Revised Emission Scenario Document for Product Type 14

Rodenticides

August 2018

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Version	Changes	

Revised Emission Scenario Document for Product Type 14 - Rodenticides

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ADME	Adsorption, distribution, metabolism, excretion
AF	Assessment factor
AHDB	Agriculture & Horticulture Development Board of the UK
AHEE	Ad hoc working group on environmental exposure
AR	Assessment report
BPC	Biocidal Products Committee
BPD	Biocidal Products Directive
BPR	Biocidal Products Regulation
bw	Body weight
CG	Coordination group
CRRU	Campaign for responsible rodenticide use
EC	European Commission
eCA	Evaluating competent authority
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
ENV	Environment
ESD	Emission scenario document
EU	European Union
FIR	Food intake rate
FGAR	First generation anticoagulant rodenticide
FOCUS	Forum of the Coordination of Pesticide Fate Models and their Use
FOCUS PEARL	Pesticide emission assessment for regional and local scales model
FOCUS PELMO	Pesticide leaching model
ha	Hectare
HEEG	Human Exposure Expert Group
HSE	Health and Safety Executive Great Britain
LD_{50}	Lethal dose at 50 % mortality
MS	Member States
NAET	No acute effect threshold
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
PCO	Pest control operator

PAR	Product assessment report
PE	Person equivalent
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
PPP	Plant protection product
PT	Product type
RMM	Risk mitigation measure
SGAR	Second generation anticoagulant rodenticide
SPC	Summary of product characteristics
STP	Sewage treatment plant
TGD	Technical guidance document
TM	Technical meeting
TSR	Technical specialist rodenticides
UBA	Environment Agency Germany
UK	United Kingdom
WG	BPC Working Group Environment

Summary

The present document was developed in the framework of the project ‘Schutz der Umwelt vor den Auswirkungen des Einsatzes von Rodentiziden: Anpassung der Bewertungsgrundlagen’, initiated by the Environment Agency Germany (UBA) in November 2015 (FKZ 371567405).

Rodenticides (active substances and products) have already been assessed by Member States (MS) evaluating Competent Authorities (eCAs) under the Biocidal Products Directive (BPD) 98/8/EC. Currently, the approvals of anticoagulant rodenticides under Biocidal Products Regulation (BPR) (EU) No. 528/2012 have been renewed. The assessment of rodenticide emissions to the environment as well as the evaluation of primary and secondary poisoning to non-target bird and mammal species have so far been conducted according to the Emission Scenario Document (ESD) for PT 14, the Guidance on the Biocidal Products Regulation, Volume IV, Environment, Parts B+C, and the addendum to the ESD for PT 14 (now Appendix 5 in the Guidance on the Biocidal Products Regulation, Volume IV, Environment, Parts B+C).

During the Member States’ environmental risk assessment for active substances and products on EU level, it became obvious that not all rodenticide uses are covered by the actual guidance, that there are deficiencies in parameter setting or unrealistic default values.

Therefore, the UBA contracted Dr. Knoell Consult GmbH on 11 November 2015 to develop a more use-oriented draft for a revised ESD for PT 14, which is based on realistic worst-case conditions. The revision is based on the environmental risk assessments as documented in the assessment reports (ARs), the product assessment reports (PARs) and the BPC (Biocidal Products Committee) opinions, discussions that took place at Technical Meetings (TMs), between evaluating Competent Authorities (eCAs), at Working Group (WG) meetings, and at BPC meetings or AHEE (ad-hoc Working Group on environmental exposure) meetings, questionnaires that have been distributed to eCAs, participants of the workshop on risk mitigation measures for anticoagulant rodenticides (held 26 February 2015 in Brussels), awarding public and private authorities, trained pest control operators (PCOs), rodenticide associations, auditors, as well as industry, recent scientific literature on the use of rodenticides and the impact on non-target species.

An essential prerequisite for the revision of the ESD for PT 14 was the collection of current use and emission information via questionnaires.

The aim of the questionnaire for the eCAs and industry was to retrieve information on the participants’ attitude regarding the existing methodology for assessing environmental emissions. Therefore, the questions mainly referred to the scenarios and parameter settings of the established ESD for PT 14 and its addendum.

Three questionnaires were developed for trained pest control operators (PCOs), rodenticide associations, auditors and awarding public and private authorities, respectively. These three questionnaires aimed at the experiences on rodent control at different sites, i.e. in sewer (rainwater and wastewater) and sluice systems (also called tidal outlets or tide gates), in and around buildings, and in open areas (including waste dumps). Furthermore, a separate questionnaire was provided to the same target groups, interrogating rodent control by contact foams and liquids.

Congruent to the original ESD for PT 14, the revised draft ESD for PT 14 is structured based on the areas of rodenticide applications, i.e., in sewer systems, in and around buildings, in open areas, waste dumps and – as a new scenario – the application at bank slopes.

With reference to rodenticide applications in **sewer systems**, new sub-scenarios are defined and parameters of the original ESD for PT 14 are modified. Since rodenticides are applied in wastewater, mixed water and rainwater sewers, a distinction is made between the three types of pipe systems with reference to effluent discharge rates and the final discharge of waters

(either STPs or surface water bodies). The questionnaire revealed that baits occasionally are flushed away with water hence the direct release to water was increased from 30 % to 40 %. Based on further collected data and information, the number of cesspools treated with rodenticides per day within a catchment area corresponding to 10 000 inhabitants feeding one STP was reduced from 300 to 200. For details of the new and revised scenarios, please see section 3.3.4.

As rodent infestations occur **in and around buildings**, both of these application surroundings are considered in the revised ESD for PT 14. For the use of rodenticides outside buildings, solid and liquid formulations are considered. Exposure of the environment can occur via direct emissions to soil (baits and drinking trough are placed on unpaved ground). The ‘direct emissions to soil’ sub-scenario was already part of the original ESD for PT 14. It was modified with respect to the direct release fraction for loose baits (release by spills and disintegration of remaining baits) which was changed from 0.01 to 0.05. For bagged baits, the release fraction of the original ESD for PT 14 (0.01) was taken over. For details, please see section 3.4.4.1.

Indoor baiting as individual baiting scenario was not part of the original ESD for PT 14 and is now integrated in the revised ESD for PT 14. Baiting indoors is done with solid bait formulations, contact formulations or drinking troughs. Emissions to the environment occur indirectly via urine, faeces and carcasses, when poisoned rodents enter the outdoor environment. This sub-scenario is limited to rat control campaigns since rats often have their nesting sites outdoors and switch between in- and outdoors. Primary receiving compartment for emissions is the soil if structures are girdled by bare soil. For details of the new scenarios, please see section 3.4.4.2.

Since outdoor and indoor control of rodents with solid baits and/or liquid formulations is often done in parallel, soil concentrations arising from in-and outdoor treatments have to be summed up (section 3.4.4.3).

For **open areas** basically the same sub-scenarios as in the original ESD are adopted. The scenario of the original ESD for PT 14 considers direct application of loose baits in rodent burrows. Although the questionnaire reveals that this use is of minor importance compared to applications in bait stations/boxes, the maintenance of the ‘loose bait’ scenario is justified as the mode of application is established and emissions represent a realistic worst case situation. Different from the original ESD for PT 14, the number of applications is set to 3 (compared to 2 in the original ESD), based on questionnaire results. Since the ‘normal’ use of rodenticides in open areas is the application within bait stations/boxes, an additional scenario has been developed, which is congruent to the scenario for applications around buildings and direct emissions to soil. The sub-scenario for calculating emissions to soil linked to burrow baiting with gassing formulations has been integrated into the revised ESD for PT 14 as being proposed in the original ESD for PT 14. For details of the scenarios, please see section 3.5.4.

The original ESD for PT 14 generated a scenario for the application of rodenticide in **waste dumps/landfills**, stipulating the 5-fold application of rodenticides (in bait boxes) within an area of 1 ha. This scenario was adopted however integrating direct emissions to soil in the revised version. Direct emissions account for 1 % (bagged baits) and 5 % (loose baits), which is in accordance to the release to soil when controlling rodents around buildings.

According to an agreement at ENV WG I/2018, regarding the assessment strategy, a distinction has to be made between temporary open collection places/waste management sites and stationary waste dumps/landfills. For temporary waste dumps/landfills, a full assessment (soil, groundwater) has to be done. For stationary waste dumps/landfills, biocide emissions to groundwater have to be assessed. However, this assessment requires the calculation of soil concentrations (as well as that for secondary poisoning ref. to 3.6.5.2). Therefore, an emission scenario for soil entries is described (chapter 3.6.4.), which has to be used for the assessment of all waste dumps and landfills. In the most unlikely case rodenticides are applied exclusively in controlled landfill sites containing more hazardous waste, a groundwater assessment is not necessary if these sites have specific layers to prevent leaching of compounds to aquifers or groundwater. Such sites are assumed to be governed by national landfill site regulations, which include the protection of groundwater.

Bank slopes of water courses (rivers, drainage channels, berm ditches) and lakes (ponds, lagoons) as well as wetlands are also a habitat of brown rats. The aim of measures against rodents close to surface waters is to prevent burrowing activities, since these can result in permeable dykes and river banks as well as in erosion. A scenario for this use is introduced in the revised ESD as the information gained indicated that the control of rats along water ways is a common practice and rodenticides can be flushed away due to high rainfall directly into surface water bodies. In the context of the revised ESD for PT 14, the application of a chemical rodenticide along a drainage channel of wetland marshes is considered. The bank slope scenario only applies at the product authorisation stage in case control of rats along water ways is a concern in the country/countries an application is made for, and not forbidden by national law. For further details of this scenario, please see section 3.7.4.

Rodenticide active substances might be vertically transported to aquifers or even **groundwater** when entering the soil compartment. Therefore, it is considered appropriate to provide guidance on the assessment of local concentrations in groundwater. This topic is now introduced in this revised ESD for PT 14. There are, in principle, two routes for emissions: firstly, the route via STP sludge if rodenticides enter sewage treatment plants, and secondly, the route of a direct exposure of soils, which can occur via direct and indirect emissions to soil.

The assessment of groundwater concentrations has to be conducted for the application of solid and liquid baits. The use of contact formulations is considered to be too low to warrant a prediction for groundwater. Also for gassing formulation, no release to groundwater is to be expected.

The calculation of groundwater concentrations should generally be conducted as a tiered procedure.

Tier 1: As an indication for potential groundwater residues, the concentration of agricultural soil in porewater is calculated according to ECHA's Guidance on the Biocidal Products Regulation, Volume IV, Environment, Parts B+C.

Tier 2: As tier 1 as a rather conservative approach may result in groundwater concentrations above 0.1 µg/L or above the maximum permissible toxicological concentration for an active substance or a degradation product, $PEClocal_{gw}$ values can be estimated alternatively by using available groundwater simulation models. These models have more sophisticated scenario definitions and more detailed estimations of transport and transformation in the soil profile. For further details of the proposed groundwater calculation, please refer to section 4.

The risk for non-target species to be poisoned by rodenticides (especially anticoagulants) - either **primarily** (via the consumption of rodenticide baits) or **secondarily** (via the consumption of poisoned organisms) - is a key issue based on the experience during active substance and biocidal product approvals. The bioaccumulation via the aquatic and terrestrial food chain (secondary poisoning via environmental emissions) is considered in ECHA's Guidance on the Biocidal Products Regulation, Volume IV, Environment, Parts B+C. Primary poisoning from the consumption of rodenticides and secondary poisoning from the consumption of primarily exposed target organisms has been dealt with in the original ESD for PT 14 and in its addendum. In the framework of the questionnaire posed to eCAs, it became obvious, that this risk assessment needs to be revised with respect to the implementation of a generic approach for non-target focal species and the implementation of a NAET for the acute poisoning situation. Moreover, the approaches for assessing risks of primary poisoning to birds and mammals for biocides and for plant protection products need to be harmonised. For further details, please see section 5.

The first draft of the revised ESD for PT 14 has been distributed to Member States' evaluating competent authorities and stakeholders in September 2017. At ENV WG Meeting WG-I-2018, a discussion amongst MS eCAs took place with reference to the comments made. In March 2018, the second draft of the ESD for PT 14, including agreed discussion points of MS eCAs was sent to MS eCAs.

The final version was agreed and endorsed in written procedure by MS eCAs in August 2018.

1 Introduction

1.1 Background

On 27 June 2012, the Regulation (EU) No 528/2012 (BPR) of the European Parliament and of the Council concerning the making available on the market and the use of biocidal products, which was adopted in May 2012, was published to repeal Directive 98/8/EC (EU, 1998). It entered into force on 17 July 2012 and became applicable on 1 September 2013. The BPR (EU, 2012) maintains the principle concept of the BPD (EU, 1998) in terms of firstly evaluating active substances for inclusion into a positive list (Union List of approved active substances), and then further authorising biocidal products for the European market, containing these active substances. During both these authorisation processes, a risk assessment needs to be carried out for human health and the environment. With reference to the environmental risk assessment, Emission Scenario Documents (ESDs) are available for almost all product types (PTs), giving instruction on the release estimation of substances from biocidal products to the environment. The risk assessment has to be carried out for all relevant life-cycle stages of the biocidal product.

According to Annex VI (14) of the BPR, the ‘risk assessment shall cover the proposed normal use of the biocidal product, together with a realistic worst-case scenario including any relevant production and disposal issues’. Annex V of the BPR lists various main groups of biocides as well as PTs. Under Main Group 3, pest control, rodenticides are listed as PT 14. They are defined as ‘products used for the control of mice, rats or other rodents, by means other than repulsion or attraction’.

Rodenticides in the present context are biocidal products used for control of rodents (rats, mice and voles). Rodents in the environment of human and livestock are controlled for serious reasons. Rodents can spread diseases to humans, livestock and pets through bites, faeces and urine. As an example, the foot and mouth disease, a highly infectious virus disease for pigs and cattle, can be spread by rats (AHDB, 2015). Rodents can destroy materials by gnawing and carry parasites in their fur. However, rodenticides are hazardous compounds which are associated with a high environmental risk. Furthermore, it has to be noted that some uses are regulated but not authorised in all Member States.

In general, all rodenticides are considered as Biocidal Products with the exclusion of products used in plant growing areas (agricultural field, greenhouse, forest) to protect plants, or to protect plant products temporarily stored in the plant growing areas, which are covered by Regulation (EC) No 1107/2009 (EU, 2009). Rodenticides used for hygienic reasons in the area of stored plants and plant products are also biocidal products (EC, 2013). Products for controlling moles are, by mutual decision of the eCAs in December 2001, Plant Protection Products and consequently they have to be authorised according to Regulation (EC) No 1107/2009. The non-agricultural areas of use of rodenticides are: sewer systems, in and around buildings (e.g. houses, animal housings, commercial and industrial sites), waste dumps and landfills, lawns, golf courses, highway medians, dikes and bank slopes.

1.2 Questionnaire

An essential prerequisite for an accurate revision of the ESD for PT 14 was the collection of current use and emission information via questionnaires that have been distributed to eCAs, trained pest control operators (PCOs), rodenticide associations of several European countries, auditors, awarding public and private authorities as well as industry.

The aim of the questionnaire for the eCAs and industry was to retrieve information on the participants’ attitude regarding the methodology for assessing environmental emissions, hitherto existing. Therefore, questions mainly referred to the scenarios and parameter settings of the established ESD for PT 14 and its addendum.

Three questionnaires were developed for trained pest control operators (PCOs), rodenticide associations, auditors and awarding public and private authorities, respectively. These three questionnaires enquired about their experiences on rodent control in different application surroundings, i.e. in sewer (rainwater and wastewater) and sluice systems (also called tidal outlets or tide gates, cf. section 2.7), in and around buildings, and in open areas (including waste dumps). Furthermore, a separate questionnaire was also provided to these individual target groups, interrogating rodent control by contact foams and liquids, although such formulations have not yet been an integral part of the ESD for PT 14. In the framework of this revised ESD, these groups of participants are combined in a group called 'technical specialists rodenticides' (TSRs) for reasons of simplification. All of the participants can be assumed to have a special knowledge of the practical use of rodenticides, but the group members cannot be attributed to defined user categories (like professionals or trained professionals).

The questionnaire asked the respondent to answer multiple choice questions and gave them the option to enter free text, if desired. An online polling platform was used for distributing the questionnaires to the participants and evaluating the responses. All information received as part of this questionnaire survey is anonymous.

The following table gives a summary of the target groups, the number of participants and the number of answers received.

Table 1: Target groups of the questionnaires and their return

Questionnaire	Target group	Number of participants	Number of participants finalising the questionnaires 1)	Number of participants partially executing the questionnaires 2)	Reference
Questionnaire to evaluating authorities and experts	eCAs and participants of RMM workshop	33	14	19	Dr. Knoell Consult, 2016a
Questionnaire to industry	Rodenticide active substance and product suppliers, CEFIC	101	24	77	Dr. Knoell Consult, 2016b
Questionnaire on the use of rodenticides in sewer (rainwater and wastewater) and sluice systems	Associations, PCOs, auditors, local authorities 3)	203	55	148	Dr. Knoell Consult, 2016c
Questionnaire on the use of rodenticides in and around buildings	Associations, PCOs, auditors, local authorities 3)	160	71	89	Dr. Knoell Consult, 2016d
Questionnaire on the use of rodenticides in open areas	Associations, PCOs, auditors, local authorities 3)	131	51	80	Dr. Knoell Consult, 2016e
Questionnaire on rodent control by contact foams and drinking troughs	Associations, PCOs, auditors 3)	96	39	57	Dr. Knoell Consult, 2016f

1) These participants went through the whole questionnaire, however it does not necessarily mean, that all the questions were answered.
2) These participants either just had a look at the questionnaire without answering questions or they started answering questions but did not go through the whole questionnaire.
3) In the framework of this ESD, these groups of participants are combined into a group called ‘technical specialists rodenticides’ (TSR) for reasons of simplification.

1.3 Harmonised presentation

The emission scenarios for the revised ESD for PT 14 are presented in the text and tables within this report. In the tables, the input and output data and calculations are specified, and units according to EUSES are used. The input and output data are divided into four groups:

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

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

2 Background information on rodenticides

2.1 Active substances

A list of rodenticidal active substances for which an application for approval has been submitted under Directive 98/8/EC (BPD; EU, 1998) or Regulation (EU) No 528/2012 (BPR; EU, 2012) can be found on the ECHA website: https://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances.

The majority of approved active substances for the use in rodenticides belong to the anticoagulants which either belong to the class of 4-hydroxocoumarines or to 1,3-indandione derivates. Anticoagulant rodenticides are grouped by their mode of action to act as vitamin K antagonists thereby inhibiting blood-clotting (Buckle & Eason, 2015). Rodents will eventually die as late as 3-7 days after bait uptake from internal or external bleeding. Due to this delayed mode of action, rodents are unable to associate the toxic effect with the poisoned bait (bait shyness). With reference to the date of their introduction on the market, anticoagulant rodenticides are subdivided into first- and second-generation anticoagulant rodenticides, abbreviated by FGARs and SGARs, respectively. After oral administration, the major route of elimination in various species is through the faeces. The metabolic degradation of warfarin and indandiones in rats mainly involves hydroxylation. However, some second-generation anticoagulants are mainly eliminated as unchanged compounds (Larsen, 2003).

First-generation anticoagulants (of which warfarin, chlorophacinone and coumatetralyl are approved in the EU) need to be consumed repeatedly by rodents to cause death. Second-generation anticoagulants (i.e. brodifacoum, bromadiolone, difenacoum, difethialone, flocoumafen) have been developed in response to resistance to FGARs. They are more toxic and more persistent in biota and the environment. A single feeding of baits is often sufficient to achieve a lethal dose.

