text{animal}} \cdot F_{\text{excreted dung}} \cdot F_{\text{leached.dung}} \cdot T_{\text{treatment}}$$

$$F_{\text{excreted dung}} = 1 - F_{\text{excreted urine}} \quad \text{unless experimentally measured.}$$

$$F_{\text{leached.dung}} = \frac{F_{\text{water.dung}}}{K_{\text{dung-water}}}$$

$$K_{\text{dung-water}} = F_{\text{water.dung}} + F_{\text{solid.dung}} \cdot \frac{Kp_{\text{dung}}}{1000} \cdot RHO_{\text{solid.dung}}$$

$$Kp_{\text{dung}} = Foc_{\text{dung}} \cdot Koc$$

$$PEC_{\text{soil}} = \frac{(Q_{\text{excreted urine}} + Q_{\text{leached dung}}) \cdot N_{\text{animal field}}}{RHO_{\text{soil}} \cdot CONV_{\text{area field}} \cdot DEPTH_{\text{field}}}$$

### input

$Q_{\text{product}}$	dosage product used	[kg.kg bw <sup>-1</sup> .d <sup>-1</sup> ]	S
$C_c$	concentration a.i. in product	[mg <sub>c</sub> .kg <sup>-1</sup> ]	S
$m_{\text{animal}}$	(averaged) body weight	[kg <sub>bw</sub> .animal <sup>-1</sup> ]	P
$T_{\text{treatment}}$	duration of treatment	[d]	D
$F_{\text{excreted urine}}$	fraction excreted in urine	[-]	S/D
$N_{\text{animal field}}$	stocking density animals	[animal.ha <sup>-1</sup> ]	P
$RHO_{\text{soil}}$	dry bulk density of soil	[kg.m <sup>-3</sup> ]	D <sup>c</sup>
$DEPTH_{\text{field}}$	mixing depth with soil	[m]	D <sup>c</sup>
$CONV_{\text{area field}}$	conversion factor for the area of the field	[m <sup>2</sup> .ha <sup>-1</sup> ]	D <sup>c</sup>
$RHO_{\text{solid.dung}}$	density of dung solids	[kg.m <sup>-3</sup> ]	D <sup>c</sup>
$RHO_{\text{water}}$	density of water	[kg.m <sup>-3</sup> ]	D <sup>c</sup>
$F_{\text{water.dung}}$	fraction water in dung	[m <sup>3</sup> .m <sup>-3</sup> ]	P
$F_{\text{solid.dung}}$	fraction solids in dung	[m <sup>3</sup> .m <sup>-3</sup> ]	P
$Foc_{\text{dung}}$	weight fraction of fraction organic carbon in dung	[kg.kg <sup>-1</sup> ]	D <sup>c</sup>
$Koc$	partition coefficient organic carbon - water	[dm <sup>3</sup> .kg <sup>-1</sup> ]	S/O

### intermediate results

$Q_{\text{excreted urine}}$	quantity a.i. excreted with urine	[mg <sub>c</sub> .animal <sup>-1</sup> ]	O
$Q_{\text{leached dung}}$	quantity a.i. leached with dung	[mg <sub>c</sub> .animal <sup>-1</sup> ]	O
$F_{\text{excreted dung}}$	fraction excreted in dung	[-]	O/S
$F_{\text{leached dung}}$	fraction leached from dung	[-]	O
$K_{\text{dung-water}}$	partition coefficient solids and water in dung	[m <sup>3</sup> .m <sup>-3</sup> ]	O
$Kp_{\text{dung}}$	partition coefficient solids and water in dung	[dm <sup>3</sup> .kg <sup>-1</sup> ]	O

### output

$PEC_{\text{soil}}$	concentration in the soil	[mg <sub>c</sub> .kg <sub>soil</sub> <sup>-1</sup> ]	O
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Table 21 Default settings for the module for spreading of urine and leaching from dung.

parameter	symbol	unit	value
duration of treatment	$T_{\text{treatment}}$	[d]	1
fraction excreted in urine	$F_{\text{excreted urine}}$	[-]	1
bulk density of soil	$RH_{\text{soil}}$	$[\text{kg} \cdot \text{m}^{-3}]$	1500
mixing depth with soil	$DEPTH_{\text{field}}$	[m]	0.05
conversion factor for area of the agricultural field	$CONV_{\text{area field}}$	$[\text{m}^2 \cdot \text{ha}^{-1}]$	10000
density of dung solids	$RH_{\text{solid dung}}$	$[\text{kg} \cdot \text{m}^{-3}]$	1675
density of water	$RH_{\text{water}}$	$[\text{kg} \cdot \text{m}^{-3}]$	1000
weight fraction of organic carbon in dung	$F_{\text{oc dung}}$	$[\text{kg} \cdot \text{kg}^{-1}]$	0.44
fraction leached from dung	$F_{\text{leached dung}}$	[-]	0

### 4.2.3. The concentration in soil by spreading of sludge from fisheries

It is assumed the sludge is only spread on arable land. In case of the total residue approach, the degradation terms are not used.

Table 22 Default settings for the calculation of the concentration in soil after spreading of sludge.

parameter	symbol	unit	value
bulk density of soil	$RH_{\text{soil}}$	$[\text{kg} \cdot \text{m}^{-3}]$	1500
conversion factor for the area of the agricultural field	$CONV_{\text{area field}}$	$[\text{m}^2 \cdot \text{ha}^{-1}]$	10000
phosphate production per day	$P_{\text{P2O5 fish}}$	$[\text{kg}_{\text{P2O5}} \cdot \text{d}^{-1}]$	8.22
reaction rate for biodegradation in slurry	$k_{\text{deg skurry}}$	$[\text{d}^{-1}]$	0
mixing depth in soil	$DEPTH_{\text{field}}$	[m]	0.20
Storage time sludge	$T_{\text{storage}}$	[d]	152

Table 23 Pick list for the default settings of the fraction of retention in sludge, treatment time and volume of waste water.

type of treatment	type of water treatment	$F_{\text{ret}}$ [-]	$N_{\text{application fish,soil}}$	$V_{\text{waste water}}$ [l]
continuous treatment	filtration and settlement tank	0.5	equals $T_{\text{storage}}$	35000
continuous treatment	settlement tank	0	equals $T_{\text{storage}}$	35000
occasional treatment	settlement tank	0	2	70000

#### input

type of treatment	[-]	S
type of water treatment	[-]	S

#### output

$F_{\text{ret}}$	fraction of chemical retained	[-]	O
$N_{\text{application fish,soil}}$	number of applications during storage period	[-]	O
$V_{\text{waste water}}$	volume of waste water	[l]	O
model	model for calculation of concentration in soil	[-]	O

Models for the calculation of the concentration in soil after spreading of sludge.

### 1. General formulas.

$$Q_{emitted} = Q_{product} \cdot C_c \cdot V_{waste\ water} \cdot (1 - F_{ret})$$

$$PEC_{soil} = \frac{Q_{P2O5} \cdot C_{P2O5}}{RHO_{soil} \cdot CONV_{area\ field} \cdot DEPTH_{field}}$$

### 2. Continuous treatment:

$$C_{P2O5} = \frac{Q_{emitted}}{T_{storage} \cdot P_{P2O5}} \cdot \frac{1 - F_{rsl}^{N_{applicati\ on\ fish}}}{1 - F_{rsl}} \cdot e^{-k_{deg\ slurry} \cdot T_{rest} / 2}$$

$$F_{rsl} = e^{-k_{deg\ slurry} \cdot 1} \quad T_{rest} = 1$$

### 3. Occasional treatment:

$$C_{P2O5} = \frac{Q_{emitted}}{T_{storage} \cdot P_{P2O5}} \cdot e^{-k_{deg\ slurry} \cdot T_{rest} / 2} \quad T_{rest} = 152$$

#### input

$Q_{product}$	dosage product used	[kg.l <sup>-1</sup> ]	S
$C_c$	concentration a.i. in product	[mg <sub>c</sub> .kg <sup>-1</sup> ]	S
$V_{waste\ water}$	volume of waste water discharged	[l]	O
$F_{ret}$	fraction of retention in sludge	[-]	O
$P_{P2O5\ fish}$	phosphate production per day	[kg <sub>P2O5</sub> .d <sup>-1</sup> ]	D
$N_{applicati\ on\ fish}$	number of applications per storage period for fish treatment	[-]	O
$T_{rest}$	maximum time remaining after last treatment	[d]	D
$Q_{P2O5}$	phosphate immission standard	[kg <sub>P2O5</sub> .ha <sup>-1</sup> ]	D
$RHO_{soil}$	bulk density of soil	[kg.m <sup>-3</sup> ]	D <sup>c</sup>
$DEPTH_{field}$	mixing depth with soil	[m]	D
$CONV_{area\ field}$	conversion factor for the area of the agricultural field	[m <sup>2</sup> .ha <sup>-1</sup> ]	D <sup>c</sup>

#### intermediate results

$k_{deg\ slurry}$	reaction constant transformation in slurry	[d <sup>-1</sup> ]	O
$F_{rs}$	fraction remaining in soil after time $T_{interval}$	[-]	O
$F_{rsl}$	fraction remaining in sludge after time $T_{interval}$	[-]	O
$Q_{emitted}$	amount of substance emitted	[mg <sub>c</sub> ]	O
$C_{P2O5}$	concentration in phosphate	[mg <sub>c</sub> .kg <sub>P2O5</sub> <sup>-1</sup> ]	O

#### output

$PEC_{soil}$	concentration in the soil	[mg <sub>c</sub> .kg <sub>soil</sub> <sup>-1</sup> ]	O
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#### 4.2.4. The concentration in soil by direct exposure

Substances used for topical application (spraying or pour-on) on grazing animals may reach the environment directly due to spillage (drift from spraying), washing off by rain and rubbing off. Initially, a calculation is performed where it is assumed that the dosage for the entire herd reaches the soil completely. This can be calculated using the model in § 4.2.2 and using  $F_{\text{excreted urine}} = 1$ . Should the trigger for soil be exceeded, a refined calculation is made, assuming spillage, uptake and excretion.

Table 24 Default settings for the calculation of the concentration in soil by direct exposure.

product type	symbol	unit	value
spray	$F_{\text{soil spillage}}$	[-]	0.2
pour-on	$F_{\text{soil spillage}}$	[-]	0

For pour-on this emission is considered negligible. Sprays are supposed to spill 20% of the dosage. In addition, sheep are supposed to rub off 20% of the dosage they receive from dipping. The  $Q_{\text{product}}$  in § 4.2.2 is corrected with  $(1 - F_{\text{soil spillage}})$  (see Table 24) and finally the concentration in soil caused by the  $F_{\text{soil spillage}}$  is added.

Discharge of sheep dips may be regulated by instructions induced by law or by good agricultural practice. When the remaining dip should be spread over the land as if it were slurry, than this scenario should be used for calculations. In the event these specific instructions are lacking, a worst-case scenario is used. The concentration in soil after discharge of dipping fluids on the land depends on the concentration of the product in the fluid. The area and volume of soil that will be contaminated depends on the volume of the fluid discharged and soil structure. Soil has a volume fraction of solids of 0.6 (see Table 26). The fluid will take maximally 40% of the soil volume by superseding the air and the present soil porewater.

Table 25 Default settings for the module for discharge of sheep dips.

parameter	symbol	Unit	value
bulk density of soil	$RHO_{\text{soil}}$	$[\text{kg} \cdot \text{m}^{-3}]$	1500
fraction of the product remaining in dip after treatments	$F_{\text{rd}}$	[-]	0.8
volume fraction of solids in soil	$F_{\text{solids soil}}$	$[\text{m}^3 \cdot \text{m}^{-3}]$	0.6

Model for calculation of the concentration in soil after discharge of sheep dips.

$$PEC_{\text{dip}} = \frac{D_{\text{product}} \cdot C_c}{V_{\text{dilution water}}}$$

$$PEC_{soil} = \frac{PEC_{dip} \cdot F_{rd} \cdot (1 - F_{solids_{soil}})}{RHO_{soil}}$$

**input**

$D_{product}$	dosage product used	[kg] or [l]	S
$C_c$	concentration a.i. in product	[mg <sub>c</sub> .kg <sup>-1</sup> ] or [mg <sub>c</sub> .l <sup>-1</sup> ]	S
$F_{rd}$	fraction of the product remaining in dip after treatments	[-]	D/S
$F_{solids_{soil}}$	volume fraction of solids in soil	[m <sup>3</sup> . m <sup>-3</sup> ]	D <sup>c</sup>
$V_{dilution\ water}$	volume of dilution water prescribed	[m <sup>-3</sup> ]	S

**intermediate results**

$PEC_{dip}$	initial (prescribed) concentration in dip fluid or foot bath	[mg <sub>c</sub> .m <sup>-3</sup> ]	O
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**output**

$PEC_{soil}$	concentration in the soil	[mg <sub>c</sub> .kg <sub>soil</sub> <sup>-1</sup> ]	O
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### 4.3. The concentration in groundwater

In Phase I the concentration in groundwater is not assessed. In Phase II experimental data on DT50 and  $K_{oc}$  are available and the groundwater leaching model PEARL is used for calculations [44].

### 4.4. The concentration in surface water

Surface water is reached by direct and indirect exposure:

- run-off;
- leaching and drainage;
- erosion;
- direct excretion into surface water;
- emission of waste water from fisheries.

Run-off and erosion are not considered to be important distribution factors in the Netherlands. An exposure assessment of surface water through leaching and drainage is not considered necessary in case the  $K_{oc}$  of the drug substance is >500 l/kg.