Occurrence of resistance in rats and mice is well documented to first- and some second-generation anticoagulants (Larsen, 2003; please note: all references cited in the former ESD for PT 14 (Larsen, 2003) are not included in this revision as separate reference but cited as 'Larsen, 2003'). For further information on rodenticide resistance please refer to the RMM report (Berny et al., 2014). Table 2 contains a summary of anticoagulant active substances and their maximum admissible concentrations in products.

Table 2: Anticoagulant active substances and their maximum admissible concentrations in products

FGAR / SGAR	Active substance	Maximum admissible concentration in product (%)
FGAR	Coumatetralyl	0.0375
FGAR	Chlorophacinone	0.005
FGAR	Warfarin	0.079
SGAR	Difenacoum	0.0075
SGAR	Bromadiolone	0.005
SGAR	Difethialone	0.0025
SGAR	Brodifacoum	0.005
SGAR	Flocoumafen	0.005

Non-anticoagulants have other modes of action. For example, cholecalciferol is a fat-soluble vitamin (D3) that can be used as an acutely toxic (single feeding) and/or chronically toxic (multiple-feeding) rodenticide. According to Buckle & Eason (2015), the mode of action of cholecalciferol in mammals is briefly described as a stimulation of absorption of calcium in the intestines and mobilisation of skeletal calcium resulting in high levels of calcium in the blood (hypercalcaemia). Death seems to be due to circulatory blockage, heart and renal failure. Symptoms of poisoning usually do not occur until 2-3 days after intake (Larsen, 2003).

Chloralose is a narcotic with a rapid effect. Buckle & Eason (2015) describe that it slows down a number of essential metabolic processes. Therefore, it is most effective against small rodents such as mice which have a high surface to volume ratio and therefore suffer rapidly from lethal hypothermia. Cool conditions are most favourable.

2.2 Formulations

According to the questionnaire (Dr. Knoell Consult, 2016c, d, e), the main type of formulations applied are solid baits, for instance bait blocks, bagged bait (e.g. sachet with impregnated grain, pellets, granules), pastes and sachets with pastes (within the framework of this revised ESD, pastes and bagged pastes are assigned to solid baits). To a minor degree, loose baits (meaning non-bagged baits like impregnated grain or granules), gassing and contact formulations (foams and gels) as well as liquid formulations are used. These results correspond well with the fact that the majority of authorised rodenticides commercially available in the EU are formulated as solid products (https://echa.europa.eu/de/information-on-chemicals/biocidal-products). Furthermore, the RMM Report (Berny et al., 2014) as well as Buckle & Eason (2015) give a concise survey of the different types of rodenticide formulations available on the market.

Since cereals are an important dietary element in the nutrition of most rodents, cereals are commonly used as a base material for rodent baits.

Some rodenticides are impregnated onto grain. For this type of a rodenticide, different cereals like wheat, rice, maize, oats or barley can be used. When producing impregnated grain, a sticker, usually oil is employed, which serves as a binder of the rodenticide active substance onto the surface of the grain.

Rodenticide pellets generally compose of milled cereals mixed with an active ingredient concentrate. The mass is forced under pressure through a die, and heat is used to alter the biochemical composition of the mixture so that the pellet is physically stable after extrusion.

Bait blocks mainly compose of cereals either whole, broken or milled, and the rodenticide active substance. In addition, most bait blocks contain a substantial proportion of paraffin wax.

The most recent development in rodenticide products include pastes, containing finely particulate cereals held together by adding fats, oils and gelling agents.

All these above mentioned bait formulations are available in a loose form or bagged in sachets made from paper or a polymer material. According to recent BPC opinions on active substance renewals for rodenticides (https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval), the addition of a warning dye as well as the inclusion of a bittering agent into the formulations is mandatory in EU countries. Additionally, some sewer baiting formulations contain mould inhibitors to slow down the rate of decomposition of the bait in humid atmospheres within the sewer environment (Chartered Institute of Environmental Health, 2013).

Baits formulated as a liquid are used for rodent control where sources of water within their habitat are scarce and where the food available is dry, such as in grain stores and cereal mills. Liquid baits are administered via drinking fonts or drinking troughs. In the past, a drinking trough has been prepared by the user by diluting liquid concentrates. Since the handling of liquid concentrates for the preparation of drinking troughs is inherently hazardous for the user, concentrates are no longer permitted in European countries. As an alternative, ready-to-use formulations are now on the market, which are already delivered in a special device for drinking.

So called ‘contact’ formulations (gels and foams) are applied on track surfaces, in pipes, wall cavities and burrows. Rodents’ feet and fur become contaminated and the rodenticide is ingested during grooming. The use of contact dusts (tracking powders) is banned in European countries because of the high concentrations of the active substance they contain and their potential to become airborne.

Only few rodenticides are applied as fumigants (i.e. carbon dioxide, aluminium phosphide, hydrogen cyanide) by trained professionals under specific circumstances. Rodenticide fumigants are used in installations that can be enclosed gas-tight, like ships’ holds, container or grain silos. On a smaller scale, fumigants are used in special rodent trapping devices. Fumigants are also applied for gassing of rodent burrows.

2.3 Mode of application

Rodenticide bait formulations can either be applied in a loose form or as bagged baits in sachets. Both types can be placed into bait stations and tamper as well as weather resistant bait boxes.

Bait boxes are frequently used as they are considered to increase the safety of rodenticides and reduce the primary poisoning hazards of non-target species if they are robust enough (tamper resistant). In case of anticoagulant rodenticides, the general public is obliged to use bait boxes (see recent BPC opinions on active substance renewals for rodenticides (https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval). Therefore, their use is included in the scenarios. The degree of box resistance to tampering by rodents, humans etc., affects the default release estimates. It is assumed that a tamper proof bait box minimises environmental releases. It is also assumed that a tamper and weather resistant bait box has much lower releases than, for example, a bait station made of cardboard.

The release can be further minimised by fixing the bait in the bait station/box, so that it cannot be easily dragged away. The UK expert working group RRAT (Rodenticide Risk Assessment Technical working group, Larsen, 2003) states that there is experimental evidence that rats often remove bait particles from bait stations/boxes and sometimes leave them where other animals can find them. Nevertheless, the use of bait boxes clearly improves the safety of bait placements and permits easy retrieval of uneaten bait at the end of a treatment.

According to Larsen (2003), bait stations can look different:

- It can be as simple as a flat board nailed at an angle to the bottom of a wall. The board should be long enough to keep pets, some non-target species and children from reaching the bait.

- It can be the length of a fixed pipe in which the bait can be placed. The pipe diameter should be 5 to 8 cm for mice and 6 to 15 cm for rats. The pipe should be long enough to keep pets, non-target species and children from reaching the bait.

- More elaborate bait stations are completely enclosed and can contain liquid as well as loose or wrapped baits. Bait stations for rats normally have two openings, approximately 6 cm in diameter.

- Tamper and weather resistant bait boxes are generally those made from robust materials, such as polypropylene, metal or wood and have internal dimensions that deter access to the bait by humans and non-target species larger than rats. They also have lids which are secured with a lock and can be anchored to the substrate.

It is important that the bait is placed out of reach of children, pets, domestic animals and non-target wildlife or in a bait station/box. Rats transfer all types of bait including fine particles. This occurs whether the bait is placed in a box or on a tray under natural cover. According to the UK working group RRAT (Larsen, 2003), the results from research on rat behaviour at bait stations/boxes suggest that some designs of tamper-resistant boxes may actually encourage bait transfer. The location for placing bait stations/boxes also has an influence on the bait transfer (UBA, 2017).

Bait stations/boxes are placed where the rodents are active, i.e. near rodent burrows, against walls, along travel routes (runways) and preferably between the rodents' place of shelter and their food supply.

On farms, the bait stations/boxes located outdoors are usually placed along the building foundations or around the perimeter of the farm building complex.

There are different baiting techniques:

Pre-baiting

Pre-baiting is used to condition the target organisms to the bait formulation, thereby increasing the likelihood of rodents to take up a lethal dose of the baits. The infested area is first treated with non-toxic baits (also referred to as 'token or test baits') of the formulation to be used in the rodent control campaign. Once the initial suspicion of the new food has subsided and rodents feed freely, toxic baits of the same formulation are laid at the same places and in the same bait stations/boxes as the pre-baits (Buckle & Eason, 2015, ECHA, 2015). Pre-baiting using non-toxic baits may also serve as a monitoring tool to determine places and degree of rodent activity. Non-toxic baits may also be used in post-treatment monitoring to assess the success of a rodent control campaign and, in the long-term, to monitor re-invasion (Brooks, 1962).

Saturation baiting

This application technique is typically applied for first-generation anticoagulant rodenticides, where rodents have to take up baits repeatedly for several days before the dose is lethal. Therefore, rodents have to have continuous access to the rodenticide over a period of days or weeks. During this time, relatively large amounts of baits are applied, and frequently replenished (Buckle & Eason, 2015). The principle of saturation baiting is to maintain a continuous supply of bait. The interval is not easy to specify and needs to be adjusted to achieve the primary objective of providing sufficient bait. The baiting campaign lasts until baits are consumed, typically for 35 days.

Pulsed baiting

Pulsed baiting is a time-limited baiting technique where small quantities of baits are applied and baiting points are visited at weekly intervals until baits are consumed. During each visit, it has to be ensured that fresh bait is available, possible spillage of bait is eliminated and dead or dying rodents are removed. The primary purpose of the pulsed baiting technique is to permit effective rodent control while reducing the quantities of rodenticide used and, thereby, the quantity of the active substance released into the environment (Berny et al., 2014). This application technique is applied for the most potent, single-feed second-generation anticoagulant rodenticides (i.e. brodifacoum, difethialone, flocoumafen) and is restricted to trained professionals in the EU. It has been observed that dominant or less neophobic rodents consume the baits completely when they are first put out. These animals die before the next pulse of baits is applied where more neophobic or less dominant rodents encounter and consume the baits (Buckle & Eason, 2015).

Permanent baiting

Permanent baiting is a timely, unlimited application technique. Rodenticide baits are maintained at one or more locations, indoors and/or outdoors, irrespective of whether or not target rodents are actually present. The baiting points are visited at intervals from several weeks to half a year. The primary intention of permanent baiting using slow-acting anticoagulant rodenticides is to prevent rodents from becoming established rather than to intercept them and to prevent them from intruding into premises. The secondary intention is to monitor rodent activity by the inspection of bait uptake. It is acknowledged that permanent baiting enhances the risk of primary and secondary poisoning of non-target species (including non-target rodents) as baits are being deployed (and non-target species thus exposed) for long time-periods without maintenance. There are also concerns that permanent baiting will lead to the selection of genetically based anticoagulant resistance (RRAC, 2015).

Within the renewal of anticoagulant rodenticides in the EU, permanent baiting has therefore been restricted to the use of less potent SGARs bromadiolone and difenacoum by trained professionals only. It has been moreover recommended that the treated area is revisited every 4 weeks in order to avoid any selection of a resistant population. According to the TSR responses to the questionnaire, permanent baiting is done:

- if there is a constant high rate of rodent reinvasion e.g. if rodents are ‘imported’ to the area of concern (e.g. rodents transported to waste dumps by refuse collection vehicles) or if structures provide (unavoidable) entrances for rodents.

- in and around hygienically sensitive premises, e.g. food producing facilities or hospitals, where rodent invasions would mean a risk for humans.

- if there is a risk for productive livestock to be infested by rodent’ transmitted diseases.

- if rodents cause high economic losses.

- if there are no other alternatives available for effective rodent control.

TSR’s responding to the questionnaires (Dr. Knoell Consult, 2016c, d, e) declared that permanent baiting is a relevant mode for controlling rodents in and around buildings as well as in open areas including waste dumps. TSRs indicated, that compared to the time-limited control of rodents in case of acute infestation, permanent pro-active baiting is characterised by a lower application amount of baits per baiting point, and/or a larger distance between the baiting points, and/or a larger interval between bait point inspections, and/or an application at sensitive areas for rodent invasions (e.g. at doors and gateways).

Emissions to environmental compartments (soil, groundwater, surface water including sediment) within a certain time period resulting from permanent baiting can be expected to be lower compared to emissions from time-limited rodent control. In this respect, emissions to environmental compartments from time-limited rodent campaigns represent the worst-case situation and will therefore be considered in the framework of this revised ESD for PT 14.

Permanent baiting however poses a very high risk for non-target species due to the extended exposure to baits and the less frequent inspections of baiting points. The risks for non-target species and wildlife arising from permanent baiting have already been addressed in more detail in the document on RMM (Berny et al., 2014). Furthermore, it has to be addressed that permanent baiting is a means for application if there is permanent food available for rodents. Therefore, the method of choice should be a limitation of all available food for rodents in order to supersede permanent baiting techniques for rodents.

Burrow baiting

Baits are deeply introduced into burrows or underground corridors, where rodents generally prefer to eat. The advantage of burrow baiting is that baits can be applied without using bait stations/boxes, making the baits more attractive especially to neophobic organisms. On the contrary, burrow baiting may result in spillage of baits outside the treated burrow, because baits may be ejected by rodents from the baited burrows, leading to an enhanced risk of primary poisoning of non-target species (Berny et al., 2014). Entrances of baited burrows have therefore to be covered or blocked to reduce the risks of baits being rejected and spilled as well as to avoid easy non-target access, but still allow rat access. It is recommended to inspect burrow baited sites daily and, if necessary, to remove spilled bait (Berny et al., 2014).

An alternative means of controlling rodents in their burrows (e.g. in embankments or dikes) is the use of pellets or tablets containing aluminium phosphide. These are placed well inside each entrance, which is then sealed. Moisture present in the tunnel atmosphere or soil causes the gas to evolve and kill the rodents (AHDB, 2015).

For product authorisation, manufacturers will need to specify the baiting processes clearly on the label for any particular end-use product.

2.4 Target species and travel distance

Rodents most frequently controlled by rodenticides are the commensal rodents, i.e. the brown rat (*Rattus norvegicus*), the house mouse (*Mus musculus*) and the roof rat (*Rattus rattus*). Commensal rodent means, that they are usually found in association with people, 'sharing the table'. From the three species, brown rats and house mouse are the more frequent pests, whereas the occurrence of roof rats is less frequent (Macdonald et al., 2015). Besides commensal rodents, voles such as the common vole (*Microtus arvalis*), the bank vole (*Myodes glareolus*) or the water vole (*Arivola terrestris*) are also considered pests in terms of the BPR and thus may be controlled. Some small non-target rodents, such as the woodmouse (*Apodemus sylvaticus*), may enter buildings as casual intruders, but they are generally not considered as target species within the scope of the BPR.

According to the result of the questionnaire distributed to TSRs (Dr. Knoell Consult, 2016d, e), the following rodents are controlled in and around buildings and in open areas:

Table 2: Target rodent species (not considering contact formulations and drinking trough)

Rodent species	Control (in % of the answers)		
	in buildings	around buildings	in open areas
Brown/Norway rat (*Rattus norvegicus*)	33	35	32
Black rat (*Rattus rattus*)	19	6.5	3.6
House mouse (*Mus musculus*)	34	29	20
Bank vole (*Myodes glareolus*)	1.6	5.2	6.3
Water vole (*Arvicola terrestris*)*	2.4	9.8	16.2
Field vole (*Microtus agrestris*)	1.6	2.0	5.4
Common vole (*Microtus arvalis*)	4.9	11	15.3
Wood mouse (*Apodemus sylvaticus*)*	1.6	0.7	0.9
Number of answers	123	153	111

* These species are protected by law in some EU countries

The home ranges for mice and rats vary according to season, population density, habitat, food supply etc. Figures given for the travel distance or the territory size are therefore variable.

Studies indicate that during its daily activities, a rat normally travels an area averaging 30 to 50 m in diameter. Rats seldom travel further away than 100 m from their burrows to obtain food or water (Larsen, 2003). Macdonald & Fenn (1995, in Larsen, 2003) and Taylor (1978, in Larsen, 2003) have however shown that rats under special circumstances may move away from and around farms. They found rats having travelled distances of more than 1300 m. According to the Agriculture & Horticulture Development Board of the UK (AHDB, 2015), male and female brown rats travel 700 m and 350 m around farms each night, respectively. Akande (2008) conducted a study on brown rat behaviour and control on a pig farm. He recorded a territory of approximately 500 m^2.

During its daily activities, a house mouse normally travels an area averaging 3 to 10 meters in diameter. House mice seldom travel further away than this to obtain food or water.

Entry holes to rodent burrows are 4 cm in diameter or less for mice and 5 cm in diameter or larger for rats.

A 10 meter zone around the farm building is considered the most frequented zone for rodents. Mice typically forage in the immediate vicinity and rats make longer foraging trips outside the location along hedgerows and the like.

2.5 Rodenticide users

In the framework of the renewal of anticoagulant rodenticide active substances and of biocidal products containing these substances, the European Commission has passed a note for guidance (EC, 2016) specifying three main categories: the ‘general public’, ‘professional users’ and ‘trained professionals’. These user groups are characterised as follows.

General public

- Sporadic and private use of rodenticides.
- No specific training on the use of rodenticides.
- Information about risks accompanying the use of the product is gained by reading the label instruction.

Professional users

- Use of rodenticides in the course of their profession, which is not primarily concerned with using rodenticides. This user category comprises e.g. farmers, janitors, workers employed in food preparation/packaging/storage/distribution, technicians, etc.
- Regular use of rodenticides on an occasional basis.

Trained professional users

- Frequent use of rodenticides as part of their profession, e.g. pest control operators (PCOs) and sewage workers.
- A specific training or certification process with respect to the use of rodenticides has been passed.
- In possession of skills and knowledge regarding the risks associated with rodenticides' use, integrated pest management, complex instructions for use and the implementation of RMM.

It should be noted that the user category and the knowledge, skills or competencies assigned to it, do not alter the parameters of the emission estimation, which is mainly influenced by the intended use (i.e. the exposure scenario), the physico-chemical properties of the active substance, the concentration of the active substance in the biocidal product, and the amount of product used.

2.6 Primary and secondary poisoning

The use of rodenticides intended for killing selected pest mammals has to be considered a general hazard to non-target mammals and birds as well. Non-target species are potentially at risk in four ways:

- From direct consumption of the baits (primary poisoning).
- From consuming primarily exposed target and non-target organisms (secondary poisoning).
- From consuming secondary exposed non-target organisms (tertiary poisoning).
- From consuming organisms (terrestrial or aquatic) that have been exposed to rodenticides via emissions to the environment (secondary poisoning via environmental emissions).

Estimation of secondary exposure to substances with bioaccumulation potential via the aquatic and terrestrial food chain (secondary poisoning via environmental emissions) is described in the Guidance on the Biocidal Products Regulation, Volume IV, Environment, Parts B+C (ECHA 2016a). Therefore, if rodenticides or their residues are emitted to water or soil (directly or indirectly), the bioaccumulation potential has to be assessed according to current guidance (ECHA, 2016a), including the exposure routes:

- Water → aquatic organisms → fish → fish-eating mammals or birds.
- Soil → earthworm → worm-eating birds and mammals.

Regarding the primary poisoning risk as well as the secondary poisoning risk from the consumption of rodenticide-containing rodents, the estimation of exposure is not described in the Guidance on the Biocidal Products Regulation, Volume IV, Environment, Parts B+C (ECHA 2016a) but refers back to the original ESD for PT 14 (Larsen, 2003). It will also be included in this revised ESD for PT 14, with some modifications. Since invertebrates have been reported to accumulate anticoagulant rodenticides, the secondary poisoning risk for invertebrate-consuming birds and mammals is also integrated in this document.

As of February 2017, about 95 % of the more than 3000 authorised rodenticide products in the EU contained anticoagulants as active substances. Since birds, mammals and other vertebrates share the same blood clotting mechanism as rodents, they are all vulnerable to the toxic effects of anticoagulants (Smith & Shore, 2015). It is obvious that this hazardous profile in combination with the given secondary exposure of predators and scavengers creates risks, which need to be assessed.