#### 4.4.1. Leaching from agricultural soil

Substances not adsorbed to soil particles may be present in the soil water and thus be prone to leaching and drainage during rainfall events. The concentration in the surface water will be influenced by the amount of rainfall relative to the interstitial pore water and subsequent dilution by the receiving water. It is assumed that catchment areas tend to be proportional in size to the receiving stream therefore no account is taken of the size of the catchment or receiving water. Further dilution occurs on entry of run-off water into receiving water (a factor of 10 is chosen)

(Table 26). For calculation of the concentration in porewater the EU-approach<sup>5</sup> is used. At the moment, no national higher tier models are operational.

Model for calculation of the concentration in surface water due to leaching.

$$PEC_{sw_{leaching}} = \frac{PEC_{porewater}}{DILUTION_{leaching}}$$

$$PEC_{porewater} = \frac{PEC_{soil} \cdot RHO_{soil}}{K_{soil-water} \cdot 1000}$$

$$K_{soil-water} = Fair_{soil} \cdot K_{air-water} + Fwater_{soil} + Fsolid_{soil} \cdot \frac{Kp_{soil}}{1000} \cdot RHO_{solid}$$

$$Kp_{soil} = Foc_{soil} \cdot Koc$$

$$K_{air-water} = \frac{VP \cdot MOLW}{SOL \cdot R \cdot TEMP}$$

#### input

DILUTION <sub>leaching</sub>	dilution factor for leaching	[-]	D
PEC <sub>soil</sub>	concentration in the soil	[mg·kg <sub>soil</sub> <sup>-1</sup> ]	O
RHO <sub>soil</sub>	fresh bulk density of soil	[kg·m <sup>-3</sup> ]	D
RHO <sub>solid</sub>	density of soil solids	[kg·m <sup>-3</sup> ]	D
Fair <sub>soil</sub>	fraction air in soil	[m <sup>3</sup> ·m <sup>-3</sup> ]	D
Fwater <sub>soil</sub>	fraction water in soil	[m <sup>3</sup> ·m <sup>-3</sup> ]	D
Fsolid <sub>soil</sub>	fraction solids in soil	[m <sup>3</sup> ·m <sup>-3</sup> ]	D
Foc <sub>soil</sub>	fraction organic carbon in soil (w/dw)	[kg·kg <sup>-1</sup> ]	D
Koc	partition coefficient organic carbon - water	[dm <sup>3</sup> ·kg <sup>-1</sup> ]	S/O
VP	vapour pressure	[Pa]	S
MOLW	molar mass	[g·mol <sup>-1</sup> ]	S
SOL	water solubility	[mg·l <sup>-1</sup> ]	S
TEMP	temperature at air-water interface	[K]	D
R	gas constant	[Pa·m <sup>3</sup> ·mol <sup>-1</sup> ·K <sup>-1</sup> ]	D

#### intermediate results

K <sub>soil-water</sub>	partition coefficient solids and water in soil (v/v)	[m <sup>3</sup> ·m <sup>-3</sup> ]	O
Kp <sub>soil</sub>	partition coefficient solids and water in soil (v/w)	[dm <sup>3</sup> ·kg <sup>-1</sup> ]	O
K <sub>air-water</sub>	partition coefficient air and water in soil	[m <sup>3</sup> ·m <sup>-3</sup> ]	O
PEC <sub>porewater</sub>	predicted concentration in pore water	[mg·l <sup>-1</sup> ]	O

#### output

PEC <sub>sw<sub>leaching</sub></sub>	predicted concentration in surface water	[mg·l <sup>-1</sup> ]	O
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<sup>5</sup> Chapter 2.3.8.6 in [46].

Table 26 Default settings for concentration in surface water due to leaching and drainage.

parameter	symbol	unit	value
dilution factor for leaching	DILUTION <sub>leaching</sub>	[-]	10
bulk density of fresh soil (not dry soil!)	RHO <sub>soil</sub>	[kg.m <sup>-3</sup> ]	1700
density of soil solids	RHO <sub>solid<sub>soil</sub></sub>	[kg.m <sup>-3</sup> ]	2500
fraction air in soil	F <sub>air<sub>soil</sub></sub>	[m <sup>3</sup> .m <sup>-3</sup> ]	0.2
fraction water in soil	F <sub>water<sub>soil</sub></sub>	[m <sup>3</sup> .m <sup>-3</sup> ]	0.2
fraction solids in soil	F <sub>solid<sub>soil</sub></sub>	[m <sup>3</sup> .m <sup>-3</sup> ]	0.6
weight fraction organic carbon in soil	F <sub>oc<sub>soil</sub></sub>	[kg.kg <sup>-1</sup> ]	0.02
temperature at air-water interface	TEMP	[K]	285
gas constant	R	[Pa. m <sup>3</sup> .mol <sup>-1</sup> .K <sup>-1</sup> ]	8.314

#### 4.4.2. Direct excretion into surface water by grazing livestock

This section applies to treatments of animals in grazing pastures with products that are subsequently excreted in dung, and where residues have insecticidal activity (See § 6.2). The model is based on the following assumptions:

- that livestock roam freely over pasture and do not spend a greater proportion of time in any one area, including any stream passing through the field;
- that excretion is as likely to occur into the stream as into the pasture;
- that a hectare of pasture contains a slow-flowing stream 100 m long, 1 m wide and 0.3 m deep;
- it is assumed that 1% of the dosage per hectare is excreted into the stream.

Table 27 Default settings of the module for concentration in surface water due to direct excretion..

parameter	symbol	unit	value
duration of treatment	T <sub>treatment</sub>	[d]	1
volume of the surface water per hectare	V <sub>surface water</sub>	[l.ha <sup>-1</sup> ]	30000
fraction excreted into surface water	F <sub>excreted</sub>	[-]	0.01

Calculation for concentration in surface water due to direct excretion.

$$PEC_{sw_{excr.}} = \frac{Q_{product} \cdot C_c \cdot m_{animal} \cdot T_{treatment} \cdot N_{animal_{field}} \cdot F_{excreted}}{V_{surface\ water}}$$

**input**

$Q_{\text{product}}$	dosage product used	$[\text{kg.kg}_{\text{bw}}^{-1}.\text{d}^{-1}]$	S
$C_c$	concentration a.i. in product	$[\text{mg}_c.\text{kg}^{-1}]$	S
$m_{\text{animal}}$	(averaged) body weight	$[\text{kg}_{\text{bw}}.\text{animal}^{-1}]$	P
$T_{\text{treatment}}$	duration of treatment	[d]	D
$N_{\text{animal}_{\text{field}}}$	stocking density animals	$[\text{animal}.\text{ha}^{-1}]$	P
$V_{\text{surface water}}$	volume of the surface water per hectare	$[\text{l}.\text{ha}^{-1}]$	D
$F_{\text{excreted}}$	fraction excreted into surface water	[-]	D
<b>output</b>			
$\text{PEC}_{\text{sw}_{\text{excr.}}}$	highest concentration in surface water	$[\text{mg}_c.\text{l}^{-1}]$	O

**4.4.3. Fisheries waste water**

The water is either discharged on surface water or into the sewage treatment plant (STP). The emission to the STP waste water is the input parameter for the STP module in USES [45]. Due to the settlement tank the total amount emitted is equally spread out over 25 days, which of course will have no effect on the surface water concentration in case of continuous treatment.

Table 28 Default settings of the module for emission to waste water.

parameter	symbol	unit	value
emission period for discharge to STP	$T_{\text{emission}_{\text{stp}}}$	[d]	25

Table 29 Pick list for the default settings of the fraction of retention in sludge, treatment time and volume of waste water.

type of treatment	type of water treatment before STP	$F_{\text{ret}}$ [-]	$N_{\text{application}_{\text{fish,water}}}$ [ $\text{yr}^{-1}$ ]	$V_{\text{waste water}}$ [l]	$\text{DILUTION}_{\text{fish}}$ [-]
continuous	filtration and settlement tank	0.5	365	35000	5
continuous	settlement tank	0	365	35000	5
occasional	settlement tank	0	4	70000	3

**input**

type of treatment		[-]	S
type of water treatment		[-]	S
<b>output</b>			
$F_{\text{ret}}$	fraction of chemical retained	[-]	O
$N_{\text{application}_{\text{fish,water}}}$	number of applications per year	[-]	O
$V_{\text{waste water}}$	volume of waste water	[l]	O
$\text{DILUTION}_{\text{fish}}$	dilution factor for fish waste water reaching the surface water	[-]	O

Model for the calculation of the emission to waste water during episode.

$$Q_{emitted} = Q_{product} \cdot C_c \cdot V_{waste\ water}$$

$$E_{local\_water} = \frac{Q_{emitted} \cdot (1 - F_{ret})}{T_{emission\_stp}}$$

$$T_{emission} = T_{emission\_stp} \cdot N_{application\_year}$$

**input**

$Q_{product}$	dosage product used	[kg.l <sup>-1</sup> ]	S
$C_c$	concentration a.i. in product	[mg <sub>c</sub> .kg <sup>-1</sup> ]	S
$V_{waste\ water}$	volume of waste water discharged	[l]	P
$F_{ret}$	fraction of retention in sludge	[-]	P
$T_{emission\_stp}$	emission period for discharge to STP	[d]	D
$N_{application\_year}$	number of applications in one year	[-]	P

**intermediate results**

$Q_{emitted}$	amount of substance emitted	[mg <sub>c</sub> .d <sup>-1</sup> ]	O
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**output**

$E_{local\_water}$	emission to waste water during episode	[mg <sub>c</sub> .d <sup>-1</sup> ]	O
$T_{emission}$	number of emission days	[d]	O

In case of direct discharge on surface water, the  $E_{local\_water}$  is used for calculation.

Model for the calculation of the concentration in surface water after direct discharge from fish settlement tank.

$$PEC_{sw\_fish} = \frac{E_{local\_water}}{DILUTION_{fish}}$$

**input**

$E_{local\_water}$	emission to waste water during episode	[mg <sub>c</sub> .d <sup>-1</sup> ]	O
$DILUTION_{fish}$	dilution factor for fish waste water reaching the surface water	[l.d <sup>-1</sup> ]	O

**output**

$PEC_{sw\_fish}$	highest concentration in surface water	[mg <sub>c</sub> .l <sup>-1</sup> ]	O
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## 4.5. The concentration in air

This route is not assessed.

## 4.6. The concentration in sediment

Concentrations in sediment are determined by the concentrations in water and the sediment-water partitioning coefficient. This coefficient is estimated from  $K_{oc}$  and  $F_{oc,ditch}$ . See Table 30.

Table 30 Default settings of the module for concentration in sediment.

parameter	symbol	unit	value
fresh bulk density sediment in ditch	$RHO_{sed}$	$[kg_{wwt} \cdot m^{-3}]$	1300
volume fraction solids in sediment ditch	$F_{solid_{sed}}$	$[m^3 \cdot m^{-3}]$	0.2
bulk density of solids	$RHO_{solid}$	$[kg \cdot m^{-3}]$	2500
weight fraction organic carbon in sediment ditch	$F_{oc,ditch}$	$[kg \cdot kg^{-1}]$	0.05

$$CONV_{sed} = \frac{RHO_{sed}}{F_{solid_{sed}} \cdot RHO_{solid}}$$

$$PEC_{sed} = \frac{F_{oc,ditch} \cdot K_{oc} \cdot PEC_{sw}}{CONV_{sed}}$$

### input

PEC <sub>sw</sub>	concentration in surface water	$[mg_c \cdot l^{-1}]$	O
RHO <sub>sed</sub>	fresh bulk density sediment in ditch	$[kg_{wwt} \cdot m^{-3}]$	D
F <sub>solid<sub>sed</sub></sub>	volume fraction solids in sediment ditch	$[m^3 \cdot m^{-3}]$	D
RHO <sub>solid</sub>	bulk density of solids	$[kg \cdot m^{-3}]$	D
F <sub>oc,ditch</sub>	weight fraction organic carbon in sediment ditch	$[kg \cdot kg^{-1}]$	D
K <sub>oc</sub>	organic carbon partitioning coefficient substance	$[l \cdot kg^{-1}]$	S

### intermediate results

CONV <sub>sed</sub>	conversion factor for sediment concentrations: wwt to dwt	$[kg_{wwt} \cdot kg_{dwt}^{-1}]$	O <sup>c</sup>
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### output

PEC <sub>sed</sub>	predicted concentration in sediment	$[mg_c \cdot kg_{wwt}^{-1}]$	O
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Instead of an acute concentration in water an average concentration can be used, e.g. an average concentration over a certain period, or after several years of emission. The PEC<sub>sed</sub> derived from this is then to be compared to the PNEC for sediment dwelling organisms. For further information see [45].

## 5. Exposure module

In the exposure module, exposure levels for predating birds and mammals are estimated. Birds and mammals are likely to be exposed to the veterinary medicinal product or its metabolites in the event the contaminated compartment still supports the development of worms, insects, and fish. Insects in the fleece of treated animals or in the grass where products (dips) have been disposed of will carry residues in the range of 2.7 - 29 times the application rate (see Table 31). The assessment of secondary poisoning of birds and mammals considers exposure through fish and earthworms. Bioconcentration may be of concern for lipophilic organic chemicals. Insects and worms in dung and soil can accumulate the residues and carry them over when they are eaten. The bioconcentration factor (BCF) between the compartment and the feed are needed. When an experimental BCF is not available, the BCF for the earthworms can be estimated using the logKow and the sorption coefficient of the substance [46]. The following food chains are assessed.

Direct food chains:

- Birds exposed through exposed product (sheep dips and foot baths);
- Birds and/or mammals exposed through drinking water;
- Birds and/or mammals exposed through feed (insects in grass and fleece);

Indirect food chains:

- Birds and/or mammals with a diet consisting of worms caught in polluted land;
- Birds and/or mammals with a diet consisting of worms caught in polluted dung;
- Birds and/or mammals with a diet consisting of fish caught in polluted water.

### 5.1. The concentration in sheep dips and footbaths

The concentration in sheep dips or foot baths follows directly from the usage instructions.

Model

$$PEC_{dip} = \frac{D_{product} \cdot C_c}{V_{dilution\ water}}$$

#### input

$D_{product}$	dosage product used	[kg] or [l]	S
$C_c$	concentration a.i. in product	[mg <sub>c</sub> .kg <sup>-1</sup> ] or [mg <sub>c</sub> .l <sup>-1</sup> ]	S
$V_{dilution\ water}$	volume of dilution water prescribed	[m <sup>3</sup> ]	S

#### output

$PEC_{dip}$	(prescribed) concentration in dip fluid or foot bath	[mg <sub>c</sub> .m <sup>-3</sup> ]	O
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## 5.2. Exposure of birds and mammals by contaminated feed

Initial concentrations in grass and insects after dipping (fleece) or after disposal of dips and foot baths (grassland) can be estimated with the table given below. Hoerger and Kenaga have described a method, which estimates the concentration of a pesticide on various types of feed after exposure [47]. It gives a relation by which the mean and maximal concentration directly after an application with a certain dosage can be determined. It must be noted, however, that measured data on feed concentrations is always preferable. Only mean concentrations will be used.

If the diet of birds or mammals consists of various kinds of crops or insects, this can be taken into account for the calculation of the  $C_{food}$  by manually calculating the feed concentration from the various sources given in the next table.

Table 31 Initial concentration in feed for birds and mammals.

Type of feed	Mean concentration on feed ( $C_{food}$ ; in $\text{kg}_c \cdot \text{kg}_{food}^{-1}$ )	Maximal concentration on feed ( $C_{food}$ ; in $\text{kg}_c \cdot \text{kg}_{food}^{-1}$ )
short grass	$112 \times \text{DOSE}_{\max} \times 10^{-2}$	$214 \times \text{DOSE}_{\max} \times 10^{-2}$
tall grass	$82 \times \text{DOSE}_{\max} \times 10^{-2}$	$98 \times \text{DOSE}_{\max} \times 10^{-2}$
seeds & small insects	$29 \times \text{DOSE}_{\max} \times 10^{-2}$	$52 \times \text{DOSE}_{\max} \times 10^{-2}$
Pods & large insects	$2.7 \times \text{DOSE}_{\max} \times 10^{-2}$	$11 \times \text{DOSE}_{\max} \times 10^{-2}$

### Input

$\text{DOSE}_{\max}$	apparent maximum dosage	$[\text{kg}_c \cdot \text{m}^{-2}]$	O
-	type of food for the bird species of choice	$[-]$	P
-	type of food for the mammalian species of choice	$[-]$	P

### Output

$C_{\text{food}_{\text{bird}}}$	initial concentration in bird food	$[\text{kg}_c \cdot \text{kg}_{\text{food}}^{-1}]$	S/O
$C_{\text{food}_{\text{mammal}}}$	initial concentration in mammalian food	$[\text{kg}_c \cdot \text{kg}_{\text{food}}^{-1}]$	S/O

The concentration in feed has to be calculated over 5 days for evaluating acute toxicity and over a longer period of time (depending on the exposure period in the toxicity test for the species) for chronic toxicity. For this calculation it is necessary that the half-life time of the pesticide in crops or insects ( $DT50_{\text{food}}$ ) is known. The half-life time should preferably be determined from residue data on crops and insects. If  $DT50_{\text{food}}$  is unknown, no disappearance of the substance is assumed.

$$k_{\text{food}} = \frac{\ln 2}{DT50_{\text{food}}}$$

if  $DT50_{food}$  is not given:

$$C_{food_{x-5}} = C_{food_{T_x}} = C_{food_x}$$

$$C_{food_{bird-5}} = \frac{C_{food_{bird}}}{k_{food} \cdot 5} \cdot (1 - e^{-k_{food} \cdot 5})$$

$$C_{food_{T_x}} = \frac{C_{food_x}}{k_{food} \cdot T_x} \cdot (1 - e^{-k_{food} \cdot T_x})$$

$$x \in \{bird, mammal\}$$

### Input

$k_{food}$	first order disappearance rate of pesticide in food	[d <sup>-1</sup> ]	O
$C_{food_{bird}}$	initial concentration in food for birds	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	S/O
$C_{food_{mammal}}$	initial concentration in food for mammals	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	S/O
$DT50_{food}$	DT50 in food	[d]	S
$T_{bird}$	duration of chronic toxicity test for birds	[d]	S
$T_{mammal}$	duration of chronic toxicity test for mammals	[d]	S

### Output

$C_{food_{bird-5}}$	mean concentration in birds food over 5 days	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	O
$C_{food_{T_{bird}}}$	mean concentration in food over $T_{bird}$ days	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	O
$C_{food_{T_{mammal}}}$	mean concentration in food over $T_{mammal}$ days	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	O

## 5.3. Secondary poisoning

### 5.3.1. Bioconcentration in earthworms

This BCF should preferably be derived experimentally. If no experimentally obtained data are available, it can be estimated by means of the Quantitative Structure Activity Relationships (QSARs) given below. BCF worm has to be calculated for the specific properties of the compartment.

$$C_{worm-T_x} = BCF_{worm} \cdot PEC_{comp_{T_x}} \quad x \in \{bird, mammal\}$$

### Input

$PEC_{comp_{T_{bird}}}$	mean concentration in compartment over $T_{bird}$ days	[mg <sub>c</sub> .kg <sup>-1</sup> ]	O
$PEC_{comp_{T_{mammal}}}$	mean concentration in compartment over $T_{mammal}$ days	[mg <sub>c</sub> .kg <sup>-1</sup> ]	O
$BCF_{worm}$	bioconcentration factor for earthworms	[kg <sub>soil</sub> .kg <sub>wwt</sub> <sup>-1</sup> ]	O

### Output

$C_{worm-T_{bird}}$	mean concentration in earthworms in birds	[mg <sub>c</sub> .kg <sub>wwt</sub> <sup>-1</sup> ]	O
$C_{worm-T_{mammal}}$	mean concentration in earthworms for mammals	[mg <sub>c</sub> .kg <sub>wwt</sub> <sup>-1</sup> ]	O

Table 32 Default setting for the module to calculate the BCF worm-compartment.

parameter	symbol	unit	value
density of earthworm	RHOworm	[kg <sub>wwt</sub> ·m <sup>-3</sup> ]	1000

Model for the calculation of the bioconcentration factor worm-compartment.

$$BCF_{worm} = \frac{K_{worm-water} \cdot RHO_{comp}}{K_{comp-water} \cdot RHO_{worm}}$$

$$K_{comp-water} = F_{water_{comp}} + F_{solid_{comp}} \cdot \frac{Kp_{comp}}{1000} \cdot RHO_{solid_{comp}}$$

$$Kp_{comp} = Foc_{comp} \cdot Koc$$

$$K_{worm-water} = 0.25 \cdot Kow \cdot 0.16$$

#### input

Koc	partition coefficient organic carbon - water	[dm <sup>3</sup> ·kg <sup>-1</sup> ]	S/O
Kow	octanol-water partition coefficient a.i.	[-]	S
RHOcomp	density of compartment	[kg·m <sup>-3</sup> ]	O
RHOsolid <sub>comp</sub>	density of compartment solids	[kg·m <sup>-3</sup> ]	O
RHOworm	density of earthworm	[kg <sub>wwt</sub> ·m <sup>-3</sup> ]	D
Fwater <sub>comp</sub>	fraction water in compartment	[m <sup>3</sup> ·m <sup>-3</sup> ]	O
Fsolid <sub>comp</sub>	fraction solids in compartment	[m <sup>3</sup> ·m <sup>-3</sup> ]	O
Foc <sub>comp</sub>	weight fraction of organic carbon in compartment	[kg·kg <sup>-1</sup> ]	O

#### intermediate results

K <sub>worm-water</sub>	partition coefficient worm and water	[m <sup>3</sup> ·m <sup>-3</sup> ]	O
K <sub>comp-water</sub>	partition coefficient between compartment and water	[m <sup>3</sup> ·m <sup>-3</sup> ]	O
Kp <sub>comp</sub>	partition coefficient between solids and water in compartment	[dm <sup>3</sup> ·kg <sup>-1</sup> ]	O

#### output

BCF <sub>worm</sub>	bioconcentration factor worm-compartment	[kg <sub>comp</sub> ·kg <sub>worm</sub> <sup>-1</sup> ]	O
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We assume that the bioconcentration factor for insects is equal to the BCF for earthworms.

Table 33 Pick-list for the bioconcentration in earthworms.

compartment	Foc <sub>comp</sub> <sup>6</sup> (kg·kg <sup>-1</sup> )	RHOsolid <sub>comp</sub> (kg·m <sup>-3</sup> )	RHOcomp (kg <sub>wwt</sub> ·m <sup>-3</sup> )	Fsolids <sub>comp</sub> (m <sup>3</sup> ·m <sup>-3</sup> )	Fwater <sub>comp</sub> (m <sup>3</sup> ·m <sup>-3</sup> )
soil	0.02	2500	1700	0.6	0.2
dung cattle	0.18	1675	1030	0.09	0.88
dung horses	0.18	1675	900	0.17	0.62
dung sheep	0.18	1675	1090	0.26	0.67

<sup>6</sup> The fraction organic carbon in dung is in fact 0.44. However, because the accumulation-sorption relationship expressed in the QSAR used is no longer valid at high (>30% o.m.) organic matter contents, the value 0.18 is used for the Foc in dung.

<b>input</b>			
-	compartment	[-]	P
<b>output</b>			
Foc <sub>comp</sub>	fraction organic carbon in compartment	[kg.kg <sup>-1</sup> ]	O
RHOSolid <sub>comp</sub>	density dry matter in compartment	[kg.m <sup>-3</sup> ]	O
RHO <sub>comp</sub>	density compartment	[kg <sub>wwt</sub> .m <sup>-3</sup> ]	O
Fsolid <sub>comp</sub>	volume fraction dry matter in compartment	[m <sup>3</sup> .m <sup>-3</sup> ]	O
Fwater <sub>comp</sub>	volume fraction water in compartment	[m <sup>3</sup> .m <sup>-3</sup> ]	O

### 5.3.2. Bioconcentration in fish

The uptake of pesticides by water organisms is calculated by means of the bioconcentration factor (BCF). If no experimentally derived BCF is available, the QSAR-calculation given below can be used.

$$C_{fish-Tx} = BCF_{fish} \cdot C_{water-Tx} \quad x \in \{bird, mammal\}$$

<b>Input</b>			
C <sub>water-Tbird</sub>	mean concentration in water over $T_{bird}$ days	[kg <sub>e</sub> .m <sup>-3</sup> ]	O
C <sub>water-Tmammal</sub>	mean concentration in water over $T_{mammal}$ days	[kg <sub>e</sub> .m <sup>-3</sup> ]	O
BCF <sub>fish</sub>	bioconcentration factor for fish	[m <sub>water</sub> <sup>3</sup> .kg <sub>wet fish</sub> <sup>-1</sup> ]	O
<b>Output</b>			
C <sub>fish-Tbird</sub>	mean concentration in fish for birds	[kg <sub>e</sub> .kg <sub>wet fish</sub> <sup>-1</sup> ]	O
C <sub>fish-Tmammal</sub>	mean concentration in fish for mammals	[kg <sub>e</sub> .kg <sub>wet fish</sub> <sup>-1</sup> ]	O

The methods that estimate a BCF for fish from log Kow are widely used and, in general, the most reliable. The following combination of QSARs is advised in Chapter 4 of the TGD [46]. Domain of physico-chemical properties: log Kow 1 to 10 (outside this range the minimum or maximum Kow is used), molecular weight less than 700 g/mol. For chemicals with a molecular weight of more than 700 g/mol, the BCF tends to decrease but in lack of experimental data, the QSAR can be used as an initial worst-case estimate.

$$\text{if } \log Kow \leq 6 \text{ then: } \log BCF_{fish} = 0.85 \cdot \log Kow - 0.70 - 3$$

$$\text{if } \log Kow > 6 \text{ then: } \log BCF_{fish} = -0.20 \cdot (\log Kow)^2 + 2.74 \cdot \log Kow - 4.72 - 3$$

<b>Input</b>			
Kow	octanol-water partition coefficient	[m <sup>3</sup> .m <sup>-3</sup> ]	S
<b>Output</b>			
BCF <sub>fish</sub>	bioconcentration factor for fish	[m <sup>3</sup> .kg <sub>wwt</sub> <sup>-1</sup> ]	O



## 6. Effect assessment

### 6.1. Deriving PNEC

#### 6.1.1. Aquatic compartments: surface water and groundwater

Depending on the available toxicity data for aquatic organisms, assessment factors are selected for extrapolating single-species toxicity tests to a PNEC for the water compartment. If intermittent release is identified for a stage of the life cycle, only short-term effects need to be considered for risk characterisation of that stage (only for the aquatic compartment). The following trophic levels are distinguished:

- algae (primary producers);
- *Daphnia* (primary consumers);
- fish (secondary consumers);
- other species (e.g. decomposers).

$$LC50_{aqua_{min}} = \min ( LC50_{aqua_i} )$$

$$NOEC_{aqua_{min}} = \min ( NOEC_{aqua_i} )$$

Available data	Additional criteria	TOX <sub>aqua</sub>	AF <sub>aqua</sub>
1-3 LC50s		LC50 <sub>aqua<sub>min</sub></sub>	1000
3 LC50s (independent of avail. NOECs)	If intermittent release is identified for a stage of the life cycle	LC50 <sub>aqua<sub>min</sub></sub>	100
	<b>Same taxonomic group as LC50<sub>aqua<sub>min</sub></sub>?</b>		
1 NOEC additional (not algae!)	yes	NOEC <sub>aqua<sub>min</sub></sub>	100
	no LC50 <sub>aqua<sub>min</sub></sub> /1000 < NOEC <sub>aqua<sub>min</sub></sub> /100	LC50 <sub>aqua<sub>min</sub></sub>	1000
	no LC50 <sub>aqua<sub>min</sub></sub> /1000 ≥ NOEC <sub>aqua<sub>min</sub></sub> /100	NOEC <sub>aqua<sub>min</sub></sub>	100
2 NOEC additional	yes	NOEC <sub>aqua<sub>min</sub></sub>	50
	no	NOEC <sub>aqua<sub>min</sub></sub>	100
3 NOEC algae, <i>Daphnia</i> and fish		NOEC <sub>aqua<sub>min</sub></sub>	10
3 NOEC <i>not</i> algae, <i>Daphnia</i> and fish	yes	NOEC <sub>aqua<sub>min</sub></sub>	10
	no	NOEC <sub>aqua<sub>min</sub></sub>	50

$$PNEC_{water} = \frac{TOX_{aqua}}{AF_{aqua}}$$

**Input**

LC50 <sub>aqua<sub>i</sub></sub>	LC50 for aquatic organisms, trophic level <i>i</i>	[kg <sub>c</sub> .m <sup>-3</sup> ]	S
NOEC <sub>aqua<sub>i</sub></sub>	NOEC for aquatic organisms, trophic level <i>i</i>	[kg <sub>c</sub> .m <sup>-3</sup> ]	S

**Output**

TOX <sub>aqua</sub>	toxicological data used for extrapolation of PNEC	[kg <sub>c</sub> .m <sup>-3</sup> ]	O
AF <sub>aqua</sub>	assessment factor applied in extrapolation of PNEC	[-]	O
PNEC <sub>water</sub>	PNEC for aquatic organisms (surface water r groundwater)	[kg <sub>c</sub> .m <sup>-3</sup> ]	O <sup>c</sup>

**6.1.2. Sediment compartment**

Toxicity data for sediment-dwelling organisms will be scarce. At the moment no standardised test methods or assessment factors have been agreed upon. Therefore, only the equilibrium-partitioning approach is suggested. It should be noted that the equilibrium partitioning method must depart from the PNEC based on chronic effects and not the PNEC derived from LC50s.

$$PNEC_{sed,ep} = \frac{K_{sed-water}}{RHO_{sed}} \cdot PNEC_{water}$$

$$PNEC_{sed} = PNEC_{sed,ep}$$

*EPsed* = 'yes'

**Input**

PNEC <sub>water</sub>	PNEC for aquatic organisms	[kg <sub>c</sub> .m <sup>-3</sup> ]	O <sup>c</sup>
K <sub>sed-water</sub>	sediment-water partition coefficient	[m <sup>3</sup> .m <sup>-3</sup> ]	O <sup>c</sup>
RHO <sub>sed</sub>	bulk density of sediment	[kg <sub>wwt</sub> .m <sup>-3</sup> ]	O <sup>c</sup>
PNEC <sub>sed,ep</sub>	PNEC for sediment-dwelling organisms derived by eq. part.	[kg <sub>c</sub> .kg <sub>wwt</sub> <sup>-1</sup> ]	O <sup>c</sup>

**Output**

EP <sub>sed</sub>	equilibrium partitioning used for PNEC in sediment?	[yes/no]	O <sup>c</sup>
PNEC <sub>sed</sub>	PNEC for sediment-dwelling organisms	[kg <sub>c</sub> .kg <sub>wwt</sub> <sup>-1</sup> ]	O

**6.1.3. Micro-organisms**

Depending on the toxicity data available for micro-organisms, assessment factors are selected for extrapolating results from toxicity tests to a PNEC for the sewage treatment plant or soil micro-organisms. Specific tests in natural media (not in agar) are strongly preferred.

Available ecotox. data	Specific bacterial population? (e.g. nitrifying bacteria or <i>P. putida</i> )	TOX <sub>micro</sub>	AF <sub>micro</sub>
EC50 <sub>micro</sub>	yes	EC50 <sub>micro</sub>	10
	no		100
EC10 <sub>micro</sub>	yes	EC10 <sub>micro</sub>	1
	no		10
NOEC <sub>micro</sub>	yes	NOEC <sub>micro</sub>	1
	no		10

If more than one toxicity value is given, the lower of the resulting PNECs is used.

$$PNEC_{micro-organisms} = \frac{TOX_{micro}}{AF_{micro}}$$

#### Input

EC50 <sub>micro</sub>	EC50 for STP or soil micro-organisms	[mg <sub>c</sub> .l <sup>-1</sup> ] or [mg <sub>c</sub> .kg <sup>-1</sup> ]	S
EC10 <sub>micro</sub>	EC10 for STP or soil micro-organisms	[mg <sub>c</sub> .l <sup>-1</sup> ] or [mg <sub>c</sub> .kg <sup>-1</sup> ]	S
NOEC <sub>micro</sub>	NOEC for STP or soil micro-organisms	[mg <sub>c</sub> .l <sup>-1</sup> ] or [mg <sub>c</sub> .kg <sup>-1</sup> ]	S

#### Output

TOX <sub>micro</sub>	toxicological data used for extrapolation of PNEC	[mg <sub>c</sub> .l <sup>-1</sup> ] or [mg <sub>c</sub> .kg <sup>-1</sup> ]	O
AF <sub>micro</sub>	assessment factor applied in extrapolation of PNEC	[-]	O
PNEC <sub>micro-organisms</sub>	PNEC for STP or soil micro-organisms	[mg <sub>c</sub> .l <sup>-1</sup> ] or [mg <sub>c</sub> .kg <sup>-1</sup> ]	O <sup>c</sup>

### 6.1.4. Earthworms

Depending on the toxicity data available for earthworms, assessment factors are selected for extrapolating results from toxicity tests to a PNEC.

Available ecotox. data	TOX <sub>earthworm</sub>	AF <sub>earthworm</sub>
EC50 <sub>earthworm</sub>	EC50 <sub>earthworm</sub>	100
NOEC <sub>earthworm</sub>	NOEC <sub>earthworm</sub>	10

If more than one toxicity value is given, the lower of the resulting PNECs is used.

$$PNEC_{earthworms} = \frac{TOX_{earthworm}}{AF_{earthworm}}$$

#### Input

EC50 <sub>earthworm</sub>	EC50 for earthworm	[mg <sub>c</sub> .kg <sup>-1</sup> ]	S
NOEC <sub>earthworm</sub>	NOEC for earthworm	[mg <sub>c</sub> .kg <sup>-1</sup> ]	S

#### Output

TOX <sub>micro</sub>	toxicological data used for extrapolation of PNEC	[mg <sub>c</sub> .kg <sup>-1</sup> ]	O
AF <sub>micro</sub>	assessment factor applied in extrapolation of PNEC	[-]	O
PNEC <sub>earthworms</sub>	PNEC for earthworms	[mg <sub>c</sub> .kg <sup>-1</sup> ]	O <sup>c</sup>

### 6.1.5. Plants

Depending on the toxicity data available for plants, assessment factors are selected for extrapolating results from toxicity tests to a PNEC

Available ecotox. data	TOX <sub>plant</sub>	AF <sub>plant</sub>
EC50 <sub>plant</sub>	EC50 <sub>plant</sub>	100
NOEC <sub>plant</sub>	NOEC <sub>plant</sub>	10

If more than one toxicity value is given, the lower of the resulting PNECs is used.

$$PNEC_{plant} = \frac{TOX_{plant}}{AF_{plant}}$$

#### Input

EC50 <sub>plant</sub>	EC50 for plant	[mg <sub>c</sub> .kg <sup>-1</sup> ]	S
NOEC <sub>plant</sub>	NOEC for plant	[mg <sub>c</sub> .kg <sup>-1</sup> ]	S

#### Output

TOX <sub>micro</sub>	toxicological data used for extrapolation of PNEC	[mg <sub>c</sub> .kg <sup>-1</sup> ]	O
AF <sub>micro</sub>	assessment factor applied in extrapolation of PNEC	[-]	O
PNEC <sub>plant</sub>	PNEC for plants	[mg <sub>c</sub> .kg <sup>-1</sup> ]	O <sup>c</sup>

### 6.1.6. Secondary poisoning

The results of mammalian repeated-dose toxicity test(s) are used to assess secondary poisoning effects. Toxicity data for birds may also be present. Extrapolation from such test results gives a predicted no-effect concentration in food that should be protective of other mammalian and avian species. Acute lethal doses LD50 (rat, bird) are not acceptable for extrapolation to chronic toxicity, as these tests are not dietary tests. Acute effect concentrations (LC50, 5-day avian dietary studies) for birds are acceptable for extrapolation. The results of these tests may be expressed as a concentration in the food (mg/kg) or a dose (mg/kg body weight/day) causing no effect. For the assessment of secondary poisoning, the results are converted to the concentration in food (kg<sub>c</sub>/kg food). NOECs converted from NOAELs have the same priority as direct NOECs. The table below gives some conversion factors for laboratory species.

Bird toxicity tests are not usually performed for the test duration specified below ( $T_{bird}$ ). This test duration is however only used to arrive at a representative assessment factor. The user therefore has to decide whether a longer-term bird toxicity test is comparable to 90 day or chronic mammal test.

Available ecotox. data	Duration of (sub-)chronic test	TOX <sub>oral</sub>	A <sub>Foral</sub>
LC50 <sub>bird</sub> only		LC50 <sub>bird</sub>	1000
NOEC <sub>bird</sub>	28 days 90 days chronic	NOEC <sub>bird</sub>	100 30 10
NOEC <sub>mammal,food,chr</sub>	28 days 90 days chronic	NOEC <sub>mammal,food,chr</sub>	100 30 10

If an NOEC for both birds and mammals is given, the lower of the resulting PNECs is used.

$$PNEC_{oral} = \frac{TOX_{oral}}{A_{Foral}}$$

#### Input

LC50 <sub>bird</sub>	LC50 in avian dietary study (5 days)	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	S
NOEC <sub>bird</sub>	NOEC for birds	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	S/O
NOEC <sub>mammal,food,chr</sub>	NOEC for mammals	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	S/O
T <sub>bird</sub>	duration of (sub-)chronic test with birds	[d]	P
T <sub>mammal</sub>	duration of (sub-)chronic test with mammals	[d]	P

#### Output

TOX <sub>oral</sub>	toxicological data used for extrapolation of PNEC	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	O
A <sub>Foral</sub>	assessment factor applied in extrapolation of PNEC	[-]	O
PNEC <sub>oral</sub>	PNEC for secondary poisoning of birds and mammals	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	O <sup>c</sup>

If toxicity data are given as NOAEL only:

$$NOEC_{bird} = NOAEL_{bird} \cdot CONV_{bird}$$

$$NOEC_{mammal,food,chr} = NOAEL_{mammal,oral,chr} \cdot CONV_{mammal}$$

#### Input

NOAEL <sub>bird</sub>	NOAEL for birds	[kg <sub>c</sub> .kg <sub>bw</sub> .d <sup>-1</sup> ]	S
NOAEL <sub>mammal,oral,chr</sub>	NOAEL for mammals	[kg <sub>c</sub> .kg <sub>bw</sub> .d <sup>-1</sup> ]	S/O
CONV <sub>bird</sub>	conversion factor from NOAEL to NOEC	[kg <sub>bw</sub> .d.kg <sub>food</sub> <sup>-1</sup> ]	S
CONV <sub>mammal</sub>	conversion factor from NOAEL to NOEC	[kg <sub>bw</sub> .d.kg <sub>food</sub> <sup>-1</sup> ]	P/S

#### Output

NOEC <sub>bird</sub>	NOEC for birds	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	S/O
NOEC <sub>mammal,food,chr</sub>	NOEC for mammals	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	S/O

Table 34 Conversion factors from NOAEL to NOEC for several mammalian species.

Species	Conversion factor (BW/DFI) CONV <sub>mammal</sub> [kg <sub>bw</sub> .d.kg <sub>food</sub> <sup>-1</sup> ]
<i>Canis domesticus</i>	40
<i>Macaca</i> spp.	20
<i>Microtus</i> spp.	8.3
<i>Mus musculus</i>	8.3
<i>Oryctolagus cuniculus</i>	33.3
<i>Rattus norvegicus</i> (> 6 weeks)	20
<i>Rattus norvegicus</i> (≤ 6 weeks)	10
<i>Gallus domesticus</i>	8

## 6.2. Insecticidal properties

According to the notes for guidance it should be established whether or not the product has insecticidal properties. This is relevant for the exposure of surface water by direct defecation into water grazing animals. Where there is no information a test should be conducted if any of the following apply:

- where residues of drug and/or metabolites are likely to be present in excreta excreted on pasture; inversely, if a substance is not excreted, there is no exposure of dung or surface water, and no further assessment is needed;
- where residues of used high volume topical application are likely to be spread onto land;
- where residues of high volume topical application are likely to be present in fleece.