The assessment of anticoagulant rodenticides according to Directive 98/8/EC (BPD) or Regulation (EU) No 528/2012 (BPR) based on the original ESD for PT 14 and its addendum (Appendix 5 in ECHA, 2016a) has resulted in a significant exceedance of the maximal permissible PEC/PNEC ratio of 1 for almost all anticoagulant active substances and products. Additionally, monitoring data on residues of anticoagulant rodenticides in wildlife have shown that wildlife predators and scavengers accumulate anticoagulants in their tissues, hence adverse effects on the welfare of these species are to be expected.

The revision of the ESD for PT 14 with respect to primary and secondary poisoning aims at:

- An approach for proposing non-target generic focal species for primary and secondary poisoning taking into consideration their diet, the food chain aspect, their habitats, their susceptibility especially for anticoagulant rodenticides, and the incidences for monitoring remains within dead animals found.

- The implementation of a no acute effect threshold (NAET) value for the acute poisoning situation, which has been assessed only qualitatively up to now.

- A harmonisation of approaches for assessing risks of primary poisoning to birds and mammals for biocides, and for plant protection products (PPPs) under consideration of the EFSA (European Food Safety Authority) guidance (EFSA, 2009).

2.7 Definition of areas of use

The area of use must be confined as much as possible, since the authorised use of a rodenticide product could be limited to one or more of the application surroundings distinguished within the framework of this ESD. Furthermore, specific provisions on the area of use could be combined with other provisions, such as the user category, which would limit the risk of primary or secondary poisoning (EC, 2009). In this ESD, five main rodenticide treatment scenarios are proposed: in and around buildings, sewer systems, open areas, waste dumps and bank slopes. The difference between ‘around buildings’ and ‘open areas’ as use areas has been discussed in detail in several fora and will also be discussed within the next sections.

2.7.1 Sewer systems

The sewer system is mainly an underground carriage system of pipes, chambers and manholes that conveys water from the point of production to the point of treatment or discharge. Several types of sewer systems exist. Sanitary sewers are transport sewers from houses and commercial buildings mainly to sewage treatment plants (STPs). In addition, separate storm drains may be constructed to transport rain water directly into surface water bodies. Mixed water sewers combine sewage water and storm water in the same pipe/system. Mixed water is generally discharged to STPs, however in case of heavy weather situations the combination of both waste- and rainwater can be discharged directly into surface water bodies (i.e. bypassing the STP, see Ahting & Müller-Knoche, 2014). The original ESD for PT 14 considers emissions to the sewer system (waste and mixed water) and the transport of waters to a STP. The ESD does neither include an STP bypass in case of storm water nor the direct drainage of rainwater into surface water bodies. Nonetheless, according to the recent questionnaire (Dr. Knoell Consult, 2016c), it is common practice that anticoagulant rodenticides are also applied in rainwater sewers (59 % positive answers of 41). As a result of discussions at WG II/2018, the bypass STP scenario in case of storm water (overflow situation in waste and mixed water pipe systems) was described as an unwanted situation and should not be used in risk assessment. Thus, the bypass scenario does not need to be calculated. In the framework of the revision of the ESD for PT 14, the emission estimation for sewer systems now includes direct rainwater discharge to surface water bodies to consider the event of 'bypassing STP' in case rainwater is drained separately.

2.7.2 In and around building

According to EC (2009):

'In and around buildings' shall be understood as the building itself, and the area around the building that needs to be treated in order to deal with the infestation of the building. This would cover uses in sewer system or ships but not in waste dumps or open areas such as farmlands, parks or golf courses.'

Berny et al. (2014) define that buildings are:

'generally thought to be associated with human activity, although the degree of human activity will vary greatly depending on who has permission of access, location and type of use. These may include domestic properties, commercial premises, farm buildings, store-houses, warehouses, grain stores, municipal buildings such as schools, hospitals and offices, animal husbandry facilities, such as stables, milking parlours, cow sheds, chicken sheds and pig arks, any building concerned in the storage, preparation, distribution, sale and consumption of food, any mode of transport including aeroplanes, trains, ships, commercial and private transport vehicles, etc.'.

In 2013 the term 'around buildings' proved controversial during a questionnaire survey distributed by HSE to stakeholders (HSE, 2013). The HSE's questionnaire dealt with the assessment of environmental risks from SGARs. The proposed HSE definition for 'around buildings' included a restriction of baiting within 5 m from a building. Over half of the stakeholders disagreed with the proposed definition. Their reasons were inter alia, that rat infestations affecting buildings are sometimes more than 5 m away from the building but rats are feeding within the building. The restriction of baiting to 5 m from buildings would increase the baiting duration necessary to achieve Norway rat control and increase overall wildlife exposure. In summary, restricting the distance for rodenticide applications around buildings was not considered reasonable.

The rationale for the 'around building' scenario in this revised ESD for PT 14 coincides with the definition made by the European Commission (EC, 2009). The basic idea for the scenario is that the building should be protected from being infested by rodents, and not a landscape area. The habitation of the rodents can be within the building (applicable for house mice) or outside the building (Norway rats) but foraging takes place inside the building in either case. It is a relevant criterion that bait stations/boxes are placed in the immediate vicinity outside the structure. In contrast to rodent control in open areas, the 'around building' scenario assumes indirect emissions to be relevant. These emissions via carcasses, urine and faeces only contribute to noteworthy emissions, if the area assumed for rodent control and rodent activity is restricted to the near circumference of the structure and the density of bait stations/boxes per area unit is comparably (compared to the control in open areas) high.

Within the framework of this revised ESD for PT 14, rodent control around buildings refers to the following situations (allowing for the examples quoted in the RMM document (Berny et al., 2014)):

- Health protection of humans and animals
- Protection of the basic structure of the building
- Protection of buildings inhabited or used by humans
- Protection of any kind of animal husbandry facilities
- Protection of buildings for ensuring hygienic and technical proper production processes
- Protection of buildings which are used for storing human and/or animal food and food products, as well as other goods (e.g. wooden products, machines, straw, etc.)
- Protection of buildings which ensure infrastructure (e.g., switchyards, transformer stations)
- Protection of structures used for the transport of humans and goods.

HSE (2013) refer to indoors as:

'situations where the bait is placed within a building or other enclosed structure and where the target is living or feeding predominantly within that building or structure, and behind closed doors. If rodents living outside a building can move freely to where the bait is laid within the building, such as bait in open barns or buildings and tamper-resistant bait stations placed in open areas, this is not classified as indoors.'

The underlying rationale in this ESD for PT 14 for the scenario 'indoor baiting' coincides with the definition given by HSE (2013). The basic structure of the building must be designed in such a way, that rodents should normally not enter the building. Unintentional intrusion of rodents takes place via temporarily open doors, gates, or windows as well as damages in the fabric and open pipes.

2.7.3 Open areas

Rodent infestations, in particular infestations of rats, may become established away from buildings when food and cover is available (Berny et al., 2014).

An open area is an area that does not fit in the definition of the 'around buildings' scenario. It can be an urban, suburban or rural space and is not associated with a building (CRRU, 2015). The document on RMM (Berny et al., 2014) as well as those by CRRU (Campaign for Responsible Rodenticide Use, CRRU, 2015) detail several examples for open areas: parks, gardens, playgrounds, sports grounds, private or public forests, areas outside food stores (potato/sugar beet clamps), railway embankments/sidings, marshalling yards, airfields, hedgerows, areas at rearing pens of game-birds as well as areas around ground-nesting seabirds on islands.

The rationale for the 'open area' scenario in this revised ESD for PT 14 is the protection of a landscape area. Habitation of the rodent is in burrows and nesting sites outside buildings, and foraging takes also place in open terrain. Baiting campaigns are assumed to comprise a larger area and a lower density of baiting points per area unit compared to rodent control around buildings. Emissions to soils are therefore predominantly attributed to direct emissions, with indirect emissions being negligible.

Waste dumps/landfills as well as bank slopes (dyke, lock and sluice embankments, bank slopes of rivers, ditches, lakes, drainage channels) are special types of open areas. Since the mode of baiting is different compared to applications in open areas, these areas of use are dealt with separately.

2.7.4 Waste dumps

Waste dumps comprise of waste-handling facilities, such as landfill sites, recycling centres and municipal composting facilities (Berny et al., 2014). Waste dumps can either be stationary landfills as well as temporary dumps or storage facilities for household waste that are e.g. necessary as buffer at incineration facilities. Due to the permanent availability of food and the ‘delivery’ of rodents by refuse collection vehicles, rodent infestations are a permanent problem in these areas. Therefore, the use of rodenticides at waste dumps is only effective when these factors are controlled, too. If waste collection and storage is well organised, rodenticide use can be minimised.

The rationale for the ‘waste dump’ scenario in this revised ESD for PT 14 is the protection of a waste dump of a defined area (1 ha) for hygienic reasons, i.e. to prevent outbreaks of rat populations and to restrict disease transmission. Compared to the ‘open area’ sub-scenario, applications in waste dumps are related to a more confined area thus both direct and indirect emissions to soils are considered to be relevant.

According to an agreement at ENV WG I/2018, regarding the assessment strategy, a distinction needs to be made between temporary open collection places/waste management sites and stationary waste dumps/landfills. For temporary waste dumps/landfills, a full assessment (soil, groundwater) has to be done. For stationary waste dumps/landfills, only biocide emissions to groundwater have to be assessed. However, this assessment requires the calculation of soil concentrations (as well as that for secondary poisoning (ref. to 3.6.5.2)). Therefore, an emission scenario for soil entries is described in chapter 3.6.4., which has to be used for the assessment of all waste dumps and landfills. In the most unlikely case rodenticides are applied exclusively in controlled landfill sites containing more hazardous waste, a groundwater assessment is not necessary if these sites have specific layers to prevent leaching of compounds to aquifers or groundwater. Such sites are assumed to be governed by national landfill site regulations, which include the protection of groundwater.

2.7.5 Bank slopes

In the framework of the revision of this ESD for PT 14, eCAs requested further information on the use of rodenticides close to surface water bodies. This information was considered to be necessary as rodenticide product applications may take place close to surface water bodies with the risk of being flushed away with water in case of heavy rainfall or high water events.

The concerned areas of use are bank slopes of water courses (rivers, drainage channel, berm ditches and lakes (ponds, lagoons)) as well as the surroundings of locks and sluices. A sluice is a water channel within a dyke, which can be closed by a gate. Sluice gates control water levels and flow rates of rivers and canals.

As summarised in section 3.7.1, mainly brown rats are controlled with rodenticides at bank slopes. The aim of measures against rodents close to surface waters is primary to prevent burrowing activities, since these can result in permeable dykes and river banks as well as advancing erosion.

The soil of the bank slope is one of the primary receiving compartments for emissions, however these emissions are covered by the ‘open area’ sub-scenario.

With respect to direct emissions to surface water bodies by rain or high water, applications along a drainage channel of wetland marshes are also considered. These channels have a limited water volume and the water body can be assumed to be stagnant. Rodenticide products being flushed away will therefore be emitted into a relatively small water volume. For this reason, drainage channels are considered to represent a realistic worst-case scenario for this use area.

Abatement of rats along water ways is not an issue in all European Member States. Therefore, the bank slope scenario only applies at the product authorisation stage in case control of rats along water ways is a concern in the country/countries an application is made for, and not regulated by national law.

3 Exposure scenarios for the environment

3.1 General issues and background

Exposure scenarios are defined as a set of conditions about sources, pathways and use patterns that quantify the release of the substance from processing, use and disposal into soil, water, air and waste. The production of the active substances, as well as the formulation of the products, and waste disposal are life cycle steps which will not be considered in the framework of this revised ESD for PT 14. The packaging material with possible residual amounts of the product will be disposed of as municipal waste. In this case, the general risk management measures based on EU waste legislation apply.

Direct environmental exposure may take place when rodenticides are applied outdoors on public and private areas, around buildings or constructions (farm buildings, railway stations, harbour areas etc.), on water banks, in and around sewer systems, waste disposal sites and waste dumps.

Indoor application may result in a diffuse release from target organisms when entering the outdoor environment, via urine, faeces and carcasses including non-degraded active substance and its transformation and metabolic residues.

The exposure of the environmental compartments soil, water and air is highly dependent on the formulation type, the physico-chemical properties of the substance involved, and the mode of application.

Emission scenarios relevant for rodenticides are based on ‘realistic worst case’ principles and the most common application and use patterns.

The scenarios are categorised in the following hierarchical way:

1. Division into five main scenarios according to the application surroundings;

2. Subdivision into scenarios according to application type;

3. Consideration of relevant exposed environmental compartments; and

4. Other relevant protection targets (primary and secondary poisoning, cf. section 5).

The respective emission scenarios are described as a sequence of equations so that emission rates and concentrations in environmental compartments can be estimated (by calculation). The calculation depends to some degree on default values and estimations. The default values are based on experiences of TSRs, eCAs and industry, as well as on literature data and expert judgement. The default values can be superseded by measured values of relevant and reliable data if available.

3.2 Exposure scenarios

Basically, there are five main scenarios to consider:

- Exposure scenario for sewer systems, i.e., waste water/mixed water as well as rainwater sewer systems (cf. section 3.3);
- Exposure scenarios in and around buildings (cf. section 3.4);
- Exposure scenarios for open areas (cf. section 3.5);
- Exposure scenarios for waste dumps (cf. section 3.6); and
- Exposure scenarios for bank slopes (cf. section 3.7).

The environmental exposure scenarios are developed on the basis of rodenticide types and the modes of application that are expected to result in the largest emissions to the environment.

According to ECHA (2016a), the estimated local predicted environmental concentration (PEC_{local}) must be added to the estimated regional concentration ($PEC_{regional}$). However, for rodenticides the consumption is estimated to be so low that the regional contribution is considered to be negligible. For exposure calculations to the soil compartment, the directly exposed area and the mixing soil depth is assumed to be 10 cm from the point source, respectively. In case of a rodenticide bait application directly into a rodent burrow, it is assumed that only the lower half of the hole and its surrounding environment is exposed (with the exemption of the gassing scenario).

3.3 Exposure scenarios for sewer systems

3.3.1 Description of use area

The brown rat is the only rodent species inhabiting sewers. Depending on the structure of the sewer, its food content and the population density, brown rats may often or rarely move to the surface to search for food. According to the questionnaire (Dr. Knoell Consult, 2016c), rats are controlled in wastewater/mixed water sewer systems as well as in rainwater sewer systems. Furthermore, the results of the questionnaire reveal that the active ingredients and the formulations used as well as the application techniques can be assumed to be identical in wastewater/mixed water sewer systems and in rainwater sewer systems.

3.3.2 Rodenticide formulations typically applied in this area

Baits for controlling rat populations living in sewer systems are generally placed in manholes/cesspools of the drainage systems. It is prescribed in the template for the Summary of Product Characteristics (SPC) of anticoagulant rodenticides (cf. Annex to document CA-Nov16-Doc4.1.b – Final, EC, 2016b) that ‘baits must be applied [in the sewer system] in a way so that they do not come into contact with water and are not washed away’.

According to the questionnaire (Dr. Knoell Consult, 2016c), rodenticide formulations are applied in sewer systems with the following priority (listed from most important to least important). The % values refer to the ratio of positive answers.

- Bait blocks: 57 % of the answers given (51 positive of 90 answers)
- Bagged baits: 30 % (27 positive of 90 answers)
- Loose baits: 7 % (6 positive of 90 answers)

- Pastes, bagged pastes and contact foams are applied to a minor extent (<5 % positive answers for each formulation)

Predominantly, either bait blocks or bagged bait are applied. The placement of loose baits in sewer systems seems to be of minor importance. It is recognised that loose grain baits should not be used in sewer systems, because they may easily fall into the water. The mentioned sewer bait formulations are in accordance with the formulations proposed in the National Sewer Baiting Protocol of the UK (Chartered Institute of Environmental Health, 2013).

The deposition of baits in bait boxes is not a standard practice in sewer systems (Dr. Knoell Consult, 2016c). Baits are mostly hung up (e.g. at the step iron of the cesspools or at a suitable point in the chamber close to ground level) or fixed otherwise (e.g. by a wire). Baits can also be placed on the benching (berm or banquette) of the drainage inspection chamber.

3.3.3 Environmental release pathway

The main release (70 to 90 %, Larsen, 2003) takes place during the service-life phase and is dominated by the intended oral ingestion of baits by target organism (rats) and indirect emissions via rat carcasses, urine and faeces. Significant unintended releases occur due to spillage during the application and caused by rodents, whereas ingestion, by e.g. cockroaches, is considered as almost negligible. Later in the use phase, unintended releases occur by disintegration of the remaining baits.

According to 42 % of the answers given (22 positive of 53 answers; Dr. Knoell Consult, 2016c), baits are not generally or only partly placed above the flood mark or water level. 34 % of the respondents affirmed that flushing away of the baits with water can happen. Therefore, a further source for unintended emissions is the water carriage of baits, e.g. at high water following heavy rainfall events.

Dependent on the application surrounding and the environmental conditions, emissions enter either STPs or surface water bodies. A summary of the primary receiving compartments and the underlying conditions is given in Table 4.

Table 3: Compartments for emissions due to rat control in sewers

Application surrounding	Environmental condition	Drainage	Primary receiving compartment
Waste water/mixed water sewers	Low and average water	Drainage of sewers to STPs	STP
Mixed water sewers	High water	Bypass STP	Surface water
Rainwater sewers	Low, average and high water	Separate rainwater sewer systems	Surface water

If a rodenticide is applied in sewer systems, the wastewater/mixed water sub-scenario has to be calculated in any case since it takes into account the distribution of a compound in STPs according to the SimpleTreat Model. With reference to the ‘bypass’ sub-scenario and the ‘separate rainwater sewer’ sub-scenario, the latter case (separate rainwater sewers) represents the worst-case since the effluent discharge rate of rainwater sewers is lower compared to those of mixed water sewers. Furthermore, the ‘bypass’ scenario for mixed water sewers represents an extremely rare event (ref. to WG II/2018) thus, the ‘bypass’ sub-scenario needs not to be calculated.

3.3.4 Emission scenarios

3.3.4.1 Emission to STP

The scenario for calculating emissions to an STP as a consequence of rodenticide applications in wastewater/mixed water systems (low to average water) is based on the scenario of the original ESD for PT 14 (Larsen, 2003), including some modifications.

$N_{cesspools,treated}$

Public and private authorities in charge of rodent control in sewer systems have different strategies for maintaining the sewers. Authorities may initiate campaigns where sewers of larger areas within cities are successively treated with rat baits, either within days/weeks/months or area by area in different years (Dr. Knoell Consult, 2016a). This comprehensive approach requires 25 % of the cesspools to be loaded with baits (UBA, 2012). The disadvantage of this procedure is that rodent-free sewers are also treated, wasting money and resources. In most cases, this strategy is therefore not common practice. Only 25 % of the TSRs (11 positive of 38 answers) responded that regular and prophylactic sewer baiting takes place. In most cases, sewers are treated following a confirmed infestation by rats. This implies that only infested areas of the sewer system are treated and these areas can be assumed to be smaller compared to the areas treated in the comprehensive approach.

To define the number of cesspools treated with a rodenticide per day within a catchment area corresponding to 10 000 inhabitants feeding one STP, data on the length of sewer systems in different cities/regions and the distances between the manholes were collected (cf. Table 5).