The following may be used as evidence of (absence of) insecticidal activity:

- product indications may include activity against arthropod species;
- other compounds in the same chemical group may have been shown to have (a lack of) activity against arthropod species;
- drug screening data show activity against arthropod species;
- other evidence, e.g. in the literature, indicating insecticidal activity.

### 6.3. Bodyweight of birds and mammals

If the bodyweight is not given, the user can choose between some species given in Table 35.

Table 35 Bodyweight of birds and mammals.

Species	Range in body weight (g)	Mean body weight (g)
<b>Birds:</b>		
Quail	-	102
Common Partridge	-	375
Common Pheasant	-	1200
Turtle Dove	-	152
Collared Dove	-	195
Woodpigeon	-	440
Chaffinch*	-	22
Goldfinch	-	15
Common Redpoll	-	14
House Sparrow	-	25
<b>Mammals:</b>		
Hedgehog	400-1000	700
Mole	65-135	100
Woodshrew	6-13	9.5
Hare	2500-6500	4500
Rabbit	1300-2500	1900
Fieldmouse*	14-40	27
Woodmouse	14-35	24.5
Brown rat	240-500	370
Badger	7500-15000	11250

\* Organism is used as default

#### Input

-	bird species of concern	[-]	P
-	mammalian species of concern	[-]	P

#### Output

BW <sub>bird</sub>	mean bodyweight of bird species of concern	[kg]	S/O
BW <sub>mammal</sub>	mean bodyweight of mammalian species of concern	[kg]	S/O

## 6.4. Daily food intake for birds and mammals

If the daily food intake (DFI) is not given in the data set, it can be estimated. The DFI of birds and mammals is strongly correlated to the body weight (BW). The relationships used in USES are presented here [45].

*All birds*

$$\log(DFI_{bird} \cdot 1000) = -0.188 + 0.651 \cdot \log(BW_{bird} \cdot 1000)$$

*Passerines*

$$\log(DFI_{bird} \cdot 1000) = -0.4 + 0.85 \cdot \log(BW_{bird} \cdot 1000)$$

*Non passerines*

$$\log(DFI_{bird} \cdot 1000) = -0.521 + 0.751 \cdot \log(BW_{bird} \cdot 1000)$$

*All mammals*

$$\log(DFI_{mammal} \cdot 1000) = -0.629 + 0.822 \cdot \log(BW_{mammal} \cdot 1000)$$

### Input

$BW_{bird}$	mean bodyweight of bird species of concern	[kg]	S/O
$BW_{mammal}$	mean bodyweight of mammalian species of concern	[kg]	S/O

### Output

$DFI_{bird}$	daily food intake for bird species of concern	[kg <sub>food</sub> ·d <sup>-1</sup> ]	S/O
$DFI_{mammal}$	daily food intake for mammalian species of concern	[kg <sub>food</sub> ·d <sup>-1</sup> ]	S/O

## 6.5. Daily water intake of birds and mammals

If no value is known, it is assumed that birds with a mean body weight of less than 100 g have a daily water intake (DWI) of at most 30% of their bodyweight per day. For birds with a mean body weight higher than 100 g this is at most 10% per day. Degradation of the pesticide is not taken into consideration.

if  $BW_x \leq 0.1$  kg then:

$$DWI_x = 0.30 \cdot BW_x \cdot 0.001$$

if  $BW_x > 0.1$  kg then:

$$DWI_x = 0.10 \cdot BW_x \cdot 0.001$$

$$x \in \{\text{bird,mammal}\}$$

**Input**

$BW_{\text{bird}}$	mean bodyweight of bird species of concern	[kg <sub>bw</sub> ]	S/O
$BW_{\text{mammal}}$	mean bodyweight of mammalian species of concern	[kg <sub>bw</sub> ]	S/O

**Output**

$DWI_{\text{bird}}$	daily water intake of bird species of choice	[m <sub>water</sub> <sup>3</sup> .d <sup>-1</sup> ]	O <sup>c</sup>
$DWI_{\text{mammal}}$	daily water intake of mammalian species of choice	[m <sub>water</sub> <sup>3</sup> .d <sup>-1</sup> ]	O <sup>c</sup>

## 6.6. Derivation of the NOEC from NOAEL

If only a NOAEL is given in the input, a NOEC can be converted using the daily food intake and the bodyweight.

$$NOEC_{\text{bird}} = \frac{NOAEL_{\text{bird}} \cdot BW_{\text{bird}}}{DFI_{\text{bird}}}$$

$$NOEC_{\text{mammal,food,chr}} = \frac{NOAEL_{\text{mammal,oral,chr}} \cdot BW_{\text{mammal}}}{DFI_{\text{mammal}}}$$

**Input**

$NOAEL_{\text{bird}}$	NOAEL for birds	[kg <sub>e</sub> .kg <sub>BW</sub> <sup>-1</sup> .d <sup>-1</sup> ]	S
$NOAEL_{\text{mammal,oral}}$	NOAEL for mammals	[kg <sub>e</sub> .kg <sub>BW</sub> <sup>-1</sup> .d <sup>-1</sup> ]	S
$BW_{\text{bird}}$	mean bodyweight of bird species of concern	[kg]	S/O
$BW_{\text{mammal}}$	mean bodyweight of mammalian species of concern	[kg]	S/O
$DFI_{\text{bird}}$	daily food intake for bird species of concern	[kg <sub>food</sub> .d <sup>-1</sup> ]	S/O
$DFI_{\text{mammal}}$	daily food intake for mammalian species of concern	[kg <sub>food</sub> .d <sup>-1</sup> ]	S/O

**Output**

$NOEC_{\text{bird}}$	NOEC for birds in food	[kg <sub>e</sub> .kg <sub>food</sub> <sup>-1</sup> ]	O
$NOEC_{\text{mammal,food,chr}}$	NOEC for mammals in food	[kg <sub>e</sub> .kg <sub>food</sub> <sup>-1</sup> ]	O



## 7. Risk assessment

In risk assessment, exposure levels are compared to suitable (no-)effect levels to yield so-called Risk Characterisation Ratios (RCR) for each protection goal.

### 7.1. RCR for birds and mammals exposed through grass and insects

Risk for birds and mammals eating insects from fleece and insects and grass on land after disposal of dips and foot baths will be assessed using acute exposure only. The short-term concentration in food is directly compared to the LC50. With the daily food intake (DFI) of the species and its bodyweight, LD50s if present, can be translated to LC50s in food.

$$RCR_{food}^{bird-1} = \frac{C_{food}^{bird} \cdot DFI_{bird} \cdot I}{LD50_{bird} \cdot BW_{bird}}$$

$$RCR_{food}^{bird-5} = \frac{C_{food}^{bird-5}}{LC50_{bird}}$$

The  $I$  in the formula above is the number of feeding days assumed to be representative with respect to the single dose toxicity value (LD50) used.

$$RCR_{food}^{mammal-1} = \frac{C_{food}^{mammal} \cdot DFI_{mammal} \cdot I}{LD50_{mammal,oral} \cdot BW_{mammal}}$$

#### Input

$LD50_{bird}$	LD50 for birds	$[mg_c \cdot kg_{BW}^{-1}]$	S
$LC50_{bird}$	LC50 in food for birds	$[mg_c \cdot kg_{food}^{-1}]$	S
$LD50_{mammal, oral}$	LD50 for mammals	$[mg_c \cdot kg_{BW}^{-1}]$	S
$DFI_{bird}$	daily food intake for bird species of concern	$[kg_{food} \cdot d^{-1}]$	S/O
$DFI_{mammal}$	daily food intake for mammalian species of concern	$[kg_{food} \cdot d^{-1}]$	S/O
$C_{food_x}$	initial concentration in food for $x$	$[mg_c \cdot kg_{food}^{-1}]$	S/O
$C_{food_{x-5}}$	mean concentration in food for $x$ over 5 days	$[mg_c \cdot kg_{food}^{-1}]$	O
$BW_{bird}$	mean bodyweight of bird species of concern	$[kg]$	S/O
$BW_{mammal}$	mean bodyweight of mammalian species of concern	$[kg]$	S/O

#### Output

$RCR_{food}^{bird-1}$	RCR for single dose toxicity to birds (PED/LD50)	$[-]$	$O^c$
$RCR_{food}^{bird-5}$	RCR for acute toxicity to birds (PEC/LC50)	$[-]$	$O^c$
$RCR_{food}^{mammal-1}$	RCR for single dose toxicity to mammals (PED/LD50)	$[-]$	$O^c$

## 7.2. RCR for birds and mammals exposed through uptake of water or dipping fluid

Besides eating granules, treated seeds, crops or insects, birds and mammals can also be exposed to a pesticide by the uptake of water. This can be either surface water or water on leaves and crops. This route will only be used if the medicinal product is used as sheep dip or foot bath.

$$RCR_{dip_{bird}} = \frac{PEC_{dip} \cdot DWI_{bird} \cdot I}{LD50_{bird} \cdot BW_{bird}}$$

$$RCR_{surf_{bird}} = \frac{PEC_{sw} \cdot DWI_{bird} \cdot I}{LD50_{bird} \cdot BW_{bird}}$$

$$RCR_{dip_{mammal}} = \frac{PEC_{dip} \cdot DWI_{mammal} \cdot I}{LD50_{mammal,oral} \cdot BW_{mammal}}$$

$$RCR_{surf_{mammal}} = \frac{PEC_{sw} \cdot DWI_{mammal} \cdot I}{LD50_{mammal,oral} \cdot BW_{mammal}}$$

### Input

LD50 <sub>bird</sub>	LD50 for birds	[mg <sub>c</sub> ·kg <sub>BW</sub> <sup>-1</sup> ]	S
LD50 <sub>mammal,oral</sub>	LD50 for mammals (oral)	[mg <sub>c</sub> ·kg <sub>BW</sub> <sup>-1</sup> ]	S
DWI <sub>bird</sub>	daily water intake of bird species of choice	[l <sub>water</sub> ·d <sup>-1</sup> ]	O/S
DWI <sub>mammal</sub>	daily water intake of mammalian species of choice	[l <sub>water</sub> ·d <sup>-1</sup> ]	O/S
BW <sub>bird</sub>	mean bodyweight of bird species of concern	[kg <sub>bw</sub> ]	O
BW <sub>mammal</sub>	mean bodyweight of mammalian species of concern	[kg <sub>bw</sub> ]	O
PEC <sub>dip</sub>	concentration in dip or foot bath	[mg <sub>c</sub> ·l <sup>-1</sup> ]	O
PEC <sub>sw</sub>	concentration in surface water	[mg <sub>c</sub> ·l <sup>-1</sup> ]	O

### Output

RCR <sub>dip<sub>bird</sub></sub>	RCR for drinking dipping fluid to birds (PEC/LC50)	[-]	O <sup>c</sup>
RCR <sub>surf<sub>bird</sub></sub>	RCR for drinking surface water to birds (PEC/LC50)	[-]	O <sup>c</sup>
RCR <sub>dip<sub>mammal</sub></sub>	RCR for drinking dipping fluid to mammals (PEC/LC50)	[-]	O <sup>c</sup>
RCR <sub>surf<sub>mammal</sub></sub>	RCR for drinking surface water to mammals (PEC/LC50)	[-]	O <sup>c</sup>

### 7.3. RCR for terrestrial organisms

Earthworms, nitrifying micro-organisms and plants are exposed to concentrations in target soil.

$$RCR_{earthworm} = \frac{PEC_{soil}}{PNEC_{earthworm}}$$

$$RCR_{nitr} = \frac{PEC_{soil}}{PNEC_{nitr}}$$

$$RCR_{plant} = \frac{PEC_{soil}}{PNEC_{plant}}$$

#### Input

PEC <sub>soil</sub>	predicted concentration in soil	[mg <sub>c</sub> .kg <sub>dwt</sub> <sup>-1</sup> ]	O
PNEC <sub>earthworm</sub>	PNEC for earthworms	[mg <sub>c</sub> .kg <sub>dwt</sub> <sup>-1</sup> ]	S
PNEC <sub>nitr</sub>	PNEC for nitrifying bacteria in soil	[mg <sub>c</sub> .kg <sub>dwt</sub> <sup>-1</sup> ]	S
PNEC <sub>plant</sub>	PNEC for plants	[mg <sub>c</sub> .kg <sub>dwt</sub> <sup>-1</sup> ]	S

#### Output

RCR <sub>earthworm</sub>	short term RCR for earthworms	[-]	O <sup>c</sup>
RCR <sub>nitr</sub>	short term RCR for nitrifying bacteria	[-]	O <sup>c</sup>
RCR <sub>plant</sub>	short term RCR for plants	[-]	O <sup>c</sup>

### 7.4. RCR for birds and mammals exposed through earthworms

$$RCR_{earthwormTbird} = \frac{C_{earthworm-Tbird}}{PNEC_{oral}}$$

$$RCR_{earthwormTmammal} = \frac{C_{earthworm-Tmammal}}{PNEC_{oral}}$$

#### Input

PNEC <sub>oral</sub>	PNEC for secondary poisoning of birds and mammals	[kg <sub>c</sub> .kg <sub>food</sub> <sup>-1</sup> ]	O <sup>c</sup>
C <sub>earthworm-Tbird</sub>	mean concentration in earthworms over $T_{bird}$ days	[mg <sub>c</sub> .kg <sub>wet worm</sub> <sup>-1</sup> ]	O
C <sub>earthworm-Tmammal</sub>	mean concentration in earthworms over $T_{mammal}$ days	[mg <sub>c</sub> .kg <sub>wet worm</sub> <sup>-1</sup> ]	O

#### Output

RCR <sub>earthwormTbird</sub>	RCR for earthworm-eating birds (PEC/PNEC)	[-]	O <sup>c</sup>
RCR <sub>earthwormTmammal</sub>	RCR for earthworm-eating mammals (PEC/PNEC)	[-]	O <sup>c</sup>

## 7.5. RCR for aquatic organisms

The water organisms fish, crustaceans and algae are supposed to be exposed to water concentrations that are the mean of the concentration over a period of time. For acute exposure the initial value is taken, for chronic exposure a different value is used, depending on the exposure period in the toxicity test. If there is only release through an STP, the concentration in the effluent after

Discharge from fisheries: the PEC used will be the exposure concentration calculated for the duration of the test for the most sensitive organisms (i.e. the species with the lowest NOEC).