Table 4: Information on the length of sewer systems and the distance between manholes

City/Region	Length of sewers per 10,000 inhabitants (km)	Distance between cesspools (m)	Cesspools per 10,000 inhabitants	Source for information
City in Denmark (name not reported)	35	50-300	350[1)]	Larsen, 2003
Berlin, Germany	18[3)] 9.4[4)]	30-60 30-60	300[2)] 156[2)]	http://www.bwb.de
Cologne, Germany	23	n.r.	230[1)]	http://www.steb-koeln.de
Cities in Germany 5000 – 20000 inhabitants	46 - 184	n.r.	460 - 1840[1)]	Krüger und Solas, 2010
Cities in Germany 50000 – 100000 inhabitants	44 - 88	n.r.	440 - 880[1)]	Krüger und Solas, 2010
St. Augustin, Germany	47	n.r.	1364	UBA, 2012
The Netherlands	44	n.r.	440[1)]	Larsen, 2003
Norway	n.r.	n.r.	70	Dr. Knoell Consult, 2016a
Barcelona, Spain	10	n.r.	100[1)]	Cembrano et al., 2002
Basel, Switzerland	18	n.r.	180[1)]	Dr. Knoell Consult, 2016a
Zürich, Switzerland	25	n.r.	250[1)]	Statistik Stadt Zürich, 2009
Switzerland	n.r.	40-100	n.r.	Gujer, 2007

1) Calculated assuming a distance between the cesspools of 100 m
2) Calculated assuming a distance between the cesspools of 60 m
3) Wastewater and mixed water sewers
4) Rainwater sewers
n.r. = not reported

The number of cesspools per 10 000 PE (person equivalent) is highly variable, ranging from 70 in Norway up to 1 840 in Germany. With the exception of the city of Berlin, the character of the sewers, i.e. whether they are wastewater/mixed water sewers or rainwater sewers, is not known. The distances between cesspools depend on their ability to keep themselves clean and range between 30 and 300 m. As a realistic average distance, a value of 100 m is assumed, keeping in mind that there is enormous variation.

According to the questionnaire (Dr. Knoell Consult, 2016c), the number of rodenticide-treated cesspools per day is limited to 200 at maximum in almost all answers. Nearly 80 % of the respondents defined the rat control area of a campaign to account for 2 km^2 at the utmost. Based on a cesspool distance of 100 m, this results in 200 manholes within a rat control area.

Kokles (2013) specified the manholes treated with rodenticides in Berlin to amount to 18 000 per year, with 10 to 15 manholes located within a single rat control area. A team consisting of two staff members is able to provide for 100 manholes at maximum per day with baits.

According to the Chartered Institute of Environmental Health (2013), access to manholes can raise several difficulties for the sewer-baiting team and is a time-consuming routine. Resurfacing of roads, tar macadam covering the manholes and parked cars can pose challenges for getting access to the channel entrances.

Taking this information into account, it is proposed to use 200 cesspools as a default value for the number of treated cesspools per day. This means a reduction of the number of manholes by 100 compared to the original ESD for PT 14 (Larsen, 2003).

$T_{emission}$

An emission scenario is described illustrating a case where rodenticides are used in a city with a serious rat problem (e.g. heavily infested areas). In this case, cesspools are baited repeatedly until rat control is achieved. The Chartered Institute of Environmental Health (2013) proposes a seven days' strategy, i.e. manholes are visited every seven days and eaten baits are replaced at that time. According to the questionnaire (Dr. Knoell Consult, 2016c), most respondents answered the question for the time of the first inspection after baiting with '7 days or longer'. Therefore, the first time of inspection is set to 7 days following the application, which is in accordance with the original ESD for PT 14 (Larsen, 2003). Emissions, either direct or indirect, are supposed to be highest in the time period between the first application and the first inspection compared to later intervals.

$Q_{prod,7days}$

The amount of rodenticide product applied per cesspools (Q_{prod}) is provided by the label instruction and should be taken directly from it.

According to the questionnaire, the amount of product that has to be replaced after 7 days is highly variable. A default value of 1/3 of the applied baits (33 %) seems to be an appropriate assumption and has also been proposed by the original ESD for PT 14 (Larsen, 2003).

$Fc_{product}$

The fraction of the active substance in the product has a product-specific value, which should be inserted accordingly.

$F_{release\text{-}D,sewer}$, $F_{release\text{-}ID,sewer}$

Emissions to wastewater/mixed water occur indirectly, i.e. via rat carcasses, urine and faeces and directly via spills by rodents and when applying the baits, as well as due to the disintegration of remaining baits. Since flushing away of baits is a relevant route for emissions, it is proposed to increase the direct release by 10 % compared to the original ESD for PT 14 (Larsen, 2003), resulting in 40 % direct and 60 % indirect emissions.

F_{metab}

The active substance can be metabolised in rats' bodies. Indirect emissions to wastewater/mixed water can therefore occur in the form of the active substance itself or as its degradation product(s). As a first tier, the metabolised fraction should be set to 0, indicating that emissions occur exclusively as the unchanged active substance. As a refinement option, metabolism of the active substance can be taken into account. Lowering the indirect release fraction by the metabolised fraction is, however, only valid if the metabolite(s) formed exhibit no toxic effects to water organisms and do not inhibit the function of STPs in the relevant concentration range.

The release to STPs is then:

Table 5: Rodenticide emissions to STPs due to the use in wastewater/mixed water systems

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product applied in one cesspool	Q_{prod}		[kg]	S
Amount of product replaced in one cesspool at the first inspection	$Q_{prod,7days}$		[kg]	O
Fraction of active substance in the product	$Fc_{product}$		[-]	S
Number of cesspools treated	$N_{cesspools,treated}$	200	[-]	D
Number of emission days	$T_{emission}$	7	[d]	D
Fraction of active ingredient released directly	$F_{release\text{-}D,sewer}$	0.4	[-]	D
Fraction of active ingredient released indirectly	$F_{release\text{-}ID,sewer}$	Tier 1: 0.6 Tier 2: Output from eq. (3.2)	[-]	D O
Fraction of active ingredient metabolised	F_{metab}	Tier 1: 0 Tier 2: S	[-]	D S
Output				
Local emission rate	$Elocal_{water}$		[kg.d^{-1}]	O
Intermediate calculation				
$Q_{prod,7days} = Q_{prod} \cdot 0.33$				(3.1)
Intermediate calculation for Tier 2				
$F_{release\_ID,sewer} = 0.6 \cdot (1 - F_{metab})$				(3.2)
Calculation				
$Elocal_{water} = Q_{prod,7days} \cdot Fc_{product} \cdot N_{cesspools,treated} \cdot (F_{release\_D,sewer} + F_{release\_ID,sewer}) / Temission$				(3.3)

The calculation of active substance concentrations in STP and subsequently in surface water, sediment, soil and groundwater should be conducted according to ECHA (2016a), considering an effluent discharge rate of the STP of 2 000 m^3/d and a distribution of the compound in the STP according to the SimpleTreat Model.

3.3.4.2 Emission to surface water bodies

If rodenticides are applied in mixed water sewers having a connection to an STP, heavy weather situation may result in a direct discharge of mixed water to surface water bodies, bypassing the STP (Ahting & Müller-Knoche, 2014). Baits, rodent carcasses and excrements being present in the sewer system are then sources for immediate surface water contamination. This route for emissions is also relevant, if baits are applied in separate rainwater sewer systems which drain rainwater (containing baits, rodent carcasses and excrements) directly into surface waters. In both of these cases (bypass of STP and separate rainwater sewer system), local emissions are calculated according to equations 3.1 to 3.3 (cf. Table 6), whereas the concentrations in surface water are calculated according to equations 3.4 to 3.7 (cf. Table 7), which are in accordance with Ahting & Müller-Knoche (2014). The heavy weather situation leading to a ‘bypass of STP’ scenario for mixed water sewers was considered as an extreme rare event in several PTs (WG II/2018), and thus the scenario should not be used for risk assessment. As this decision was taken after the official commenting period and final discussion of this revised ESD PT14 (WG I/2018), the calculation routine according to equation 3.4 and 3.6 can be regarded as information and is not deleted here. In conclusion, the local concentration in surface water due to mixed water in case of "bypass of STP" does not need to be calculated for PT14.

Table 6: Rodenticide concentrations in surface water due to applications in mixed water(*) and rainwater sewer systems and direct discharge to surface water bodies

Parameters	Nomenclature	Value	Unit	Origin
Input				
Local emission rate	$Elocal_{water}$		[$kg.d^{-1}$]	O (cf. Table 6, eq. 3.3)
Effluent discharge rate of mixed water sewer	$EFFLUENT_{mixed\ water}$	$2.0 \cdot 10^{6}$	[$L.d^{-1}$]	D
Effluent discharge rate of rainwater sewer	$EFFLUENT_{rainwater}$	$0.6 \cdot 10^{6}$	[$L.d^{-1}$]	D
Solids-water partitioning coefficient of suspended matter	Kp_{susp}		[$L.kg^{-1}$]	S (cf. ECHA, 2016a, eq. 26)
Concentration of suspended matter in the river	$SUSP_{water}$	15	[$mg.L^{-1}$]	D
Dilution factor	DILUTION	10	[-]	D
Concentration in mixed water	$Clocal_{mw\_eff}$		[$kg.L^{-1}$]	O
Concentration in rainwater	$Clocal_{rw\_eff}$		[$kg.L^{-1}$]	O
Output				
Local concentration in surface water due to mixed water	$Clocal_{water\_mw}$		[$kg.L^{-1}$]	O
Local concentration in surface water due to rainwater water	$Clocal_{water\_rw}$		[$kg.L^{-1}$]	O
Intermediate calculation				
Mixed water:				
$^{(*)}Clocal_{mw\_eff} = Elocal_{water} / EFFLUENT_{mixed\ water}$				(3.4)
Rainwater:				
$Clocal_{rw\_eff} = Elocal_{water} / EFFLUENT_{rainwater}$				(3.5)
End calculation				
Mixed water:				
$^{(*)}Clocal_{water\_mw} = Clocal_{mw\_eff}/((1 + Kp_{susp} \cdot SUSP_{water} \cdot 10^{-6}) \cdot DILUTION)$				(3.6)
Rainwater:				
$Clocal_{water\_rw} = Clocal_{rw\_eff}/((1 + Kp_{susp} \cdot SUSP_{water} \cdot 10^{-6}) \cdot DILUTION)$				(3.7)

(*) The local concentration in surface water due to mixed water in case of "bypass of STP" does not need to be calculated for PT14 (ref. to information above the Table 7).

3.3.5 Other protection targets

3.3.5.1 Primary poisoning

Apart from the brown rat, no other mammals (or birds) are live or occur in sewers. According to the questionnaire (Dr. Knoell Consult, 2016c), almost all TSRs confirmed, that rodent baits applied in sewers remain underground and will not be transported by rats to the surface.

Therefore, the primary poisoning potential for non-target mammals and birds is considered negligible when baits are applied in sewer systems.

3.3.5.2 Secondary poisoning

The potential for secondary poisoning is relevant if poisoned rats move to the surface. With reference to the questionnaire, 18 % of the TSRs (9 of 51 answers) observed dead rats on the surface during rat control campaigns in sewers. Therefore, the consumption of dead rodents by non-target mammals or birds cannot be excluded and the secondary poisoning risk has to be assessed. The secondary poisoning risk for the food chain contaminated invertebrate – non-target mammal or bird is however, not relevant.

Besides, remains of the rodenticide bait may enter surface water bodies, either directly or via STP. Therefore, the secondary poisoning risk via environmental emissions has also to be assessed for fish-consuming mammals or birds according to ECHA (2016a). Since STP sludge containing rodenticides can be used as a fertilizer to soil, the secondary poisoning risk via environmental emissions for worm-eating birds and mammals has also to be considered according to ECHA (2016a).

3.4 Exposure scenarios for the application in and around buildings

3.4.1 Description of use area

Rodents survive best where the supply of food, water and shelter is uninterrupted. Under these conditions, they can breed all year round and reach a substantial population size. Farm buildings often supply favourable conditions for rodents with an abundance of food present, either seasonally or permanently. Other convenient habitats include industrial food processing premises, food stores, waste incineration plants, restaurants, etc. Commensal rodents such as brown rats, black rats and house mice have perfectly adapted to these conditions and are thus frequently found in and around buildings.

As rodent infestations occur in and outside buildings, both of these application surroundings will be considered in this ESD.

According to the questionnaire, house mice are the major species being controlled indoors (34 %). Consensus of the document on risk mitigation measures for anticoagulant rodenticides (Berny et al., 2014) is that the natural behaviour of house mice is frequently restricted to the indoor environment. However, the publication of Murphy et al. (2005) indicates, that mice are ‘easily moving between adjoining properties (such as semi-detached houses or terraces-defined as housing blocks)’, i.e. premises that are open to a certain extent and next to each other. Hence, premises open to a certain degree seem to be no real barrier for house mice and do not prevent cross-over to the outdoor environment. Furthermore, besides house mice, also other mice species are controlled by indoor baiting. These species might switch more frequently from indoors to outdoors and vice versa. These aspects were acknowledged at WG I/2018 but for the time being it was decided that emissions to the outdoors by mice are considered to be minor and do not need to be assessed. If experience shows, that this is a relevant exposure pathway, mice moving from indoors to outdoors should be included.

In contrast, Norway rats often have their nesting sites outdoors and switch between indoors and outdoors. Therefore, emissions by poisoned rodents (from indoor baiting) dying outside buildings have to be assessed only for rat control.

3.4.2 Rodenticide formulations typically applied in and around buildings

According to the questionnaire survey (Dr. Knoell Consult, 2016d), rodenticide formulations are used in and outside buildings with the following priority (listed from most important to least important). The % values refer to the ratio of positive answers.

Table 7: Rodenticide formulations used in and outside buildings

Formulation	In buildings	Outside buildings
Wax blocks	19.6 % (38 of 194 answers)	24.1 % (48 of 199 answers)
Bagged baits	19.0 % (37 of 194 answers)	19.1 % (38 of 199 answers)
Pastes	19.6 % (38 of 194 answers)	18.1 % (36 of 199 answers)
Bagged pastes	15.5 % (30 of 194 answers)	15.6 % (31 of 199 answers)
Contact foams	14.4 % (28 of 194 answers)	11.1 % (22 of 199 answers
Loose baits	6.7 % (13 of 194 answers)	8.0 % (16 of 199 answers)
Drinking trough	4.6 % (9 of 194 answers)	3 % (2 of 199 answers)

There is no pronounced difference regarding the formulation types used in or around buildings. Wax blocks, bagged baits, pastes and bagged pastes are generally preferred and more frequently used than any other formulation types. According to the TSRs, contact foams are employed in as well as outside buildings. However, with reference to recent BPC opinions on active substance renewals for rodenticides (https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval), rodenticide products in the form of contact formulations shall only be authorised for use indoors. Contact foams as well as drinking troughs are generally applied as supplemental measures to the application of baits (Dr. Knoell Consult, 2016f). Contact foams are used in cases of limited bait acceptance of the rodents, when infestation is high, and if locations for placing solid baits are restricted. The use of a drinking trough containing rodenticides is only reasonable if the environment where rodents live is lacking natural opportunities for drinking sources. For example, this would apply in grain silos or granaries. Drinking troughs are chosen as appropriate means for rodent abatement if rodents show pronounced bait shyness, when there is excess supply of food for rodents and in case of limited opportunities to place solid baits.

According to 75 % of the TSR replies, rodenticides are applied in tamper resistant bait boxes, whereas about 25 % of the answers revealed an application of baits hidden inaccessible without bait stations/boxes. Pursuant to about three fourth of the TSR respondents, rodenticides are fixed in bait boxes. There is no difference in the use of tamper-resistant bait boxes between in and around building baiting.

3.4.3 Environmental release pathway

3.4.3.1 Outdoor use

With reference to recent BPC opinions on active substance renewals for rodenticides (https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval), rodenticide products in the form of contact formulations, other than tracking powder, shall only be authorised for use indoors.

Therefore, for the use of rodenticides outside buildings, solid bait formulations (in this context, the term ‘solid’ also comprises pasty formulations) and liquid formulations (drinking trough) have to be contemplated.

An exposure of the environment can occur via the following pathways:

a) Via direct emissions to soil if baits and drinking trough are placed around buildings on unpaved ground.

A scenario for baits used in bait stations/boxes as the prominent mode of application has already been established in the original ESD for PT 14 (Larsen, 2003) and will be adopted with modifications. This scenario is also applicable for drinking troughs, since it is to be assumed that these will also be placed in bait stations/boxes. Direct exposure of soil occurs by spillage during the application, refill and disposal, as well as transport by rodents. Indirect exposure of soils takes place by rodent carcasses, urine and faeces.

b) Via emissions to paved ground and drainage into the sewer system if baits and drinking trough are placed on concreted or otherwise covered ground around buildings.

Rodenticides in bait stations/boxes are also applied outside buildings surrounded by paved ground. The rodenticide products as well as dead rodents and excrements could potentially reach the sewer system following heavy rainfall events. However, at WG I/2018 it was decided, that with respect to the RMM being implemented in the template for SPC of anticoagulant rodenticides ('place the bait stations in areas not liable to flooding', EC, 2016b) emissions due to the flushing away of products into sewers are not considered to be relevant. Also the flushing of excrements and dead rodents into the sewer system was regarded as negligible as e.g. the transport of carcasses into the sewer system requires extremely high rainfall events.

3.4.3.2 Indoor use

Gaseous formulations

Gaseous rodenticides can be used as fumigants for rodent control within closed structures like containers, storehouses, depositories, transport facilities, etc. Prerequisite for using fumigants is that facilities are not inhabited by people and non-target organisms. The only fumigant authorised for this purpose so far is hydrogen cyanide.

CO_2 is authorised as a rodenticide on a much smaller scale but with the same intended purpose. The gas is used within rodent traps. Once the rodent enters the trap a pressure pad is activated which causes the doors to shut, trapping the rodent inside. Subsequently CO_2 is released from an aerosol canister, which kills the rodent inside the trap (EC, 2007).

The primary receiving compartment for emissions is the surrounding atmosphere during ventilation of the treated structure. However, for hydrogen cyanide as well as for CO_2, the release to air from individual applications as rodenticides is negligible compared to the anthropogenic production of these gases e.g. due to motor vehicle exhaust fumes (EC, 2012a). Since there are currently no other fumigants authorised for these purposes nor volatile substances appearing to be authorised for rodent control within closed structures, an emission scenario for this application has not been developed. Primary and secondary poisoning is also not a subject of concern for this application.

Solid bait formulations

Solid bait rodenticides are widely-used inside buildings, e.g. in stables, restaurants and food preparing premises. 95 % of the TSR respondents (59 positive of 62 respondents, Dr. Knoell Consult, 2016d) confirmed that anticoagulant rodenticides are used for rodent control indoors. An exposure to the environment could occur via the following pathways:

a) Via cleaning of surfaces (meaning surfaces of treated premises, not surfaces of bait boxes) that came into contact with the rodenticides.

   As reported above, baits are placed inside buildings either in bait boxes or they are hidden inaccessible. According to TSRs, spillage of baits indoors occurs but is observed to a limited extent (15 % of the respondents (7 positive of 46 answers) observed spillage indoors). Hence, premises' surfaces that come into contact with baits are restricted. Baits not having been taken up by rodents were declared by 94 % of the TSRs (43 positive of 46 respondents) to be collected and disposed of accordingly. Furthermore, it is assumed that contaminated surfaces might only be eligible to wet cleaning operations to a minor extent. TSRs indicated that one-time wipes and clothes used for wiping away of foam traces are disposed as special waste and in accordance with local requirements. Although it cannot be excluded that wet cleaning operations might result in emissions to STPs, this route is considered to be of minor importance.

b) Via spillage of baits by rodents and transport to outside areas.

   According to 96 % of the TSR replies (44 positive of 46 answers), spilled baits outdoors were not observed when baits are applied indoors. This route for emissions is therefore considered to be negligible.

c) Via poisoned rodents (from indoor baiting) dying outside buildings.

   When rodenticides are applied indoors, poisoned rodents may enter the outdoor environment and die. 41 % of the TSRs (19 positive of 27 respondents) confirmed that dead rodents can be observed outdoors during indoor campaigns. Therefore indirect emissions to the surrounding of the treated structures in form of carcasses, urine and faeces may occur. The primary compartment for these emissions is the soil if structures are surrounded by bare soil. If treated structures are surrounded by paved ground, rodent carcasses and excretions could potentially enter the drainage system at heavy rainfall events. However, at ENV WG I/2018 it was decided, that emissions to STPs do not need to be assessed for reasons outlined above (see point b, section 3.4.3.1)

Contact formulations

Contact formulations (foams, gels) are applied indoors to the entrances of air canal systems, to cracks in walls and holes frequented by rodents. The formulations adhere to the fur upon contact when the rodents squeeze through the treated openings. According to the result of the questionnaire distributed to TSRs (Dr. Knoell Consult, 2016f), the main rodent species controlled by contact foams are brown and black rats as well as house mice. 96 % of the respondents (21 positive of 22 answers) indicated, that contact formulations are applied as an additional option in parallel to other formulations.

Direct release of contact formulations to outdoor soil does not occur since the formulations are only applied indoors. Furthermore, it can be expected that most of the contact formulation on the fur is already taken up during grooming shortly after the rodent has passed the treated hole or passageway and before leaving the building. Therefore, direct release of residues of the biocidal product is not considered. Indirect releases of active substances and/or metabolites to the outdoor soil via urine, faeces and carcasses of poisoned rodents cannot be excluded. Also in the case of contact formulations, this route for emissions is only applicable for rats. The cleaning of e.g. expansion tubes of foam formulations may cause emissions of the product to the sewer system. However, this is assumed as insignificant and therefore not considered here.

Drinking trough

Drinking troughs are applied indoors if rodents show bait shyness, if there is excess supply of food and in case of limited natural water supply.

The main rodent species controlled by liquid bait are rats (brown and black rats) and to a lesser extent also house mice (Dr. Knoell Consult, 2016f). Like contact formulations, drinking troughs are applied as a supplement to solid baiting.

The direct release of the liquid bait to outdoor soil does not occur since the formulations are only applied indoors. Spillage of liquid bait to indoor surfaces may occur, however, wet cleaning of these surfaces and emissions to the sewer system are considered to be negligible.

Notable releases of active substances and/or metabolites to the outdoor soil may, however, occur via urine, faeces and carcasses of rodents. This route of emissions is only applicable for rats and considered in this revised ESD for PT 14.

3.4.3.3 Indoor and/or outdoor use

Via wet cleaning of bait stations/boxes.

22 % of the TSRs (10 positive of 46 respondents) indicated that wet cleaning of bait stations/boxes is common practice. 41 % answered that wet cleaning of bait stations/boxes is done under certain conditions. However, MSs agreed that the regular cleaning of bait stations is not realistic and if be done, emissions might drain to different sewers since the locations for treatment and for cleaning of bait stations might be different. Therefore, emissions by the wet cleaning of bait stations/boxes are not considered.

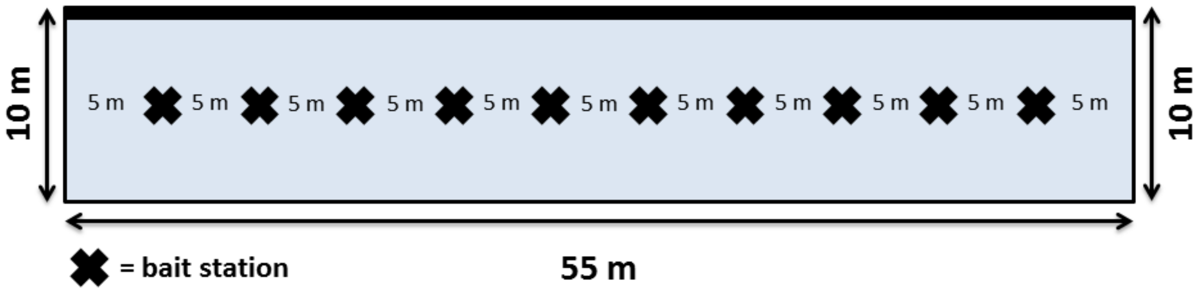
3.4.4 Emission scenarios

3.4.4.1 Outdoor use around buildings

Direct emissions to soils if rodenticides are placed around buildings on unpaved ground

The original ESD for PT 14 (Larsen, 2003) generated an easily interpreted model, consisting of a 55 m wall of a structure, in front of which bait stations/boxes (dimension: 30x20 cm) are placed with their back against the building wall.

Figure 1: Placement of bait stations/boxes along a building wall



Q_{prod}

The amount of rodenticide product applied per bait station/box is provided by the label instruction and should be taken directly from it. Generally, the application amount and the distance between the bait stations/boxes are dependent on the rodent species to be controlled. Mice control is often done with a lower amount of rodenticide product per bait station/box and a lower distance between the bait stations/boxes (distance between the bait stations/boxes is mostly 2 – 5 m) compared to rat control (distance between the bait stations/boxes is mostly 5 – 10 m). Soil concentrations from direct emissions are always highest at the bait station/box containing the highest product amount. Direct emissions contribute to a high extent to the overall soil concentration as the receiving soil compartment is relatively small. Indirect emissions however, depend on the product amount per baiting point and the distance between the bait stations/boxes. Indirect emissions contribute to a lower extend to the overall exposure to soils due to the much larger size of the receiving soil compartment.

$Fc_{product}$

The fraction of the active substance in the product has a product specific value which should be inserted accordingly.

N_{sites}

The default number of sites used for the proposed wall length of 55 m (see above) is 10 for rat control (taking a distance between bait stations/boxes of 5 m) and 20 for mice control (taking a distance between bait stations/boxes of 2.5 m). These figures are guiding values and can be replaced by the label instruction on the number of sites required for outdoor control of a 55 m wall.

N_{appl}

This parameter includes the initial baiting as well as the number of follow-up refilling operations. The initial baiting plus the number of inspections (at each inspection a refill will be done) was assumed to account for 5 in the original ESD for PT 14 (Larsen, 2003). This value is supported by the results of the questionnaire (Dr. Knoell Consult, 2016d).

$F_{release\text{-}D,soil}$ and $F_{release\text{-}ID,soil}$

Emissions to soil occur indirectly, i.e. via rat carcasses, urine and faeces, and directly via spills and disintegration of remaining baits. As default value for the indirect release 90 % ($F_{release\text{-}ID,soil}$ = 0.9) is proposed. For the direct release a default value of 1 % ($F_{release\text{-}D,soil}$ = 0.01) is suggested for bagged baits bagged (bagged baits cover bagged blocks, bagged pastes and bagged grain, bagged pellets and other bagged formulations) as well as drinking trough, and a value of 5 % is suggested for loose baits, not bagged ($F_{release\text{-}D,soil}$ = 0.05). Compared to the original ESD for PT 14, the direct release for loose baits was enhanced by 4 %.

F_{metab}

The active substance can be metabolised in rats' bodies. Indirect emissions to soil can therefore occur in the form of the active substance itself or as its degradation product(s). As a first tier, the metabolised fraction should be set to 0, indicating that emissions occur exclusively as active substance. As a refinement option, metabolism of the active substance can be taken into account. Lowering the indirect release fraction by the metabolised fraction is only valid if the metabolite(s) formed exhibit no toxic effects to soil organisms in the relevant concentration range.

$AREA_{exposed\text{-}D}$, $AREA_{exposed\text{-}ID}$

The directly exposed soil area is assumed to be 10 cm around three sides of the bait box and the soil depth is 10 cm. The directly exposed soil volume is thus 0.009 m^3 per bait box. Indirect emissions via carcasses, urine and faeces are assumed to be distributed over a 10 m zone surrounding the 55 m wall, resulting in an area of 550 m^2 and a soil volume of 55 m^3 soil, considering 10 cm soil depth.

Please note: The above indicated assumptions lead to the conclusion that one bait station/box is considered for 55 m^2, i.e. 5.5 m^3 soil volume for indirect emissions. If the distance between two stations/boxes is modified, or if the intended use is characterised by application of one station/box per e.g. 10 m^2, the affected soil area/volume should be adapted accordingly.

Table 8: Rodenticide emissions to soil due to use around buildings on unpaved ground

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product used at each refill for one bait station/box	Q_{prod}		[g]	S
Fraction of active substance in the product	$Fc_{product}$		[-]	S
Number of application sites Rat control Mice control	N_{sites}	 10 20	[-]	D
Number of applications	N_{appl}	5	[-]	D
Fraction of active ingredient released directly	$F_{release\text{-}D,soil}$	0.01 (bagged baits, drinking trough) 0.05 (loose baits	[-]	D
Fraction of active ingredient released indirectly	$F_{release\text{-}ID,soil}$	Tier 1: 0.9 Tier 2: Output from eq. 3.8	[-]	D S
Fraction of active ingredient metabolised	F_{metab}	Tier 1: 0 Tier 2: S	[-]	D S
Output				
Local direct emission rate to soil from a campaign	$Elocal_{soil\text{-}D}$		[g]	O
Local indirect emission rate to soil from a campaign	$Elocal_{soil\text{-}ID}$		[g]	O
Intermediate calculation for Tier 2				
$F_{release\text{-}ID,soil} = 0.9 \cdot (1 - F_{metab})$				(3.8)
Calculation				
$Elocal_{soil\text{-}D} = Q_{prod} \cdot Fc_{product} \cdot N_{appl} \cdot F_{release\text{-}D,soil}$				(3.9)
$Elocal_{soil\text{-}ID} = Q_{prod} \cdot Fc_{product} \cdot N_{sites} \cdot N_{appl} \cdot F_{release\text{-}ID,soil}$				(3.10)

Table 9: Soil concentrations due to the use of rodenticides around buildings on unpaved ground

Parameters	Nomenclature	Value	Unit	Origin
Input				
Local direct emission rate to soil from a campaign	$Elocal_{soil\text{-}D}$		[g]	O
Local indirect emission rate to soil from a campaign	$Elocal_{soil\text{-}ID}$		[g]	O
Soil area exposed directly	$AREA_{exposed\text{-}D}$	0.09	[m^2]	D
Soil area exposed indirectly	$AREA_{exposed\text{-}ID}$	550	[m^2]	D/S
Depth of exposed soil	$DEPTH_{soil}$	0.1	[m]	D
Bulk density of wet soil	RHO_{soil}	1700	[kg wwt.m^{-3}]	D
Output				
Local concentration of active ingredient in soil resulting from direct exposure	$Clocal_{soil\text{-}D}$		[mg.kg wwt^{-1}]	O
Local concentration of active ingredient in soil resulting from indirect exposure	$Clocal_{soil\text{-}ID}$		[mg.kg wwt^{-1}]	O
Local concentration of active ingredient in soil resulting from direct plus indirect exposure	$Clocal_{soil}$		[mg.kg wwt^{-1}]	O
Calculation				
$Clocal_{soil\text{-}D} = Elocal_{soil\text{-}D} \cdot 10^3 / (AREA_{exposed\text{-}D} \cdot DEPTH_{soil} \cdot RHO_{soil})$				(3.11)
$Clocal_{soil\text{-}ID} = Elocal_{soil\text{-}ID} \cdot 10^3 / (AREA_{exposed\text{-}ID} \cdot DEPTH_{soil} \cdot RHO_{soil})$				(3.12)
$Clocal_{soil} = Clocal_{soil\text{-}D} + Clocal_{soil\text{-}ID}$				(3.13)

3.4.4.2 Indoor use

Rats poisoned indoors but dying outside buildings

Indirect emissions to the surrounding soil of an indoor-treated structure occur in the form of rat carcasses, urine and faeces.

Solid bait formulations

Rodents may enter structures via cracks and crevices, funnels, damaged pipes, open doors or clearances between door frame and door leaf. They move along preferred tracks and often along walls. Baits inside buildings are therefore preferably placed close to entrances, along tracks close to walls or into pipes serving as trails. Hence baits or bait stations/boxes will not be distributed evenly within a building but the placement will preferably take place at infested parts of the structure where rodent activity has been previously observed.

According to TSRs (Dr. Knoell Consult, 2016d) the number of bait stations/boxes within infested structures is highly variable. For an inside area of 100 m^2, 2-10 bait stations/boxes are proposed for rat and 4-40 for mice control.

The calculation of soil concentrations should be conducted according to Table 11 and Table 12. Only indirect releases from rat control operations have to be considered. The following setting should be made.

N_{sites}

Structures protected indoors from rodent infestations are often large buildings like industrial food processing industry premises, and warehouses, hence sensitive areas with reference to hygiene. As a size for the treated structure, a warehouse with an area of 1 000 m^2 and a circumference of 140 m (50 m x 20 m) is assumed. The area size of the warehouse is based on the ESD for PT 18 (OECD No. 18; OECD, 2008). As a model, it is assumed that bait stations/boxes are placed evenly inside, along the exterior wall and along two walls separating the interior area into smaller spaces. Bait stations/boxes are placed at both sides of the interior walls. So the complete wall length being equipped with bait stations/boxes is 220 m (140 m exterior wall plus 4 x 20 m internal wall). Assuming a rodenticide product is applied at a distance of 10 m apart for rat control, this would yield 22 bait stations/boxes. This figure is a guiding value and can be replaced by the label instruction on the number of sites required for indoor control of a 1 000 m^2 warehouse.

$F_{release\text{-}ID,soil}$

Emissions to soil occur only indirectly, i.e. via rat carcasses, urine and faeces. A default value of 50 % indirect release ($F_{release\text{-}ID,soil}$ = 0.5) is considered appropriate.

$AREA_{exposed\text{-}ID}$

Indirect emissions via carcasses, urine and faeces are assumed to be distributed over a 10 m zone surrounding the 140 m exterior wall, resulting in an area of 1 800 m^2 (considering also the corners of the 50 m x 20 m building) and a soil volume of 180 m^3 soil, considering 10 cm soil depth.

Contact formulations

The calculation of soil concentrations for contact formulations should be conducted according to Table 11 and Table 12. Only indirect releases from rat control operations have to be considered. The following assumptions should be made.

Q_{prod}

For rodent control with foams, the applied dosages range from 5-50 g per spot (Dr. Knoell Consult 2016f). The parameter Q_{prod} is generally defined as the amount of product at each refill for each bait station/box. In this case, it is assumed that the content of one tube/spray is completely used for one rodent control operation. As an example, assuming a 500 g spray can and an application amount of 30 g per spot, this would result in approximately 17 treated places, which is considered as a reliable figure. Therefore, the parameter Q_{prod} is a product specific input parameter and dependent on the content of the tube/spray can.

N_{sites}

Since the complete content of one spray container is used for the assessment, N_{sites} is not required and should be set to 1.

N_{appl}

A campaign consisting of two applications is assumed.

$F_{release\text{-}ID,soil}$

Emissions to soil occur only indirectly, i.e. via rodent carcasses, urine and faeces. A default value of 50 % indirect release ($F_{release\text{-}ID,soil}$ = 0.5) is considered appropriate.

$AREA_{exposed\text{-}ID}$

Indirect emissions via carcasses, urine and faeces are assumed to be distributed over a 10 m zone surrounding the 140 m exterior wall, resulting in an area of 1 800 m^2 (considering also the corners of the 50 m x 20 m building) and a soil volume of 180 m^3 soil, considering 10 cm soil depth.

When assessing the environmental risk with respect to contact formulations, it has to be taken into account that these products are generally applied as a supplement to solid rodent baits. The sole allowance for emissions from contact formulations will therefore underestimate potential emissions that could arise. eCA shall consider this fact when evaluating rodenticide contact products.

Drinking trough

The calculation of soil concentrations for drinking trough should be conducted according to Table 11 and Table 12. Only indirect releases from rat control operations have to be considered. The following assumptions should be made.

Q_{prod}

The parameter Q_{prod} is a product specific input parameter. The volume of diluted liquid bait per baiting point is typically 100 – 250 mL, sometimes up to 500 mL.

N_{sites}

Liquid baiting is a niche option for rodent control and always a supplement to solid baiting. It is therefore unlikely, that a complete 1 000 m^2 structure as described above is solely equipped with liquid bait for rodent control. However, as a first approximation the number of sites equipped with drinking trough is assumed to be the same as for the solid bait formulations, i.e., 22 per 1 000 m^2 structure. This figure is a guiding value and can be replaced by the label instruction on the number of sites required for 1 000 m^2.

N_{appl}

The number of applications (including the initial placement of the drinking trough and refills) is assumed to be 5.

$F_{release\text{-}ID,soil}$

Emissions to soil occur only indirectly, i.e. via rat carcasses, urine and faeces. A default value of 50 % indirect release ($F_{release\text{-}ID,soil}$ = 0.5) is considered appropriate.

$AREA_{exposed\text{-}ID}$

Indirect emissions via carcasses, urine and faeces are assumed to be distributed over a 10 m zone sur-rounding the 140 m exterior wall, resulting in an area of 1 800 m^2 (considering also the corners of the 50 m x 20 m building) and a soil volume of 180 m^3 soil, considering 10 cm soil depth.

When assessing the environmental risk with respect to drinking troughs it has to be taken into account that these products are generally applied as a supplement to rodent baits. The sole allowance for emissions from drinking troughs will therefore underestimate potential emissions that could arise. eCA shall consider this fact when evaluating these products.

Table 10: Rodenticide emissions to soil due to the use in buildings and emissions to soil via rat carcasses, urine and faeces

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product used at each refill for one bait station/box (solid bait and drinking trough)	Q_{prod}		[g]	S
Amount of product used at each refill per building (contact formulation	Q_{prod}	1 spray can/tube		S
Fraction of active substance in the product	$Fc_{product}$		[-]	S
Number of application sites	N_{sites}	22 (solid bait and drinking trough) 1 (contact formulation)	[-]	D
Number of applications	N_{appl}	5 (solid bait and drinking trough) 2 (contact formulation)	[-]	D
Fraction of active ingredient released indirectly	$F_{release\text{-}ID,soil}$	Tier 1: 0.5 Tier 2: Output from eq. 3.14	[-]	D S
Fraction of active ingredient metabolised	F_{metab}	Tier 1: 0 Tier 2: S	[-]	D S
Output				
Local indirect emission rate to soil from a campaign	$Elocal_{soil\text{-}ID}$		[g]	O
Intermediate calculation for Tier 2				
$F_{release\text{-}ID,soil} = 0.5 \cdot (1 - F_{metab})$				(3.14)
Calculation				
$Elocal_{soil\text{-}ID} = Q_{prod} \cdot Fc_{product} \cdot N_{sites} \cdot N_{appl} \cdot F_{release\text{-}ID,soil}$				(3.15)

Table 11: Soil concentrations due to the use of rodenticides in buildings and emissions to soil via rat carcasses, urine and faeces

Parameters	Nomenclature	Value	Unit	Origin
Input				
Local indirect emission rate to soil from a campaign	$Elocal_{soil\text{-}ID}$		[g]	O
Soil area exposed indirectly	$AREA_{exposed\text{-}ID}$	1800	[m^2]	D
Depth of exposed soil	$DEPTH_{soil}$	0.1	[m]	D
Bulk density of wet soil	RHO_{soil}	1700	[kg wwt.m^{-3}]	D
Output				
Local concentration of active ingredient in soil resulting from indirect exposure	$Clocal_{soil\text{-}ID}$		[mg.kg wwt^{-1}]	O
Calculation				
$Clocal_{soil\text{-}ID} = Elocal_{soil\text{-}ID} \cdot 10^3 / (AREA_{exposed\text{-}ID} \cdot DEPTH_{soil} \cdot RHO_{soil})$				(3.16)

3.4.4.3 Addition of environmental concentrations arising from indoor and outdoor use of solid baits

Since outdoor and indoor control of rats with solid baits and/or liquid formulations is often done in parallel, soil concentrations arising from indoor and outdoor treatments have to be summed up, where applicable.