Indirect exposure: The PEC used will be the initial exposure concentration.

Effects/Exposure	Exposure	Effects
$RCR_{water}$	if $NOEC_{algae} = \text{lowest}$ : $C_{water_{pest-4}}$ if $NOEC_{crus} = \text{lowest}$ : $C_{water_{pest-21}}$ if $NOEC_{fish} = \text{lowest}$ : $C_{water_{pest-28}}$	$PNEC_{water}$

$$RCR_{water} = \frac{PEC_{sw_{vmp-T}}}{PNEC}$$

### Input

$PEC_{water_{vmp-T}}$	concentration in water over $T$ days, $T \in \{0,4,21,28\}$	$[mg_c.l^{-1}]$	O
$PNEC_{water}$	PNEC for aquatic organisms	$[mg_c.l^{-1}]$	O <sup>c</sup>

### Output

$RCR_{water}$	RCR for the aquatic ecosystem	$[-]$	O <sup>c</sup>
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dilution and sorption to suspended matter will be used as exposure concentration.

## 7.6. RCR for sediment-dwelling organisms

The sediment are supposed to be exposed to water concentrations in the ditch that are the mean of the concentration over a period of time. The value chosen depends on the exposure period in the toxicity test. If there is only release through an STP, the concentration in the effluent after dilution and sorption to suspended matter will be used as exposure concentration.

$$RCR_{sed} = \frac{C_{sed_T}}{PNEC_{sed}}$$

**Input**

$C_{sed,T}$	mean concentration in sediment over $T$ days, $T \in \{7,28\}$	$[\text{mg}_c \cdot \text{kg}_{\text{wwt}}^{-1}]$	O
$PNEC_{sed}$	PNEC for sediment-dwelling organisms	$[\text{mg}_c \cdot \text{kg}_{\text{wwt}}^{-1}]$	O

**Output**

$RCR_{sed-7}$	short term RCR for sediment organisms (PEC/LC50)	[-]	O <sup>c</sup>
$RCR_{sed-28}$	long term RCR for sediment organisms (PEC/NOEC)	[-]	O <sup>c</sup>

## 7.7. RCR for birds and mammals exposed through fish

The uptake of veterinary medicinal products by water organisms is calculated by means of the bioconcentration factor (BCF). If no experimentally derived BCF is available, the QSAR-calculation given in § 5.3.2 is used.

$$RCR_{fish_{bird}} = \frac{C_{fish-Tbird}}{PNEC_{oral}}$$

$$RCR_{fish_{mammal}} = \frac{C_{fish-Tmammal}}{PNEC_{oral}}$$

**Input**

$PNEC_{oral}$	PNEC for secondary poisoning of birds and mammals	$[\text{kg}_c \cdot \text{kg}_{\text{food}}^{-1}]$	O <sup>c</sup>
$C_{fish-Tbird}$	mean concentration in fish over $T_{bird}$ days	$[\text{mg}_c \cdot \text{kg}_{\text{wet fish}}^{-1}]$	O
$C_{fish-Tmammal}$	mean concentration in fish over $T_{mammal}$ days	$[\text{mg}_c \cdot \text{kg}_{\text{wet fish}}^{-1}]$	O

**Output**

$RCR_{fish_{bird}}$	RCR for fish eating birds (PEC/NOEC)	[-]	O <sup>c</sup>
$RCR_{fish_{mammal}}$	RCR for fish eating mammal (PEC/NOEC)	[-]	O <sup>c</sup>

## 7.8. RCR for groundwater organisms

For veterinary medicinal products an RCR for the groundwater ecosystem will be calculated.

$$RCR_{ground\ water} = \frac{PEC_{gw_{vmp}}}{PNEC_{ground\ water}}$$

**Input**

$PEC_{gw_{vmp}}$	predicted concentration in groundwater	$[\text{mg}_c \cdot \text{l}^{-1}]$	O
$PNEC_{ground\ water}$	PNEC for groundwater organisms	$[\text{mg}_c \cdot \text{l}^{-1}]$	O <sup>c</sup>

**Output**

$RCR_{ground\ water}$	RCR for the groundwater ecosystem	[-]	O <sup>c</sup>
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## 7.9. RCR for micro-organisms in STP

The concentration of the chemical in the aeration tank of the sewage treatment plant (STP) is compared to the no-effect concentration for micro-organisms. The concentration during an emission episode is used.

$$RCR_{stp} = \frac{PEC_{stp}}{PNEC_{micro-organisms}}$$

### Input

PEC <sub>stp</sub>	local PEC in STP during emission episode	[mg <sub>c</sub> .l <sup>-1</sup> ]	O
PNEC <sub>micro-organisms</sub>	PNEC for STP micro-organisms	[mg <sub>c</sub> .l <sup>-1</sup> ]	O <sup>c</sup>

### Output

RCR <sub>stp</sub>	RCR for sewage treatment plant	[-]	O <sup>c</sup>
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## 7.10. RCR for beneficial arthropods

The effect of the chemical present in dung at field concentrations to dung fly and dung beetle is compared to the trigger for field testing (50% effect).

The effect of the chemical present in dung at field concentrations to grassland arthropods (insects, mites, Collembola, etcetera) is compared to the trigger for field testing (79% effect).

Table 36 Default setting for the module to calculate the RCR<sub>dung insects</sub>.

parameter	symbol	unit	value
trigger value for field testing dung insects	-	[-]	50
trigger value for field testing grassland arthropods	-	[-]	79

$$RCR_{dung\ insects} = \frac{\%effect}{50}$$

$$RCR_{grassland\ arthropods} = \frac{\%effect}{79}$$

### Input

%effect	effect percentage at field concentration	[-]	O
-	trigger value for field testing	[-]	D <sup>c</sup>

### Output

RCR <sub>dung insects</sub>	RCR for dung insects	[-]	O <sup>c</sup>
RCR <sub>grassland arthropods</sub>	RCR for grassland arthropods	[-]	O <sup>c</sup>

## 8. Evaluation

The reviewer performs the assessment with the data provided to the extent applicable to the phase under consideration.

### 8.1. Phase I

No evaluation is performed unless the dosage is available.

- ✓ an exposure evaluation is performed using the dosage.
- ✓ compare the available information to the trigger values in Phase I [33].

### 8.2. Phase II-a

- ✓ dossier completeness check: no further evaluation is performed unless all compulsory information is made available.
- ✓ hazard assessment or risk characterisation: in Phase II Tier A the exposure is compared to the effect.
- ✓ risk estimation: in the event Phase II Tier A trigger values are exceeded, a quantitative estimation of probabilities of effects by including uncertainty analysis is performed, including proposed risk management strategies.
- ✓ requests for supplementary information: When certain (necessary or desirable) information is lacking, or when phase II Tier B evaluation is necessary, requests for complementary or supplementary information are drawn up.

The Phase II Tier A hazard assessment is a complete assessment including emission, distribution, exposure, effects, and hazard identification. At this point, it is important to consider all available documentation relevant to the environmental risk assessment of the product.

### 8.2.1. Emission and distribution assessment

The second phase starts with a more detailed evaluation of the possible fate of the product. All default values can be changed due to cogent argumentation for circumstances deviating from the model parameters: e.g. body weights at administration, percentage of the herd treated, incidence of treatment over the year when more cycles are grown.

Proceed with further assessment only for the relevant compartments according to Figure 1.

- In case of emission to slurry or excretion by grazing animals studies on metabolism in slurry, soil and manure, and on animal excretion may be required and/or delivered. This elaborated assessment yields environmental concentrations in soil, water and groundwater. In Phase II, when at least three  $DT50_{\text{soil}}$  and three  $K_{oc}$  are available, the model PEARL is used to calculate the concentration in the ground water<sup>7</sup>.
- In case grazing animals excrete the substance, dung pat degradation may be a point of concern and studies to investigate this aspect may be asked for.
- In case grazing animals excrete the substance and it has insecticidal properties, assess the exposure of the surface water. Run-off into surface water is not taken into consideration in case the soil is reached via grazing animals.
- In case of external use of high-volume topical applications of insecticidal substances emission to surface dwelling grassland invertebrates and fleece dwelling parasites is direct, and so is distribution to birds via the dipping bath. Birds are then also exposed through contaminated insects that they use as food source.
- The prescribed instructions on how to deal with residual dipping fluid are used for the assessment. When these are not specified, the concentration of the substance in the dipping fluid is divided by the expected surface area the fluid is spread over to give the dosage for the soil, ground water and for the grassland invertebrates. This dosage is also used to make the exposure assessment for birds via invertebrates. The concentration in the dipping fluid is the exposure concentration for birds. One should be aware of the possibility that disposal of sheep dips onto land (or even into the ditch) might not be part of recognised good agricultural practice, and as such may not be assessed.
- In case of use in fisheries, the concentrations in the STP aeration tank, in the surface water and in the soil and ground water are calculated based on the scenario presented in Chapter 3 and the models in Chapter 4. Depending on the use in the fish industry a long term exposure might be expected and in that event the concentration in the sediment is calculated over a longer period.

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<sup>7</sup> The model choice follows the requirements from the Netherlands Pesticide Act.

### 8.2.2. Exposure assessment

When a product has an internal or external application and will enter the environment one has assessed the concentration in relevant compartments. See Chapter 4. Gather all calculated concentrations.

For other emission routes and specific distribution routes an exposure assessment needs to be performed. Choose from the possibilities mentioned below.

The product is used in fisheries:

- Substances with a  $\log K_{ow} > 3$  or a  $BCF_{fish} > 1000$  (readily degradable substances) or a  $BCF_{fish} > 100$  (persistent substances) are assessed on secondary poisoning of vertebrates by fish.

The product has an external application and will enter the environment directly:

- Concentrations in feed and 'drinking water' for birds are calculated and presented.

The product has an external or internal application and will enter the environment via slurry:

- Assess secondary poisoning via earthworms from soil in case  $BCF_{earthworm} > 20$  l/kg ( $\log K_{ow} > 5$ ).

The product has an internal or external application and will enter the environment via excreta of grazing livestock:

- Assess secondary poisoning via earthworms from dung.

### 8.2.3. Effect assessment

Chapter 6 contains general procedures for effect assessment. The regulatory minimum requirements on toxicity data are different for the various routes of exposure reported below. Should more information be available, then this can be used.

#### *Effect assessment for residues reaching the soil (via manure, dung, or fish sludge).*

##### Persistence

Three soil transformation rate studies are required to assess the potential for residues to build up in the soil. This effect is considered relevant at a mean  $DT_{90soil} > 1$  year. In case the mean  $DT_{50soil} > 60$  days hazard identification for soil micro-organisms is considered necessary, and the trigger for earthworms is lowered (see figure 1).

##### Mobility and leaching

Three soil adsorption studies are required to assess the potential for residues to run off to the surface water. In case the mean  $K_{oc}$  is  $< 500$  l/kg and the soil is reached via spreading of slurry the  $PEC_{surface\ water}$  is calculated and the effect assessment is continued there for surface water.

### Phytotoxicity

The most useful EC50 for plants (germination, growth, and vigour) is determined. This value is not used for residues on pastures, only for arable land.

### Earthworms

The most useful LC50 for earthworms is determined. The result is normalised to 3.5% organic matter for soil and to 30% organic matter for dung.

### Soil micro-organisms

In case the DT50soil >60 days, the data on inhibition of soil nitrification are required to derive a PNEC.

### Birds

For substances with logKow >5 at least one NOEC from an avian reproduction test is required to calculate the PNEC. Endpoints should be growth, mortality or reproduction (e.g. blood parameters are not relevant). Feeding studies with mammals are acceptable as alternative: see §6.1.6.

### ***Effect assessment for residues reaching the ground water***

Concentration in the groundwater.

The standard for groundwater of 0.1 µg/l as given in Directive 80/778/EEG is used. Should the standard be exceeded, a Phase II Tier B assessment is required.

Ground water organisms.

In case the PECgroundwater is >0.1 µg/l, one acute *Daphnia* test is required. Based on the one *Daphnia* test the PNEC for groundwater organisms is derived.

### ***Effect assessment for residues reaching the surface water indirectly.***

Via leaching.

Using at least the results from one acute algae test, one acute *Daphnia* test, and one acute fish test, a PNEC is derived.

Via direct excretion into surface water.