3.4.5 Other protection targets

3.4.5.1 Primary poisoning

Regarding the possible primary hazard to non-target species, only birds and mammals of the same size or smaller as the target rodents, i.e. rats and mice, may be able to enter the bait stations/boxes. This means, in practice, that birds, other rodents and possible pet animals may gain access to the bait stations/boxes. Birds may be attracted by the loose bait or cereal containing bait block placed in the bait station/box, and thereby they may be motivated to try to get access to the rodenticide product. Furthermore, spilled baits or parts of baits may be consumed by non-target organisms. The risk for primary poisoning of non-target organisms is valid for outdoor applications of rodenticides.

3.4.5.2 Secondary poisoning

Secondary poisoning hazard via contaminated rodents can only be ruled out completely when the rodenticide is used in fully enclosed spaces so that rodents cannot move to outdoor areas or to (parts of) buildings where predators may have access. Otherwise, non-target predators may be affected by anticoagulants following indoor as well as outdoor applications of rodenticides. Predators among mammals and birds may occur inside buildings and they may hunt in the immediate vicinity of buildings, e.g. in parks and gardens. Scavengers may also search for food close to buildings. Detailed exposure scenarios for the assessment of secondary poisoning are given in section 5.5. Section 5.5 also contains an assessment for the food chain contaminated invertebrate – non-target birds and mammals. This approach is considered to be not relevant for indoor baiting, as e.g. the indoor environment is hostile to snails which might be the most relevant species in this context. For outdoor baiting, however, this route for exposure has to be assessed.

The secondary poisoning risk via environmental emissions has also to be assessed for worm consuming mammals or birds according to ECHA (2016a), if appropriate.

3.5 Exposure scenarios for open areas

3.5.1 Description of use area

This scenario covers the control of rodents in open areas, such as around farmland, public parks and golf courses, where the aim is to prevent “nuisance” from burrows and “soil heaps” or due to public hygiene reasons. Rodenticides are also used to reduce impact on game rearing or outside food stores (potato/sugar beet clams). Rodent species controlled in open areas are predominantly brown rats and voles (water plus common voles, cf. Table 3).

3.5.2 Rodenticide formulations typically applied in this area

According to the questionnaire (Dr. Knoell Consult, 2016e), rodenticide formulations are applied in open areas with the following priority (listed from most important to least important). The % values refer to the ratio of positive answers.

- Bait blocks: 27 % of the answers given (30 of 110 answers)
- Bagged baits: 25 % (27 of 110 answers)
- Pastes: 14 % (15 of 110 answers)
- Bagged pastes: 11 % (12 of 110 answers)
- Gassing formulations: 11 % (12 of 110 answers)
- Loose baits: 7 % (8 of 110 answers)

Contact foams were stated to be used in seldom cases (<5 % of the answers given). However, contact formulations are no longer authorised for applications outdoors (see above).

For open areas, either bait blocks or bagged baits as well as pastes (loose plus bagged) are predominantly applied. Gassing formulations are used less frequently. The placement of loose baits in open areas is of minor importance, according to the results of this survey.

Tamper resistant bait boxes are employed in most cases when rodenticides are applied in open areas, however, to a lesser extent compared to the use in and around buildings. Compared to the 75 % positive answers received for the use in/around buildings, only 66 % of the respondents use tamper resistant bait boxes for applications in open areas. In 34 % of the cases, baits are hidden at places not accessible for humans and non-target species.

3.5.3 Environmental release pathway

3.5.3.1 Solid bait formulations

According to 77 % of the TSRs, the use of rodenticides in rodent burrows is a common practice (Dr. Knoell Consult, 2016e). However, it has to be pointed out that the direct application of baits in burrows is not authorised in every European country. As indicated above, baits for rodent control in open areas are predominantly bait blocks, bagged baits, or pastes (loose or bagged) which are mostly applied in tamper resistant bait boxes. The scenario of the original ESD for PT 14 (Larsen, 2003) considers the direct application of loose baits in rodent burrows.

Although this scenario does not reflect the common use of rodenticides in open areas, the maintenance is justified as the mode of application is established and emissions represent a realistic worst case situation. If baits are placed into bait stations/boxes, the exposure scenario for the application around buildings on unpaved ground applies (section 3.4.3.1, option a) with some modifications.

The main release to soil is expected when loose bait formulations like impregnated grain are applied directly into rodent holes. The product is normally poured approximately 30 cm into the holes by a spoon or a small shovel. The depth of bait placement should be as deep as possible, but depends on the slope and the general accessibility of the burrow. The treated holes are closed by a stone, a piece of board or sod immediately after the application to prevent unintended exposure of children or non-target species (e.g. birds, cats and dogs).

Though rat burrows often have their origin in or close to eroded sewerage systems, the direct exposure of the sewerage system is assessed to be very limited, i.e. less than 1 % of the applied dose.

For bait products applied in open areas in bait stations/boxes, emissions to the soil surrounding the station/box are the predominant release pathway.

3.5.3.2 Gassing formulations

For the purpose of gassing rodent burrows, there is presently only one active substance approved within the EU, i.e., aluminium phosphide, releasing phosphine gas. Gassing formulations (mostly pellets or tablets) generating phosphine gas are used for the control of rats and voles in rodents' underground tunnel systems. Gassing operations are normally conducted in areas where burrows can be satisfactorily capped to contain the phosphine gas, and in locations well away from buildings or other structures. At temperatures above 5°C and in the presence of moisture, the pellets containing 56-57 % aluminium phosphide react with the moisture and evolve toxic hydrogen phosphide (phosphine) gas:

$$AlP + 3H_2O \rightarrow Al(OH)_3 + PH_3$$

The evolved gas reaches a maximum concentration within a few hours. After decomposition, the aluminium phosphide leaves a grey powder of aluminium hydroxide. The phosphine gas is finally transformed into phosphorous compounds with a half-life of a few days to 20 days (Larsen, 2003). Hilton & Robison (1972, in Larsen, 2003) introduced phosphine at 1.4 g/m^{-3} (1 000 ppm) (as P) in the headspace of tubes containing 3 types of soil at 5 moisture levels, i.e. 0 %, 25 %, 50 %, 75 %, and 100 % saturation. It was not stated whether the soils had been sterilised. Phosphine disappeared within 18 days from all air-dried soils, whereas up to 40 days was necessary for disappearance from moisture-saturated soils. Quantities of phosphorous recoverable as phosphate from the soils after incubation for 40 days varied widely with different soil types and reached about 70 % of the total phosphine in a slightly acidic soil, containing 12-15 % organic matter content and at 25 % moisture saturation. Variation in phosphate recovery probably reflected rates of diffusion of phosphine into the soil matrix as a function of moisture content, as well as differences in the efficiency of different soils with different moisture contents as oxidising substrate for phosphine. It becomes obvious, that soils are able to entrap the phosphine in the air or oxidise it to orthophosphate.

Emissions due to gassing of burrows mainly affect the soil and to a limited extent also the air compartment. The release to groundwater is considered negligible due to the transformation into phosphine gas and further to phosphorous compounds.

3.5.4 Emission scenarios

3.5.4.1 Solid bait formulations

Loose solid baits directly applied into rodent burrows

The scenario for calculating emissions to soil linked to burrow baiting with loose baits (e.g. impregnated grain) is based on the scenario of the original ESD for PT 14 (Larsen, 2003), including some modifications.

Q_{prod}

The amount of rodenticide product applied per rodent hole at each refill is provided by the label instruction and should be taken directly from it.

$Fc_{product}$

The fraction of the active substance in the product has a product specific value which should be inserted accordingly.

N_{sites}

Since the release to soil is only calculated for the direct release and not for the indirect release, just one site has to be considered.

N_{appl}

This parameter includes the initial baiting as well as the number of follow-up refilling operations. In the original ESD f or PT 14 (Larsen, 2003) the default value for this parameter was 2. Although the number of usable answers in the questionnaire on the quantity of burrow baitings within a campaign is limited (12 answers, Dr. Knoell Consult, 2016e), it became obvious that 3 or more baitings of a hole take place. According to the respondents, the number of refilling operations (without considering the initial bait application) ranges from 2 to 15. Therefore, a value of 3 is proposed, including one initial application and 2 refilling operations.

$F_{release\text{-}D,soil,\ appl}$ and $F_{release\text{-}D,soil,\ use}$

For direct emissions to soil, the original ESD for PT 14 (Larsen, 2003) proposes a fraction of 0.05 for emissions during the application and 0.20 for emissions during the use (service life) of the baits. In the absence of further data, these release fractions are still valid. Indirect emissions to soil are not considered to be relevant, since dead rodents as well as excrements are assumed to be distributed over a large area, so that soil concentrations arising from indirect emissions are assumed to be negligible.

Table 12: Rodenticide emissions to soil due to burrow baiting with solid baits

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product used at each refill for one rodent hole	Q_{prod}		[g]	S
Fraction of active substance in the product	$Fc_{product}$		[-]	S
Number of application sites	N_{sites}	1	[-]	D
Number of applications	N_{appl}	3	[-]	D
Fraction of active ingredient released directly during application	$F_{release\text{-}D,soil,appl}$	0.05	[-]	D
Fraction of active ingredient released directly during use	$F_{release\text{-}D,soil,use}$	0.2	[-]	D
Output				
Local direct emission rate to soil from a campaign	$Elocal_{soil\text{-}D}$		[g]	O
Calculation				
$Elocal_{soil\text{-}D} = Q_{prod} \bullet Fc_{product} \bullet N_{sites} \bullet N_{appl} \bullet (F_{release\text{-}D,soil,appl} + F_{release\text{-}D,soil,use})$				(3.17)

The exposed soil area is assumed to be the lower half of the burrow wall surrounding an 8 cm diameter tunnel, with the mixing soil depth of 10 cm and up to 30 cm from the entrance hole. Therefore, the exposed soil volume will be divided by two. Thus the total soil volume is:

Table 13: Exposed soil volume for burrow baiting

Parameters	Nomenclature	Value	Unit	Origin
Input				
Radius of exposed soil around a hole	R	0.14	[m]	D
Radius of a hole	r	0.04	[m]	D
Length of exposed hole	l	0.3	[m]	D
Mathematical constant Pi	π	3.1416	[-]	D
Output				
Soil volume exposed to rodenticide	$Vsoil_{exposed}$	0.0085	[m^3]	O
Calculation				
$Vsoil_{exposed} = ((R^2 - r^2) \bullet \pi \bullet l)/2$				(3.18)

Table 14: Local soil concentration after burrow baiting

Parameters	Nomenclature	Value	Unit	Origin
Input				
Local direct emission rate to soil from a campaign	$Elocal_{soil-D}$		[g]	O (cf. Table 13)
Soil volume exposed to rodenticide	$Vsoil_{exposed}$	0.0085	[m^3]	O (cf. Table 14)
Bulk density of wet soil	RHO_{soil}	1700	[kg wwt.m^{-3}]	D
Output				
Local concentration of active ingredient in soil resulting from direct exposure	$Clocal_{soil-D}$		[mg.kg wwt^{-1}]	O
Calculation				
$Clocal_{soil-D} = Elocal_{soil-D} \cdot 10^3 / (Vsoil_{exposed} \cdot RHO_{soil})$				(3.19)

Solid baits applied in bait boxes

If baits are placed into bait stations/boxes, the exposure scenario for the application around buildings applies (section 3.4.3.1, option a), with some modifications.

N_{sites}

Since only direct emissions to soil are relevant for this scenario, only one site has to be considered.

$F_{release-D,soil}$ and $F_{release-ID,soil}$

Indirect emissions to soil are negligible for this scenario, since the area inhabited by rodents is too large to make indirect emissions (via rat carcasses, urine and faeces) a relevant source for soil contamination ($F_{release-ID,soil} = 0$). For direct emissions, a value of 1 % ($F_{release-D,soil} = 0.01$) should be taken for bagged baits and a value of 5 % ($F_{release-D,soil} = 0.05$) for loose baits (please refer to section 3.4.4.1).

$AREA_{exposed-D}$

The directly exposed soil area is assumed to be 10 cm around four sides of the bait box (dimension: 30x20 cm) and the soil depth is 10 cm. The directly exposed soil volume is thus 0.014 m^3 per bait box.

The calculation of soil concentrations should be conducted according to Table 9 and Table 10 (section 3.4.4.1). For reasons of convenience, the tables including the relevant parameters are included below.

Table 15: Rodenticide emissions to soil due to the use in open areas in bait boxes

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product used at each refill for one bait station/box	Q_{prod}		[g]	S
Fraction of active substance in the product	$Fc_{product}$		[-]	S
Number of applications	N_{appl}	5	[-]	D
Fraction of active ingredient released directly	$F_{release\text{-}D,soil}$	0.01 (bagged baits) 0.05 (loose baits)	[-]	D
Output				
Local direct emission rate to soil from a campaign	$Elocal_{soil\text{-}D}$		[g]	O
Calculation				
$Elocal_{soil\text{-}D} = Q_{prod} \bullet Fc_{product} \bullet N_{appl} \bullet F_{release\text{-}D,soil}$				(3.20)

Table 16: Soil concentrations due to the use of rodenticides in open areas in bait boxes

Parameters	Nomenclature	Value	Unit	Origin
Input				
Local direct emission rate to soil from a campaign	$Elocal_{soil\text{-}D}$		[g]	O
Soil area exposed directly	$AREA_{exposed\text{-}D}$	0.14	[m^2]	D
Depth of exposed soil	$DEPTH_{soil}$	0.1	[m]	D
Bulk density of wet soil	RHO_{soil}	1700	[kg wwt.m^{-3}]	D
Output				
Local concentration of active ingredient in soil resulting from direct exposure	$Clocal_{soil\text{-}D}$		[mg.kg wwt^{-1}]	O
Calculation				
$Clocal_{soil\text{-}D} = Elocal_{soil\text{-}D} \bullet 10^3 / (AREA_{exposed\text{-}D} \bullet DEPTH_{soil} \bullet RHO_{soil})$				(3.21)

3.5.4.2 Gassing formulations

Emission to soil after gassing

The scenario for calculating emissions to soil linked to burrow baiting with gassing formulations is based on the scenario of the original ESD for PT 14 (Larsen, 2003).

Q_{prod}

The amount of gassing product applied per 2 ha must be derived from the label instruction. The area of 2 ha as a representative area for water vole control is proposed in Larsen (2003). Water voles often occupy mole's burrow systems if found deserted. Thus information on both animals is used for the scenario development. The burrows of moles are slightly oval, approximately 5 cm wide and 4 cm high, located in a depth of 5 to 100 cm, of which the main parts are located in a depth of 10 to 20 cm. The area covered by the galleries is depending on the amount of food available. In areas with plenty of food, a relatively small burrow system is needed.

The home range for water voles living in the Nordic countries is estimated based on a study from Sweden (Larsen, 2003). The home ranges were observed to vary from 6 m^2 to 4 000 m^2 per individual water vole. As water voles prefer to stay in family groups the total area may be large. A realistic gassing area is estimated to be 2 ha (20 000 m^2).

The length of the superficial burrows is estimated to be 333 m/2 ha (not including the lower galleries). To cover all burrows in a given area, the length of the superficial burrows is multiplied with a factor of 3. Thus the total length is estimated to be about 1 000 m/2 ha.

$Fc_{product}$

The fraction of the active substance in the product has a product specific value which should be inserted accordingly.

Fc_{gas}

Phosphine gas is formed due to the reaction of aluminium phosphide with moisture. To account for different molecular weights of the precursor and the gas, a factor of 0.586 has to be inserted. Aluminium phosphide is currently the only active substance approved for controlling rodents by gassing. In principle, also other metal phosphides might be used for that purpose. In this case, the molecular weight correction has to be done using the respective correction factors. These are summarised in the following table.

Table 17: Fraction of rodenticide gas formed from the precursor product

Compound	Fc_{gas}
Aluminium phosphide	0.586
Magnesium phosphide	0.504
Calcium phosphide	0.373

N_{appl}

Vole abatement with gassing formulations is generally done repeatedly. In case of metal phosphide, the phosphine gas is transformed into phosphorous compounds with a half-life of a few days to 20 days (Larsen, 2003). In this case, it may be sufficient to estimate the local emission of active substance to soil after one application instead of the emission to soil per campaign.

$F_{release\text{-}D,soil}$

For direct emissions to soil, the original ESD for PT 14 (Larsen, 2003) proposes a fraction of 0.99. In the absence of further data, this release fraction is still valid. Indirect emissions to soil are not considered to be relevant. Though lethal for the target organisms (and possible non-target species being present in the vole galleries, e.g. toads and mice), the dose actually inhaled (and thereby removed from environmental exposure of air and soil) is assessed to be insignificant compared to the total dose applied.

Table 18: Rodenticide emissions to soil due to gassing

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product used in one control operation for an area of 2 ha	Q_{prod}		[g]	S
Fraction of active substance in the product	$Fc_{product}$		[-]	S
Fraction of gas formed from the precursor product	Fc_{gas}		[-]	P (cf. Table 18)
Number of applications	N_{appl}	1	[-]	D
Fraction of active ingredient released directly	$F_{release\text{-}D,soil}$	0.99	[-]	D
Output				
Local direct emission rate to soil after one application	$Elocal_{soil\text{-}D}$		[g]	O
Calculation				
$Elocal_{soil\text{-}D} = Q_{prod} \bullet Fc_{product} \bullet Fc_{gas} \bullet N_{appl} \bullet F_{release\text{-}D,soil}$				(3.22)

The exposed area is assumed to be the whole burrow wall surrounding a tunnel of 8 cm diameter and the mixing soil depth is 10 cm. Thus the total soil volume is 56.5 m^3 (cf. Table 20).

Table 19: Exposed soil volume for gassing

Parameters	Nomenclature	Value	Unit	Origin
Input				
Radius of exposed soil around a hole	R	0.14	[m]	D
Radius of a hole	r	0.04	[m]	D
Length of exposed hole	l	1000	[m]	D
Mathematical constant Pi	π	3.1416	[-]	D
Output				
Soil volume exposed to rodenticide	$Vsoil_{exposed}$	56.5	[m^3]	O
Calculation				
$Vsoil_{exposed} = (R^2 - r^2) \bullet \pi \bullet l$				(3.23)

Table 20: Local soil concentration after gassing

Parameters	Nomenclature	Value	Unit	Origin
Input				
Local direct emission rate to soil after one application	$Elocal_{soil\text{-}D}$		[g]	O (cf. Table 19)
Soil volume exposed to rodenticide	$Vsoil_{exposed}$	56.5	[m^3]	O (cf. Table 20)
Bulk density of wet soil	RHO_{soil}	1700	[kg wwt.m^{-3}]	D
Output				
Local concentration of active ingredient in soil resulting from direct exposure	$Clocal_{soil\text{-}D}$		[mg.kg wwt^{-1}]	O
Calculation				
$Clocal_{soil\text{-}D} = Elocal_{soil\text{-}D} \bullet 10^3 / (Vsoil_{exposed} \bullet RHO_{soil})$				(3.24)

Emission to air after gassing

Exposure to air is considered to occur by diffusion from the soil, when not all entrance holes are covered or the application takes place under windy circumstances. Usually the application is performed during calm and dry weather conditions. Thus a minor fraction of about 1 % is assumed to be released to air.

The fraction of emissions to air is a function of the vapour pressure of the active substance. A relevant model for the release to air is the one described in USES 3.0 (Larsen, 2003) developed for pesticides. The general total emission factors and the initial 1-hour and 24-hours averaged source strengths correspond to an application amount of 1 kg/m^2 per application for field use. The emission factors for the initial 1-hour averaged source strength are calculated assuming that 30 % of the total emission occurs in the first hour after application. For the calculation of the initial 24-hour averaged source strength, it is assumed that 90 % of the total emission occurs during the first day after application, which can be considered a realistic worst case. The emission factors and source strengths to air for field uses of pesticides are given in Table 22.