Only in case the substance has insecticidal properties the result from one acute *Daphnia* test is required. Based on the one *Daphnia* test the PNEC is derived.

Via these indirect routes the risk on secondary poisoning via fish is considered negligible.

***Effect assessment for residues reaching the surface water via discharge from fisheries.*****Waterorganisms.**

Using the results from at least one acute algae test, one acute daphnid test, and one acute fish test, a PNEC is derived.

When the DT50 hydrolysis/photolysis is >4 days or the Kow >1000, the long-term exposure is calculated for both water and sediment.

NOEC and PNEC values are derived for aquatic and sediment organisms, as are BCF values from fish bioconcentration studies and MPC for sediment. PNEC based on three NOECs are derived.

**Birds.**

For substances with logKow >3 at least one NOEC from an avian reproduction test is required.

***Effect assessment for residues from high-volume topical application fluids.*****Grassland invertebrates.**

In a laboratory toxicity test with a susceptible stage of at least two grassland dwelling species a test is performed and the percentage effect is determined. If data from worst-case laboratory tests indicate a more than 79% effect, in any of the test species, then the next stage of testing will be required: a dose-response laboratory test using natural substrate. This test should be performed with a maximum of four species ( $\geq 1$  used in previous test) and a natural substrate (grass). If data from these tests indicate a more than 79% effect, in any of the test species, then the next stage of testing will be required: field studies. For this field study the reader is referred to the EMEA (1997) document, as this stage is part of the Phase II Tier B testing.

**Birds.**

From avian acute toxicity tests LD50 values are derived. From avian short-term dietary toxicity tests LC50 values are derived. The lowest values are used for the assessment of the dietary route.

***Effect assessment for residues in dung.*****Dung fauna.**

In case the substance has a DT50 (soil) >60 days, the LC50 for earthworms needs to be determined. The corrected value for 18% o.c. is used.

In case the substance has insecticidal properties, for 1 species dung fly and 1 species dung beetle it is determined whether the effect of the residue is >50% (mortality, reproduction, parasitising capacity). In the event the effect is >50% for dung insects, field studies are required.

#### **8.2.4. Hazard quotients**

The hazards quotients are presented and comments are given on the results; e.g. when trigger are exceeded. The hazards quotients are given as RCR values: Risk Characterisation Ratio (see Chapter 7). The RCR are presented related to the route of exposure:

- via spreading of slurry and sludge;
- earthworms, plants, nitrification, ground water, waterorganisms, secondary poisoning via earthworms;
- via excretion of dung and urine;
- earthworms, nitrification, ground water, waterorganisms, poisoning of birds and mammals via dung; dung fly and dung beetle.
- via discharge to STP/surface water from fisheries;
- activated sludge, waterorganisms, sediment organisms, secondary poisoning via fish;
- via external application of (high volume) topical applications:
- earthworms, nitrification, ground water, grassland invertebrates, dietary poisoning birds and mammals, direct uptake fluid by birds.

Below the Phase II Tier A decision schemes are given.

### **8.3. Phase II-b**

A phase II-b assessment is performed by the notifier in co-operation with the evaluating institute (RIVM) and is made to measure the type of product and the usage. This stage of assessment is subject to expert judgement. As a general rule: all decisions on requests for information should be reported and motivated before the research is carried out.

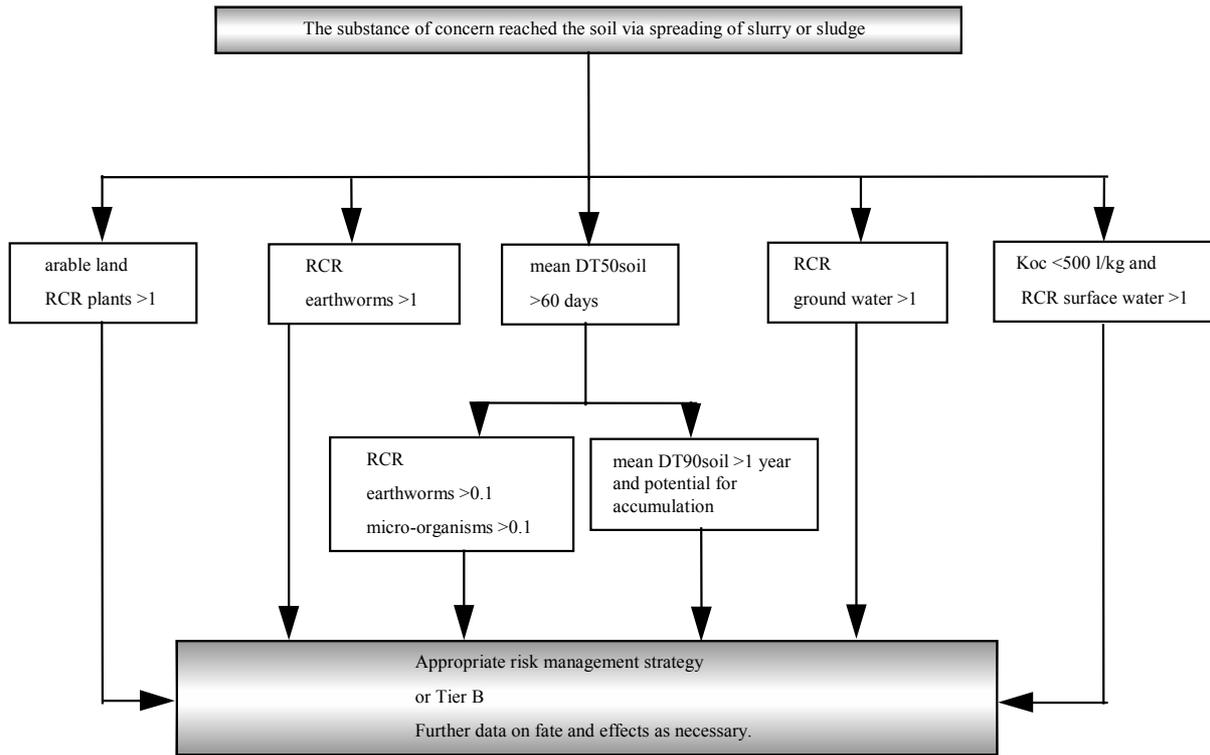


Figure 1. Phase II tier A decision tree for residues spread with slurry.

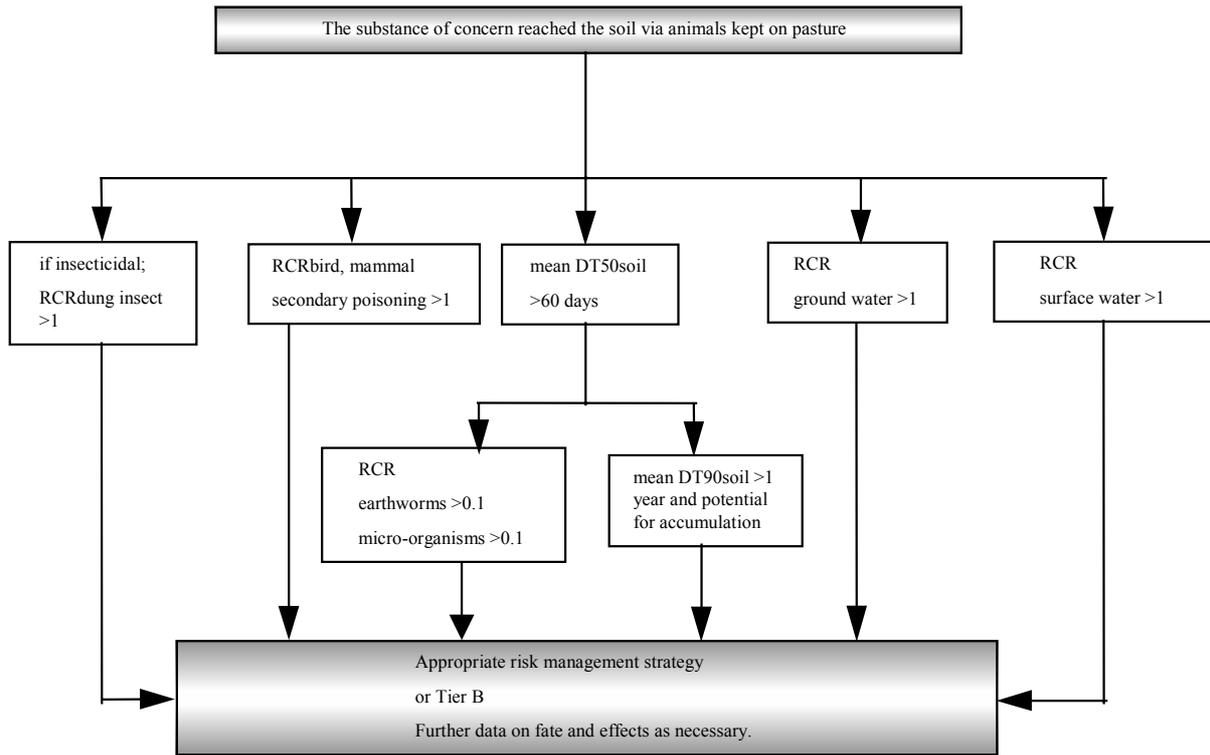


Figure 2. Phase II Tier A decision tree for residues spread by grazing animals.

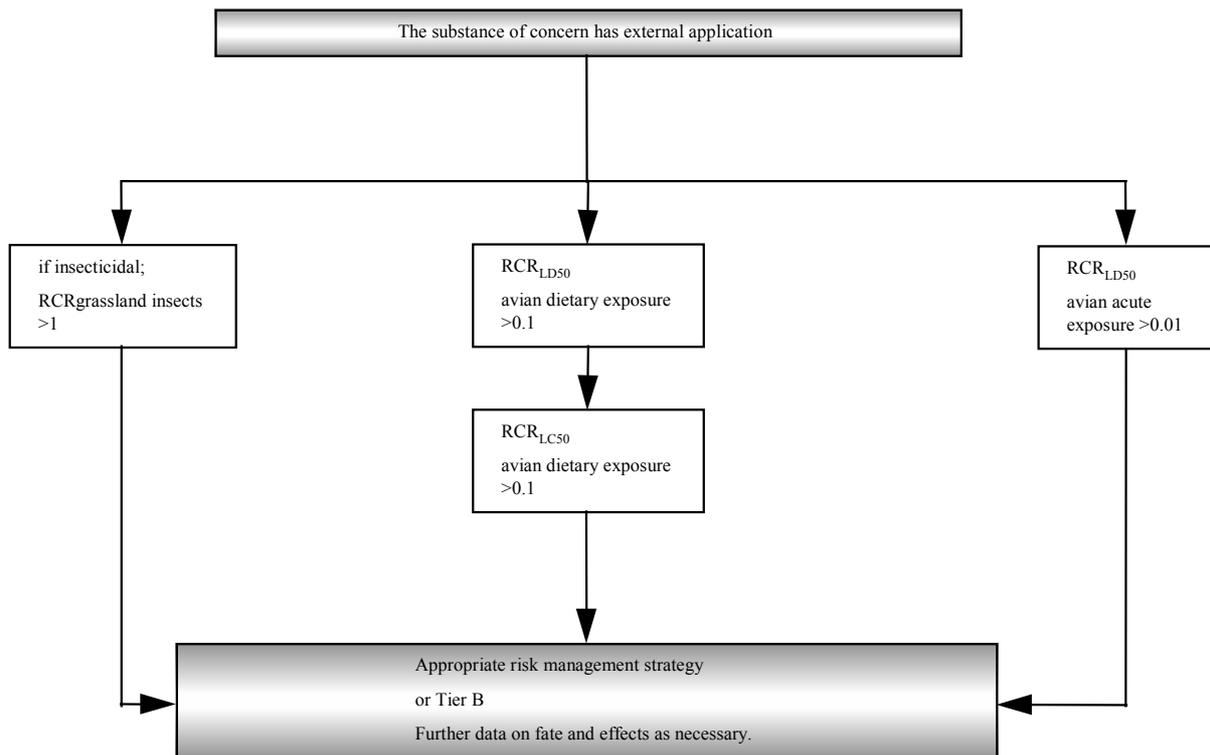


Figure 3. Phase II Tier A decision tree for residues spilled outdoors.

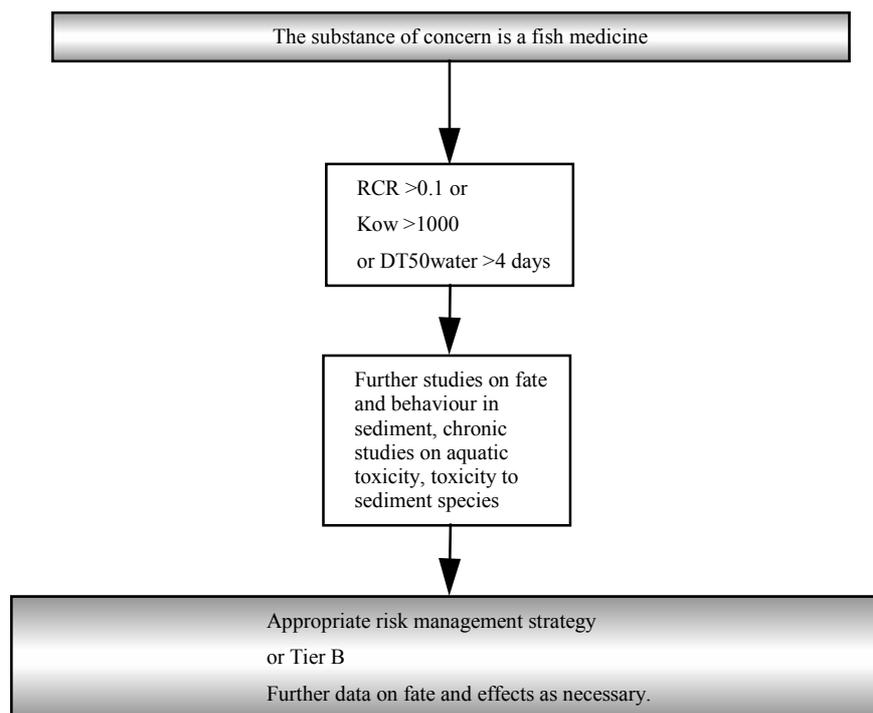


Figure 4. Phase II Tier A decision tree for fish medicines.

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## Appendix I Dung production

### I.1 Dung production in relation to animals and habitat

Many medicine residues will be excreted with the urine and faeces. These two excreta are therefore important emission routes. The excreta consist of faeces and urine. In the field these two components are dispersed separately, whereas in the stable they are mixed.

The excreta obtained indoors, referred to as manure, are collected and stored for some time. Slurry is the mixture of manure and materials from the housing of animals (e.g. spilled feed, straw, litter, sand, water, down).

The faeces of grazing animals in the field is referred to as dung. As the dung is not collected and stored over time, for the hazard assessment the peak concentrations and the drug excretion pattern in time are important. We need to know how much faeces and urine the grazing animals produce and how many times they defecate. The figures used for the mass balance of dry matter and water are drawn up in association with Mr. van Vuren of ID-DLO Lelystad and Dr. G. Bruin of PR Lelystad (see I.2.3). They are based on indicative values for a 600 kg dairy cow. For a Phase II Tier B assessment more detailed information should be gathered.

Faeces production is related to feed intake. Grazing animals feed on grass that contains 80 to 85% water [48]. When grazing they ingest 0.4-14% of the daily dry matter (DM) intake as soil. We assume the soil intake amounts to 2.5% of the daily dry feed intake [45]. This soil contains approx. 33% w/w water. About 75% of the ingested feed is digested for growth, metabolism and milk production. The milk contains approx. 12.5% dry matter. The large animals loose approx. 10 kg water/day from transpiration and breathing. Depending on the mineral intake (Na, K, Mg) dairy cow produce 20-60 litre urine a day. The density of cow dung is approx. 1.04 kg/l; of horses 0.9 kg/l [40].

In some investigations in the period 1945-1966, cows were observed to defecate 10.5 times a day. The fresh cow dung contains up to 89% water. The dry matter consists of 10-20% dead and living bacteria, 20-40% ashes, and mostly undigested plant material. Beef cattle was reported to void approx. 1-3 kg organic matter (o.m.) per day, and dairy cows 2.8-3.5 kg o.m. per day: mean 3.22 kg o.m. (s.d. 0.3, n=5). With 20% ash on dry weight this means 4 kg dry matter. Marsh assumes that the faeces contain 14% dry matter: the production corresponds with 28.6 (s.d. 2.7) kg faeces per day for dairy cows. Four data points are obtained from grazed dairy cows, and one from housed dairy cows. Housed dairy cows produced 3.5 kg o.m.; 31 kg faeces. The bodyweight of these cattle however, was not reported [49].

In an investigation into the nutritional limitations of free-ranging cattle, [50] measured the Daily Feed Intake (DFI) of the steers. In April on the riverine grassland the cattle (319 kg) had a high DFI of 40 g dw/kg bw: 12.76 kg dw per day. After six months, in November, the cows weighed 528 kg and the DFI was 20 g dw/kg bw: 10.56 kg dw per cow per day. Apparently grazing cattle do eat more in spring than in autumn, the difference can be as much as 170%. Season, habitat, and body weight influence the amount of dry matter eaten.

## I.2 Partitioning of dung

### I.2.1 Dung dry matter

Table 37 Default settings for the calculations on dung dry matter.

parameter	symbol	unit	value
density of solids	RHOSolid	[kg.m <sup>-3</sup> ]	2500
density of o.m.	RHOom	[kg.m <sup>-3</sup> ]	1400
weight fraction solids (not o.m.) in dung solids	Fsolid <sub>dung</sub>	[kg.kg <sup>-1</sup> ]	0.25
weight fraction organic matter in dung solids	Fom <sub>dung</sub>	[kg.kg <sup>-1</sup> ]	0.75

Model calculation

$$RHOSolid_{dung} = Fsolid_{dung} \cdot RHOSolid + Fom_{dung} \cdot RHOom$$

$$Foc_{dung} = 0.59 \cdot Fom_{dung}$$

#### input

RHOSolid	density of solids in soil	[kg.m <sup>-3</sup> ]	D
RHOom	density of organic matter	[kg.m <sup>-3</sup> ]	D
Fsolid <sub>dung</sub>	weight fraction solids (not o.m.) in dry dung	[kg.kg <sup>-1</sup> ]	D
Fom <sub>dung</sub>	weight fraction organic matter in dry dung	[kg.kg <sup>-1</sup> ]	D

#### output

Foc <sub>dung</sub>	weight fraction of organic carbon in dry dung	[kg.kg <sup>-1</sup> ]	O
RHOSolid <sub>dung</sub>	density of dung solids	[kg <sub>dwt</sub> .m <sup>-3</sup> ]	O

For calculations of partitioning of organic substances between organic matter and water in dung a value of 18% organic carbon is used, because at high organic matter levels (>18%) the relationship between sorption and Foc is different from the one at lower levels (1-18% o.c.).

## I.2.2 Partitioning in fresh dung

Table 38 Pick-list for the partitioning of dung.

animal	Fair <sub>dung</sub> [m <sup>3</sup> .m <sup>-3</sup> ]	Fsolid <sub>dung</sub> [m <sup>3</sup> .m <sup>-3</sup> ]	Fwater <sub>dung</sub> [m <sup>3</sup> .m <sup>-3</sup> ]
dairy cow	0.025	0.075	0.90
beef cattle	0.03	0.09	0.88
horse	0.21	0.17	0.62
sheep	0.07	0.26	0.67

### input

- livestock main category [-] P

### output

Fcomp<sub>dung</sub> volume fractions in dung [m<sup>3</sup>.m<sup>-3</sup>] O

Table 39 Default settings for the partitioning of dung.

parameter	symbol	unit	value
density of dung solids	RHOSolid <sub>dung</sub>	[kg <sub>dwt</sub> .m <sup>-3</sup> ]	1675
density of water	RHOwater	[kg.m <sup>-3</sup> ]	1000
density of air	RHOair	[kg.m <sup>-3</sup> ]	1.3

### Model calculation

$$RHO_{dung} = Fair_{dung} \cdot RHO_{air} + Fwater_{dung} \cdot RHO_{water} + Fsolid_{dung} \cdot RHOSolid_{dung}$$

### input

RHOair density of air [kg.m<sup>-3</sup>] D

RHOwater density of water [kg.m<sup>-3</sup>] D

RHOSolid<sub>dung</sub> density of dung solids [kg<sub>dwt</sub>.m<sup>-3</sup>] O

Fair<sub>dung</sub> fraction air in dung [m<sup>3</sup>.m<sup>-3</sup>] O

Fwater<sub>dung</sub> fraction water in dung [m<sup>3</sup>.m<sup>-3</sup>] O

Fsolid<sub>dung</sub> fraction solids in dung [m<sup>3</sup>.m<sup>-3</sup>] O

### output

RHOdung density of fresh dung [kg<sub>wwt</sub>.m<sup>-3</sup>] O

## I.2.3 Calculation of dung production.

The values in the mass balance (Table 40) are derived from Berende [41,51]. The data for the dairy cow are based on cows with a milk production of 40 kg milk/day, for cattle on data of 28 cattle with body weight of 212-479 kg. The data on sheep are averages based on two-and-a-half year old and four year old ewes, year-round. The body weight and dung production of

the lambs is chosen at 32 calendar weeks (end of May) as the average for ewes and rams, single and twins [41].

Table 40 Dietary mass balance for grazing livestock.

animal	intake in [kg dwt]		metabolism and excretion in [kg dwt]		
	body weight [kg]	feed	soil	metabolism	excreted
600 dairy cow		25	0.625	19.3	6.29
330 beef cattle		5.6	0.14	4.04	1.65
82 sheep		1.413	0.035	1.04	0.41

The different grazing animal categories (cattle, sheep, horses) produce different dung, which has consequences for partitioning calculations in dung. Weight fractions are derived from [41,51] for cattle and sheep and from [40] for horses (Table 41).

Table 41 Pick list for calculation of the wet weight and wet volume of dung.

animal	dry weight production dung $P_{dung_{dwt}}$ [kg <sub>dwt</sub> ·d <sup>-1</sup> ]	weight fraction water in dung $F_{water_{dung}}$ [kg·kg <sup>-1</sup> ]	weight fraction solids in dung $F_{dwt_{dung}}$ [kg·kg <sup>-1</sup> ]	density of fresh dung $RHO_{dung}$ [kg <sub>wwt</sub> ·m <sup>-3</sup> ]
cattle 600 kg	6.29	0.88	0.12	1030
cattle 330 kg	1.65	0.85	0.15	1030
horse 600 kg	3.00	0.69	0.31	900
pony 250 kg	1.25	0.69	0.31	900
sheep 82 kg	0.41	0.6	0.4	1090

## Model calculation

$$Pd_{dung} = \frac{Pd_{dung_{dwt}}}{F_{dwt_{dung}}}$$

### input

$P_{dung_{dwt}}$	livestock dung production dry matter	[kg <sub>dwt</sub> ·d <sup>-1</sup> ]	O
$F_{dwt_{dung}}$	weight fraction dry matter in dung	[kg·kg <sup>-1</sup> ]	P

### output

$P_{dung}$	fresh dung production	[kg <sub>wwt</sub> ·d <sup>-1</sup> ]	O
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For the calculations of the amounts of dung produced in the meadow we suggest to use the figures in Table 42 and Table 43. As there were no data available for horses these were manufactured using the data for beef cattle (as this animal is not lactating; the average dung production (dry weight) per kg bw is 0.005 kg/kg).

*Table 42 Pick list dung production in the meadow.*

<b>animal</b>	<b>body weight</b> $m_{\text{animal}}$ [kg <sub>bw</sub> .animal <sup>-1</sup> ]	<b>production dung</b> $P_{\text{dung}}$ [kg <sub>wwt</sub> .d <sup>-1</sup> ]
dairy cows	600	52
beef cattle	330	11
horses	600	9.7
ponies	250	4.0
sheep	82	1.025

*Table 43 Pick list excretion events and stocking densities.*

<b>animal</b>	<b>body weight</b> [kg <sub>bw</sub> .animal <sup>-1</sup> ]	<b>number of excretion events</b> [d <sup>-1</sup> ]	<b>stocking density</b> [animals.ha <sup>-1</sup> ]
dairy cows	600	10.5	3.5 <sup>8</sup>
beef cattle	330	10.5	9.5
horses	600	10.5	3
ponies	250	10.5	5
sheep	82	10.5	15

<sup>8</sup> The range 1.5-3.5 cows/ha applies to 81.5% of all cattle. The density 2-2.5 is the median value and applies to 30% of all animals (CBS 1996).

## Appendix II Mailing list

- 1 Hoofd Bureau Registratie Diergeneesmiddelen, drs C. Kuijper
- 2 CVMP, Bureau Registratie Diergeneesmiddelen, dr J.P. Hoogland
- 3 LNV, Directoraat Generaal Landbouw, Directie Voedings- en Veterinaire  
Aangelegenheden, drs M.E. Siemelink
- 4 LNV, Directoraat Generaal Landbouw, Directie Voedings- en Veterinaire  
Aangelegenheden, drs G.T.J.M. Theunissen
- 5 VROM, Directoraat Generaal Milieubeheer, Directie Stoffen, Afvalstoffen en  
Straling, dr J.A. van Zorge
- 6 VenW, Directoraat-Generaal Water, Directie Gebruik en Waterkwaliteit, dr P.GJ.  
de Maagd
- 7 EMEA, Safety of Veterinary Medicines, London, UK, dr K. Grein
- 8 Depot Nederlandse Publikaties en Nederlandse Bibliografie
- 9 Directie RIVM
- 10 Directeur Sector Voeding en Consumentenveiligheid, prof dr ir D. Kromhout
- 11 Hoofd Stoffen Expertise Centrum, dr W.H. Könemann
- 12 ir G.J. Schefferlie, RIVM/SIR, projectleider Beoordeling Diergeneesmiddelen
- 13 ing P.L.A. van Vlaardingen, RIVM/SEC, projectleider Beoordeling  
Diergeneesmiddelen
- 14 mw H. Willemen, RIVM/SIR, projectleider Beoordeling Diergeneesmiddelen
- 15 drs R. Luttk, RIVM/SEC, projectleider Risicobeoordelingsmethodologie
- 16 dr J.A. de Knecht, RIVM/SEC
- 17 ir J.B.H.J. Linders, RIVM/SEC
- 18 drs M. Post, RIVM/SEC
- 19 ir P. van der Poel, RIVM/SEC
- 20 Auteur
- 21 SBC / afdeling Communicatie
- 22 Bureau Rapportenregistratie
- 23 Bibliotheek CSR
- 24 Bibliotheek RIVM
- 23-27 Bureau Rapportenbeheer RIVM