Table 21: Emission factors and source strength to air for field use of pesticides (Larsen, 2003)

Vapour pressure of active substance [Pa]	Total emission factor to air for field application (outdoor use)	24-hour averaged source strength ($Estd_{field,air,24h}$, based on 1 kg/m^2)
$> 1 \bullet 10^{-2}$	1	0.9
$1 \bullet 10^{-2}$ - $1 \bullet 10^{-3}$	0.5	0.45
$1 \bullet 10^{-3}$ - $1 \bullet 10^{-4}$	0.2	0.18
$1 \bullet 10^{-4}$ - $1 \bullet 10^{-5}$	0.1	0.09
$\leq 1 \bullet 10^{-5}$	0.01	0.009

The emission to air within 24 hours is calculated according to Table 23.

Table 22: Rodenticide emissions to air due to gassing

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product used in one control operation per m^2	Q_{prod}		$[kg.m^{-2}]$	S
Fraction of active substance in the product	$Fc_{product}$		[-]	S
Fraction of gas formed from the precursor product	Fc_{gas}		[-]	P (cf. Table 18)
Averaged source strength	$Estd_{field,air,24h}$		[-]	D (cf. Table 22)
Fraction of active ingredient released to air	$F_{release,air}$	0.01	[-]	D
Output				
Local emission rate to air during 24 hours	$Elocal_{air,\ 24\ h}$		$[kg.m^{-2}]$	O
Calculation				
$Elocal_{air,\ 24\ h} = Q_{prod} \cdot Fc_{product} \cdot Fc_{gas} \cdot Estd_{field,air,24h} \cdot F_{release,air}$				(3.25)

The local concentration in air is derived by dividing the emission by the air volume considered. It is suggested to use an air height of 2 m for realistic worst-case considerations in windy situations. For the calculation of the local concentration in air, both the photodegradation and the dilution in air, e.g. caused by wind, should be considered. The phosphine gas is heavier than air and is expected to remain below soil surface if correct application methods are followed. If release occurs due to diffusion or from uncovered holes and during windy weather conditions, the gas will remain close to the ground. It should be noted that the ECHA document (ECHA, 2016a) does not cover this kind of an exposure situation as the local concentration in air calculated there is the annual average local concentration and not a 24 h local air concentration which is calculated here.

The estimated concentration in air is then:

Table 23: Rodenticide concentration in air after 24 hours following gassing

Parameters	Nomenclature	Value	Unit	Origin
Input				
Local emission rate to air during 24 hours	$Elocal_{air,\ 24\ h}$		$[kg.m^{-2}$	O (cf. Table 23)
Air height	$HEIGHT_{air}$	2	[m]	D
Output				
Local concentration in air after 24 hours	$Clocal_{air}$		$[mg.m^{-3}]$	O
Calculation				
$Clocal_{air} = Elocal_{air,\ 24\ h} / HEIGHT_{air} \cdot 10^6$				(3.26)

3.5.5 Other protection targets

3.5.5.1 Primary poisoning

Solid baits or parts of them, either applied directly into rodents' burrows or placed in bait boxes may attract other mammals and birds. Therefore, a risk assessment according to section 5.4 has to be conducted.

Primary poisoning due to gassing operations could theoretically occur if non-target organisms dig out a hole where metal phosphide pellets/tablets have been applied and eat them. In this case, the non-target organisms are highly endangered of being severely intoxicated. However, gassing of rodent burrows is only conducted by trained professionals who can be assumed to apply the pellets or tablets in a way that they are effective. This means that the holes, where the gassing products have been applied, are sufficiently sealed. Furthermore, the formulations are unattractive for being ingested by non-target species and the generated phosphine gas has a strong smell of garlic, ammonia and carbide and is likely to act as a repellent. Primary poisoning by ingestion of the gassing pellets is therefore considered to be negligible.

A risk for primary poisoning occurs when non-target species occupy target rodents' tunnel systems or part of it. This risk refers for example to weasel (*Mustela nivalis*), moles (*Talpa europaea*), ground squirrel (*Spermophilus*) and hamster (*Cricetus cricetus*). The guidance for assessing primary poisoning does not contain an approach for quantifying this risk since there is no PNECmammal for the inhalative exposure available. However, the rationale of such a quantitative risk assessment is challenged anyway, since it is quite certain that the non-target inhabitants are affected in the same way as the target organisms. A quantitative assessment is therefore not considered to be reasonable. To prevent exposure of non-target species by inhalation of phosphine gas, the professional applicator should ensure as far as possible, that only the burrow system of the target organisms is treated and that these burrow systems are not inhabited by non-target species. Fumigation of burrows should only be done in areas, where there are no spoors of non-target organisms.

3.5.5.2 Secondary poisoning

There is a risk for secondary poisoning when solid baits (applied in burrows or placed into bait stations/boxes) are applied in the open areas. Predators among mammals and birds may consume poisoned rodents or poisoned invertebrates, so the risk for secondary poisoning has to be calculated according to section 5.5. Besides, secondary poisoning via environmental emissions has to be considered for worm-eating birds and mammals according to ECHA (2016a). With reference to gassing in underground tunnel systems, the presence of intoxicated animals on the soil surface should be negligible. A relevant exposure of non-target species via the food chain is therefore not considered to be relevant.

3.6 Exposure scenarios for waste dumps/landfills

3.6.1 Description of use area

In waste dumps and landfills, rodents occur quite frequently due to an unlimited food supply, excess shelter for nesting sites, and a continuous transport of rodents to waste dumps by garbage collection trucks. Therefore, it has to be pointed out that rodent control by baiting is only a successful means if there is in parallel a responsible management of the waste dump/landfill, limiting the rodent attracting factors.

According to the responses of TSRs (Dr. Knoell Consult, 2016e), the application of (anticoagulant) rodenticides in waste dumps is an established practice. Mostly the use is limited to occasions of population outbreaks of rodents. Often the rodenticides are deployed around the perimeter of the dump, more than in the disposal area itself.

3.6.2 Rodenticide formulations typically applied in this area

A customised question was not developed for the TSRs to address the use of formulations for rodent control in waste dumps/landfills as this was considered to be covered by the question on formulations used in open areas. With the exception of gassing formulations, the formulations used in waste dumps/landfills are supposed to be applied with the same priority as those indicated by TSRs to be employed in open areas. It is assumed that as a common practice, available coverings (inter alia tamper resistant bait boxes) are used.

3.6.3 Environmental release pathway

The soil is the primary receiving compartment for biocide emissions. Direct exposure of soil occurs by spillage during the application, refill and disposal, as well as transport by rodents. Indirect exposure of soils takes place by rodent carcasses, urine and faeces. Emissions to soil may result in groundwater contaminations.

According to an agreement at ENV WG I/2018, regarding the assessment strategy, a distinction should be made between temporary open collection places/waste management sites and stationary waste dumps/landfills. For temporary waste dumps/landfills, a full assessment (soil, groundwater) has to be done. For stationary waste dumps/landfills, only biocide emissions to groundwater have to be assessed. However, this assessment requires the calculation of soil concentrations (as well as that for secondary poisoning, chapter 3.6.5.2). Therefore, an emission scenario for soil entries is described in chapter 3.6.4., which has to be used for the assessment of all waste dumps and landfills. In the most unlikely case rodenticides are applied exclusively in controlled landfill sites containing more hazardous waste, a groundwater assessment is not necessary if these sites have specific layers to prevent leaching of compounds to aquifers or groundwater.

3.6.4 Emission scenarios

The original ESD for PT 14 (Larsen, 2003) generated a scenario for the application of rodenticides in bait boxes, which is adopted with some modifications.

Q_{prod}

The amount of a rodenticide product applied per bait station/box is provided by the label instruction and should be taken directly from it.

$Fc_{product}$

The fraction of the active substance in the product has a product specific value which should be inserted accordingly.

N_{sites}

The original ESD for PT 14 suggests a scenario that entails 40 kg of blocks placed inside bait boxes, which are distributed over an area of 1 ha. During the evaluation of products applied in waste dumps/landfills, it became obvious, that this application amount per ha might be an overestimation. In order to generate a more realistic application amount, a revised approach was developed based on the assumption that baits are placed in a grid, with rat- and mice-specific distances between them. It has to be pointed out that this approach is a model for obtaining more realistic application amounts. At a common distance of 10 m apart for rat control and a default exposure area of 10 000 m^2, a maximum of 11 x 11 bait points is assumed. Using a typical application amount of 200 g anticoagulant rodenticide product per bait station for rat control, this yields an application amount of 24.2 kg/ha. Mice control is done with a lower distance (5 m) between the bait stations/boxes compared to rat control. It is however not considered realistic to increase the number of bait stations/boxes for mice control to 441, which would be the result from placing bait stations/boxes in a grid with a distance of 5 m. Therefore 242 bait stations/boxes should be taken for mice control, which is twice the number for rat control.

N_{appl}

With reference to the number of rodenticide applications during a campaign in waste dumps, only limited information could be gained from the TSR answers (Dr. Knoell Consult, 2016e). The available responses (5 answers) indicated that 1 to 5 applications are made during a campaign. However, since the database is rather limited, and perhaps not representative, it is proposed to maintain the value of 7 as proposed by the original ESD for PT 14 (Larsen, 2003).

$F_{release\text{-}D,soil}$ and $F_{release\text{-}ID,soil}$

The former ESD for PT 14 considered indirect emissions in the form of rodent carcasses, urine and faeces distributed to a soil area of 10 000 m^2. The value proposed ($F_{release,\ ID\_soil}$ = 0.9) is in line with the default value taken for indirect emissions for the outdoor use of rodenticides around buildings. However, the direct exposure to soils via spilled rodenticides was so far not integrated in the waste dump scenario but is considered to be relevant. For reasons of consistency with the ‘outdoor use of rodenticides around buildings’ sub-scenario, the revised ESD for PT 14 also includes the direct release to soils ($F_{release\text{-}D,soil}$ = 0.01 (bagged baits) and 0.05 (loose baits)).

F_{metab}

The active substance can be metabolised in rodents’ bodies. Indirect emissions to soil can therefore occur in the form of the active substance itself or as its degradation product(s). As a first tier, the metabolised fraction should be set to 0, indicating that emissions occur exclusively as the unchanged active substance. As a refinement option, degradation of the active substance can be taken into account. Lowering of the indirect release fraction by the metabolised fraction is only valid if the metabolite(s) formed exhibit no toxic effects to soil organisms in the relevant concentration range.

$AREA_{exposed\text{-}D}$, $AREA_{exposed\text{-}ID}$

The directly exposed soil area is assumed to be 10 cm around four sides of the bait box and the soil depth is 10 cm. The directly exposed soil volume is thus 0.014 m^3 per bait box. Indirect emissions via carcasses, urine and faeces are assumed to be distributed over an area of 10 000 m^2 resulting in a soil volume of 1 000 m^3 soil, considering 10 cm soil depth.

Table 24: Rodenticide emissions to soil due to the use in waste dumps/landfills

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product used at each application for one bait station/box	Q_{prod}		[g]	S
Fraction of active substance in the product	$Fc_{product}$		[-]	S
Number of application sites Rat control Mice control	N_{sites}	 121 242	[-]	D
Number of applications	N_{appl}	7	[-]	D
Fraction of active ingredient released directly	$F_{release\text{-}D,soil}$	0.01 (bagged baits) 0.05 (loose baits)	[-]	D
Fraction of active ingredient released indirectly	$F_{release\text{-}ID,soil}$	Tier 1: 0.9 Tier 2: Output from eq. (3.27)	[-]	D O
Fraction of active ingredient metabolised	F_{metab}	Tier 1: 0 Tier 2: S	[-]	D S
Output				
Local direct emission rate to soil from a campaign	$Elocal_{soil\text{-}D}$		[g]	O
Local indirect emission rate to soil from a campaign	$Elocal_{soil\text{-}ID}$		[g]	O
Intermediate calculation for Tier 2				
$F_{release\text{-}ID} = 0.9 \cdot (1 - F_{metab})$				(3.27)
Calculation				
$Elocal_{soil\text{-}D} = Q_{prod} \cdot Fc_{product} \cdot N_{appl} \cdot F_{release\text{-}D,soil}$				(3.28)
$Elocal_{soil\text{-}ID} = Q_{prod} \cdot Fc_{product} \cdot N_{sites} \cdot N_{app} \cdot F_{release\text{-}ID,soil}$				(3.29)

Table 25: Soil concentrations due to the use of rodenticides in waste dumps/landfills

Parameters	Nomenclature	Value	Unit	Origin
Input				
Local direct emission rate to soil from a campaign	$Elocal_{soil\text{-}D}$		[g]	O
Local indirect emission rate to soil from a campaign	$Elocal_{soil\text{-}ID}$		[g]	O
Soil area exposed directly	$AREA_{exposed\text{-}D}$	0.14	[m^2]	D
Soil area exposed indirectly	$AREA_{exposed\text{-}ID}$	10,000	[m^2]	D/S
Depth of exposed soil	$DEPTH_{soil}$	0.1	[m]	D
Bulk density of wet soil	RHO_{soil}	1700	[kg wwt.m^{-3}]	D
Output				
Local concentration of active ingredient in soil resulting from direct exposure	$Clocal_{soil\text{-}D}$		[mg.kg wwt^{-1}]	O
Local concentration of active ingredient in soil resulting from indirect exposure	$Clocal_{soil\text{-}ID}$		[mg.kg wwt^{-1}]	O
Local concentration of active ingredient in soil resulting from direct plus indirect exposure	$Clocal_{soil}$		[mg.kg wwt^{-1}]	O
Calculation				
$Clocal_{soil\text{-}D} = Elocal_{soil\text{-}D} \cdot 10^3 / (AREA_{exposed\text{-}D} \cdot DEPTH_{soil} \cdot RHO_{soil})$				(3.30)
$Clocal_{soil\text{-}ID} = Elocal_{soil\text{-}ID} \cdot 10^3 / (AREA_{exposed\text{-}ID} \cdot DEPTH_{soil} \cdot RHO_{soil})$				(3.31)
$Clocal_{soil} = Clocal_{soil\text{-}D} + Clocal_{soil\text{-}ID}$				(3.32)

3.6.5 Other protection targets

3.6.5.1 Primary poisoning

Concerning the risk of primary poisoning, the situation is regarded similar to that described above for rodent control in open areas.

3.6.5.2 Secondary poisoning

The secondary poisoning hazard applies to predators among mammals and birds and scavengers, and thus the situation is comparable to that described above for rodents in open areas.

3.7 Exposure scenarios for bank slopes

3.7.1 Description of use area

Bank slopes of water courses (rivers, drainage channels, berm ditches) and lakes (ponds, lagoons) as well as wetlands are the habitat of semi-aquatic rodents, like two species of the sub-family arvicolinae, i.e. the water vole (*Arvicola terrestris*) and the muskrat (*Ondatra zibethicus*). Semiaquatic organisms are primarily or partly terrestrial but they also spend time in the water for feeding or other activities.

Muskrats feed on cattails and other aquatic vegetation. They also eat corn and other farm and garden crops growing near water bodies. Muskrats build burrows into the bank with an underwater entrance. These entrances are 15–20 cm. In marshes, lodges are constructed from vegetation and mud. In some European countries like Belgium and the Netherlands, muskrats are considered to be a serious pest, as their burrowing damages the dykes and levees on which these low-lying countries depend for protection from flooding. In Germany, muskrats and water voles are among those species, which have been explicitly exempted from the legal species protection status for all mammals to allow their control as pests (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, 2005).

Water voles live in burrows excavated within the banks of rivers, ditches, ponds and streams. Burrows are normally located adjacent to slow moving, calm water with low or no significant fluctuation of the water level. A water depth of about 1 m is optimal. They also live in reed beds where they weave ball shaped nests above ground if no suitable banks exist in which to burrow. Water voles mainly feed on lush stems, leaves and flowers of the vegetation at the water's edge. In the winter months, when such food is scarce, they feed on roots, willow bark, rhizomes and bulbs (Gloucestershire Wildlife Trust, 2009). Water voles have complex underground burrows which have many entrances, interconnecting tunnels, food storage and nest chambers. They live in colonies but spread themselves along a watercourse through a series of neighbouring territories.

In some European countries like the UK, water voles are legally protected. Within the framework of the Wildlife and Countryside Act 1981 (Parliament of the United Kingdom, 1981), 'it is illegal to damage, destroy or obstruct access to any structure or place which water voles use for shelter, protection and breeding and or to disturb a water vole whilst it is using such a place' (http://www.ecologysurveyors.co.uk/water-vole).

With some exceptions, brown rats (*Rattus Norvegicus*) generally live wherever humans live, particularly in urban areas. In the absence of humans, brown rats prefer damp environments, such as river banks. Brown rats dig well, and often excavate extensive burrow systems. The brown rat is an omnivore species and consumes almost anything, but cereals form a substantial part of its diet.

The primary aim of measures against rodents close to surface waters is therefore to prevent burrowing activities since these can result in permeable dykes and river banks as well as in erosion.

Abatement of rats along water ways is not an issue in all European Member States. At ENV WG I/2018, it has been agreed that the bank slope scenario only applies at the product authorisation stage, in case control of rats along water ways is a concern in the country/countries an application is made for and not forbidden by national law.

3.7.2 Rodenticide formulations typically applied in this area

Despite intensive research, the information gained on the use of control techniques on and around bank slopes and dykes is rather limited.

According to the Regulatory Agency of the German Island Föhr (2016, personal communication), amongst rodents muskrats and rabbits are the most prominent species for damaging dykes and bank slopes by burrowing activities. Due to the risk for non-target species, no chemical rodenticides are employed for the control of muskrats, but cage traps are used.

A documentary on the German TV station NDR (Norddeutscher Rundfunk) reported the work of a muskrat controller in the coastal area of northern Schleswig Holstein (http://www.ndr.de/fernsehen/sendungen/die_nordstory/Die-

Kuestenschuetzer,sendung489592.html; last accessed 2016-12-13). Also in this case, non-chemical rodenticides are employed, i.e. break-back traps, which are equipped with fruits or vegetables as baits. With reference to information gained by the Nationalparkverwaltung Schleswig-Holsteinisches Wattenmeer (2016, personal communication), muskrat control on the northern Islands of the North Sea in Germany is done with mechanical methods and not with chemical rodenticides.

Nonetheless, also chemical rodenticides are used at surface waters, obviously mostly against brown rats rather than muskrats and water voles. TSRs reported that rats in sluices are controlled with anticoagulant rodenticides (45 % of 33 answers, Dr. Knoell Consult, 2016c). The Institute of Hygiene and the Environment of the Agency for Health and Consumer Protection of the city of Hamburg (Germany) is responsible for rodent control in public areas. Upon request (Institute of Hygiene and the Environment, 2016, personal communication), the Institute confirmed that rodents (mostly brown rats) are controlled along the rivers Alster and Elbe as well as along smaller rivers and ditches. Rat control is not done pro-actively but in cases of confirmed infestation with chemical rodenticides. Rodenticides are applied into rodent burrows if the risk for flushing away of baits with water can be excluded. Nonetheless the flushing away of baits with water has been observed in seldom cases.

According to the eCA of the Netherlands, rat burrows are often located near drainage channels and chemical rodenticides are used for rat control (AHEE, 2016).

With respect to the information gained, especially brown rats are controlled along water ways. The use of chemical rodenticides, inter alia anticoagulant rodenticides, is a common practice. Flushing away of baits with water cannot be excluded.

With the exception of fumigants, the formulations used against rodents at bank slopes are supposed to be applied with the same priority as those indicated by TSRs to be employed in open areas. It is assumed that baits are either applied without bait stations/boxes in rodents' burrows, or they are placed in coverings (e.g. tamper resistant bait boxes).

3.7.3 Environmental release pathway

In the context of this revised ESD for PT 14, the application of a chemical rodenticide along a drainage channel of wetland marshes is considered. The soil of the bank slope is one of the primary receiving compartments for emissions. Direct exposure of soil occurs by spillage during the application, refill and disposal, as well as transport by rodents. Indirect exposure of soils takes place by rodent carcasses, urine and faeces. These emissions are however covered by the open area scenario.

A further route for emissions is the flushing away of rodenticide baits into the drainage channel due to high rainfall events. Burrows might be flooded and baits carried away into the surface water channel. This route of intake is going to be considered in the framework of this revised ESD for PT 14.

3.7.4 Emission scenarios

Q_{prod}

The amount of rodenticide product applied per bait station/box (Q_{prod}) is provided by the label instruction and should be taken directly from it.

$Fc_{product}$

The fraction of the active substance in the product has a product specific value which should be inserted accordingly.

N_{sites}

The proposed model comprises of a 500 m segment of a drainage channel, which is infested by rats and which is going to be equipped with baits. It is assumed that baits (either without bait stations/boxes in rodent burrows or within bait stations/boxes) are placed on both sides of the channel with a distance of 100 m, resulting in 12 baiting sites. This default value is superseded if the label instruction recommends a different distance between bait points.

N_{appl}

The route for emissions considered in this context is a heavy rainfall event resulting in a washing off of baits. In parallel, the rising water surface results in a flooding of the bait stations/boxes and burrows. Since it is not considered to be realistic that during such a high water period baits will be laid out repeatedly, only one application is considered.

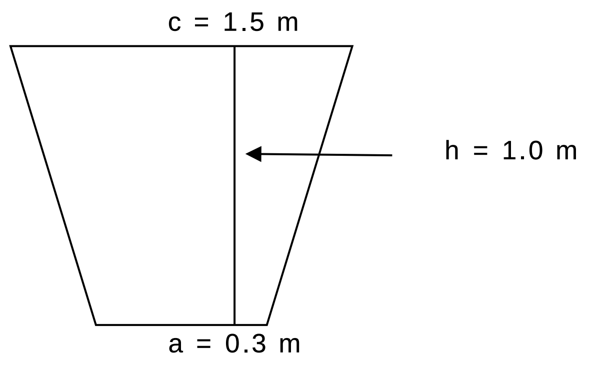
$F_{release\text{-}D,channel}$

For direct rodenticide emissions to the drainage channel a release fraction of 0.4 is proposed, congruent to the release fraction for direct emissions in sewer systems. Indirect emissions are not considered in this context as these are assumed to be of minor importance compared to direct emissions.

$V_{channel}$

The drainage channel has the profile of a trapeze. On the bottom, the channel is 0.3 m wide, the surface has a width of 1.5 m and the water level is 1 m. The water level of the channel differs from the water depth used for predicting PPP concentrations in ditches with FOCUS models (maximum water depth = 36 cm, FOCUS, 2012) due to the fact, that flushing away of baits is assumed to occur due to high water after a heavy rainfall event.

Figure 2: Profile of drainage channel



The water volume of a channel with a length of 500 m is calculated according to:

$V_{channel}$ = (a + c) • h •500/2 eq. (3.33)

$V_{channel}$ = 450 m^3 corresponding to 450,000 L

The channel water is supposed to be stagnant.

Table 26: Rodenticide emissions to surface water due to flushing of rodenticides used on channel banks

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product used for one bait station/box	Q_{prod}		[g]	S
Fraction of active substance in the product	$Fc_{product}$		[-]	S
Number of application sites	N_{sites}	12	[-]	D/S
Number of applications	N_{app}	1	[-]	D
Fraction of active ingredient released directly	$F_{release\text{-}D,water}$	0.4	[-]	D
Water volume of channel	$V_{channel}$	450,000	[L]	D
Output				
Local concentration in channel water	$Clocal_{water\text{-}D}$		[g.L^{-1}]	O
Calculation				
$Clocal_{water\text{-}D} = Q_{prod} \cdot Fc_{product} \cdot N_{app} \cdot N_{sites} \cdot F_{release\text{-}D,water} / V_{channel}$				(3.34)

3.7.5 Other protection targets

3.7.5.1 Primary poisoning

Concerning the risk of primary poisoning, the situation is regarded similar to that described above for rodent control in open areas.

3.7.5.2 Secondary poisoning

The secondary poisoning hazard applies to predators among mammals and birds and scavengers, and thus the situation is comparable to that described above for rodents in open areas. Secondary poisoning via environmental emissions has to be considered for fish-eating birds and mammals according to ECHA (2016a).

4 Exposure scenarios for groundwater

4.1 Introduction and background

The focus of this revised ESD for PT 14 is the estimation of local emissions and local concentrations of rodenticides in the primary receiving environmental compartments. However, since rodenticide active substances might be vertically transported to aquifers or even groundwater when entering the soil compartment, it is considered appropriate to provide guidance on the assessment of local concentrations in groundwater.

According to the BPR (EU, 2012), 'the evaluating body shall conclude that the biocidal product does not comply with criterion (iv) (annotation: criterion (iv) means that the biocidal product should not have unacceptable effects itself or as a result of its residues, on the environment) under point (b) of Article 19(1) where, under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in groundwater exceeds the lower of the following concentrations:

- the maximum permissible concentration laid down by Drinking Water Directive 98/83/EC, (annotation: the maximum permissible concentration is 0.1 µg/L for any one biocidal active and plant protection active substance), or

- the maximum concentration as laid down following the procedure for approving the active substance under this Regulation (annotation: Regulation (EU) No. 528/2012), on the basis of appropriate data, in particular toxicological data,

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.'

This passage of the BPR (EU, 2012) has already been an integral part of the BPD (EU, 1998) with slight modifications (e.g. with reference to the actual version of the Drinking Water Directive).

Hence, if there are relevant emissions to soil which might result in a vertical transport of the rodenticide active substance to aquifers and to groundwater, these emissions have to be assessed and potential concentrations in groundwater must be calculated.

At the Coordination Group (CG) meeting on 7 July 2016 (CG-18 meeting, ECHA, 2016c) on the 'Renewal of anticoagulant rodenticides', this point was discussed and forwarded to the ENV WG. At BPC-WG ENV (ECHA, 2016d), it was concluded that for PT 14 a groundwater assessment should always be performed, even for so-called hot spot applications.

4.2 Emission scenarios for rodenticides where concentrations in groundwater have to be assessed

Table 28 contains a summary of the scenarios and sub-scenarios that may result in emissions of rodenticides to the soil compartment. There are, in principle, two routes for emissions: firstly, the route via STP sludge if rodenticides enter sewage treatment plants, and secondly, the route of a direct exposure of soils which can occur via direct and indirect emissions to soil.

The assessment of groundwater concentrations has to be conducted for the application of solid and liquid baits. The use of contact formulations is considered to be too low to warrant a prediction for groundwater.

Also for gassing formulations, no release to groundwater is to be expected for reasons outlined in section 3.5.3.2.

Emissions to soil may furthermore occur by indoor poisoned rats dying outside buildings. This scenario however, will not be considered with reference to groundwater concentration since the main exposure to soil takes place if rodents are controlled outside buildings and baits are placed on bare soil.

Table 27: Emission scenarios for rodenticides relevant for the calculation of groundwater concentrations

Scenario	Sub-scenario	Exposure to soil
Sewer systems	Application in wastewater/mixed water sewers	Via STP sludge
In and around buildings	Application around buildings in bait boxes/stations	Direct exposure via direct + indirect emissions
Open areas	Application in rodent burrows	Direct exposure via direct emissions
	Application in bait boxes/stations	Direct exposure via direct emissions
Waste dumps	Application in bait boxes/stations	Direct exposure via direct + indirect emissions
Bank slopes	Refer to open area scenario	Direct exposure via direct emissions

4.3 Approach for groundwater assessment and available groundwater models

The calculation of groundwater concentrations is generally conducted as a tiered procedure.

Tier 1: As an indication for potential groundwater residues, the concentration in porewater of agricultural soil is calculated pursuant to ECHA (2016a). According to this method, porewater concentrations are derived based on predicted soil concentrations by applying a partitioning method between the water and the soil phase, which itself is based on the adsorption properties of a compound and the weight fractions of solids and water in soils. Transport in deeper soil layers as well as transformation and dilution processes are not considered in this approach.

Tier 2: As Tier 1 is a rather conservative approach and may result in groundwater concentrations above 0.1 µg/L or above, the maximum permissible toxicological concentration for an active substance or a degradation product, $PEClocal_{gw}$ values can be estimated alternatively by using available groundwater simulation models. These models have more sophisticated scenario definitions and more detailed estimations of transport and transformation in the soil profile.

The FOCUS working group (FOCUS = Forum of the Coordination of Pesticide Fate Models and their Use) developed two models, i.e. FOCUS PEARL (Pesticide Emission Assessment for Regional and Local scales model) and FOCUS PELMO (Pesticide Leaching Model) for the purpose of simulating the transport of PPPs in soils. The models make use of harmonised European standard scenarios, including environmental conditions of nine locations distributed all over Europe. In the context of a research and development project on the 'standard scenarios and parameter setting of the FOCUS groundwater scenarios when used in biocide exposure assessments' (Klein, 2011), both models have been compared regarding their appropriateness and sensitivity for predicting the transport of biocidal active substances into deeper soil layers and groundwater. The outcome of this study reveals that both models are comparably sensitive. However, within the framework of groundwater assessments in the EU for biocides, FOCUS PEARL has become the method of choice. The model has extensively been adapted to biocides use and is an EU accepted tool for simulating the vertical transport of biocidal active substances. The 'Technical Agreements for Biocides' published by ECHA contain already several default values to be used as input parameters for FOCUS PEARL modelling. Substance specific input parameters are going to be included in the near future.

FOCUS PEARL will not further be described in the context of this revised ESD for PT 14. Extensive guidance is available on the model, e.g. Tiktak et al., 2000; Leistra et al, 2001. The revised ESD for PT 8 (wood preservatives) also contains a comprehensive summary of the properties of the model.

4.4 Input parameters

The model requires substance specific input parameters as well as application and crop-specific information, and the appropriate choice of standard scenarios.

4.4.1 Substance specific input parameter

The relevant substance specific input parameters are intended to be included in the 'Technical Agreements for Biocides' published by ECHA.

4.4.2 Application and crop parameter

The following table describes the application and crop parameter and values to be used for the modelling of groundwater concentrations with FOCUS PEARL.

Table 28: Application scheme and crop parameter for FOCUS PEARL calculations

Input parameter	Exposure of soil via STP sludge	Direct exposure via direct (+ indirect) emissions		
		In and around buildings	Waste dumps and landfills	Open areas
Rodenticide application amount per ha	Cf. section 4.4.2.1	Cf. section 4.4.2.2	Cf. section 4.4.2.3	Cf. section 4.4.2.4
Application type	Incorporation Agricultural soil: 0.20 m Grassland: 0.10 m	Surface application	Surface application	Surface application
Application time	Agricultural soil: 20 days before emergence Grassland: March: 1st	On day 1, 3, 7, 14, 21 of the control campaign: September: 15th, 17th, 21th, 28th October: 5th	7 weekly applications: September: 1st, 8th, 15th, 22th, 29th October: 6th, 13th	On day 1, 3 and 8 of control campaign, two campaigns per year: March: 15th, 17th, 22th September: 15th, 17th, 22th
Crop type	Agricultural soil: Maize Grassland: Grass/alfalfa	Grass/alfalfa,	Grass/alfalfa	Grass/alfalfa
Plant uptake factor	0	0	0	0

Since FOCUS PEARL was originally developed to assess groundwater concentrations for PPP, the application amounts must be inserted for an area of one ha. The rodenticide application amounts per ha are derived in the following chapters.

4.4.2.1 Rodenticide application amount per ha: Exposure of soil via STP sludge

For emissions to soil via sewage sludge application, the rodenticide concentration in dry sewage sludge (C_{sludge}) has to be assessed according to equation 39 of ECHA (2016a). The application rate of the active substance per ha for agricultural soil and grassland is calculated according to Table 30.

Table 29: Rodenticides application amount to agricultural soil and grassland via sewage sludge applications

Parameters	Nomenclature	Value	Unit	Origin
Input				
Concentration of the active substance in dry sewage sludge	C_{sludge}		[mg.kg^{-1}]	O (cf. equation 39 of ECHA, 2016a)
Annual sewage sludge application rate to agricultural soil	$App_{sewage\_sludge\_agr}$	5,000	[kg.ha^{-1}]	D
Annual sewage sludge application rate to grassland	$App_{sewage\_sludge\_grass}$	1,000	[kg.ha^{-1}]	D
Output				
Application rate of the active substance per ha to agricultural soil	App_rate_{agr}		[kg.ha^{-1}]	O
Application rate of the active substance per ha to grassland	App_rate_{gras}		[kg.ha^{-1}]	O
Calculation				
$App\_rate_{agr} = App_{sewage\_sludge\_agr} \cdot C_{sludge} \cdot 10^{-6}$				(4.1)
$App\_rate_{gras} = App_{sewage\_sludge\_gras} \cdot C_{sludge} \cdot 10^{-6}$				(4.2)

4.4.2.2 Rodenticide application amount per ha: Exposure of soil following the rodenticide use in and around buildings

Emissions to soil may occur by rats poisoned indoors dying outside buildings. This scenario however, will not be considered with reference to groundwater concentration, since the main exposure to soil takes place if rodents are controlled outside buildings and baits are placed on bare soil.

In the following table, the rodenticide application amount arising from direct and indirect emissions per application for an area of 1 ha is calculated. It is assumed that 11 buildings with a wall length of 55 m are located per ha. The number of houses per ha was deduced from standard house scenarios used in other ESDs, e.g. from the ESD for PT 8 (OECD, 2013). The standard house is 17.5 m long and 7.5 m wide and covers an area of 131.25 m². Taking into account the 10-meter zone around the house as the zone most frequented by rodents, the resulting $AREA_{exposed\text{-}ID}$ is 900 m² (= $AREA_{total} – AREA_{house}$). So 11 houses are located on 1 ha (11 x 900 m^2 = 9900 m^2). Hence, the number of bait stations/boxes per ha accounts for 110 for rat control and 220 for mice control.

Table 30: Rodenticide emissions to soil for groundwater calculations arising from applications around buildings on unpaved ground

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product used per application for one bait station/box	Q_{prod}		[g]	S
Fraction of active substance in the product	$Fc_{product}$		[-]	S
Number of application sites Rat control Mice control	N_{sites}	 110 220	[ha^{-1}]	D
Fraction of active ingredient released directly	$F_{release\text{-}D,soil}$	0.01 (bagged baits) 0.05 (loose baits)	[-]	D
Fraction of active ingredient released indirectly	$F_{release\text{-}ID,soil}$	Tier 1: 0.9 Tier 2: Output from eq. (4.3)	[-]	D O
Fraction of active ingredient metabolised	F_{metab}	Tier 1: 0 Tier 2: S	[-]	D S
Output				
Local direct emission rate to soil from one application per ha	$Elocal_{soil\text{-}D,one\ appl}$		[$g.ha^{-1}$]	O
Local indirect emission rate to soil from one application per ha	$Elocal_{soil\text{-}ID,\ one\ appl}$		[$g.ha^{-1}$]	O
Application rate to soil from one application per ha	App_rate		[$kg.ha^{-1}$]	O
Intermediate calculation for Tier 2				
$F_{release\text{-}ID} = 0.9 \bullet (1 - F_{metab})$				(4.3)
Calculation				
$Elocal_{soil\text{-}D,\ one\ appl} = Q_{prod} \bullet Fc_{product} \bullet N_{sites} \bullet F_{release\text{-}D,soil}$				(4.4)
$Elocal_{soil\text{-}ID,\ one\ appl} = Q_{prod} \bullet Fc_{product} \bullet N_{sites} \bullet F_{release\text{-}ID,soil}$				(4.5)
$App\_rate = (Elocal_{soil\text{-}D,\ one\ appl} + Elocal_{soil\text{-}ID,\ one\ appl}) \bullet 10^{-3}$				(4.6)

4.4.2.3 Rodenticide application amount per ha: Exposure of soil following the rodenticide use in open areas

For open areas, burrow baiting as well as the application of baits in stations/boxes are relevant application modes to be considered with respect to groundwater. The number of application sites per ha is dependent on the rodent infestation. As a reference value, an estimation of 100 bait points per ha is proposed for rat control. For mice control, the number of treated burrows is expected to be 2-fold higher, i.e. 200 bait points/ha.

Table 31: Rodenticide emissions to soil for groundwater calculations arising from burrow baiting and application in bait stations/boxes in open areas

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product used per application for one application site	Q_{prod}		[g]	S
Fraction of active substance in the product	$Fc_{product}$		[-]	S
Number of application sites per ha Rat control Mice control	N_{sites}	 100 200	[ha^{-1}]	D
Fraction of active ingredient released directly, burrow baiting	$F_{release\text{-}D,soil\_burrow}$	0.25	[-]	D
Fraction of active ingredient released directly, bait station	$F_{release\text{-}D,soil\_bait\ station}$	0.01 (bagged baits) 0.05 (loose baits)	[-]	D
Output				
Local direct emission rate to soil from one application per ha, burrow baiting	$Elocal_{soil\text{-}D,one\ appl,\ burrow}$		[$g.ha^{-1}$]	O
Local direct emission rate to soil from one application per ha, bait station	$Elocal_{soil\text{-}D,one\ appl,\ bait\ station}$		[$g.ha^{-1}$]	O
Application rate to soil from one application per ha, burrow baiting	App_rate_{burrow}		[$kg.ha^{-1}$]	O
Application rate to soil from one application per ha, bait station	$App\_rate_{bait\ station}$		[$kg.ha^{-1}$]	O
Calculation				
Burrow baiting				
$Elocal_{soil\text{-}D,\ one\ appl,\ burrow} = Q_{prod} \cdot Fc_{product} \cdot N_{sites} \cdot F_{release\text{-}D,soil,\ burrow}$				(4.7)
$App\_rate_{burrow} = Elocal_{soil\text{-}D,\ one\ appl,\ burrow} \cdot 10^{-3}$				(4.8)
Use of bait stations				
$Elocal_{soil\text{-}D,\ one\ app,\ bait\ stationl} = Q_{prod} \cdot Fc_{product} \cdot N_{sites} \cdot F_{release\text{-}D,soil,\ bait\ station}$				(4.9)
$App\_rate_{bait\ station} = Elocal_{soil\text{-}D,\ one\ appl,bait\ station} \cdot 10^{-3}$				(4.10)

4.4.2.4 Rodenticide application amount per ha: Exposure of soil following the rodenticide use in waste dumps/landfills

Emissions to soil following the use of rodenticides in waste dumps/landfills have also to be calculated according to Table 31 (use in bait stations). The number of sites used for the 1 ha area is 121 for rat control and 242 for mice control.

Groundwater calculations need not to be conducted in case rodenticides are applied exclusively in controlled landfill sites containing more hazardous waste, if these have specific layers to prevent leaching of compounds to aquifers or groundwater. Such sites are assumed to be governed by national landfill site regulations which include the protection of groundwater.

5 Primary and secondary poisoning of non-target species

5.1 Introduction

Comments of eCAs in the framework of the questionnaire dealt with the integration of small non-target granivorous rodents into the list of generic focal species for assessing the risk for primary poisoning (Dr. Knoell Consult. 2016a). Due to a similar body size compared to target species, non-target small mammals may enter bait stations/boxes and are prone to be poisoned primarily. It could be shown that *Apodemus* species, bank voles (*Myodes glareolus*), greater white toothed shrews (*Crocidura russula*), *Sorex spp.* and *Microtus spp.* caught during and after Norway rat control campaigns with brodifacoum baits had residues of the active substance in their liver tissues (Geduhn et al., 2014). Contaminated non-target organisms can be the prey for rodent-consuming wildlife, like foxes (Geduhn et al., 2015) and barn owls (Geduhn et al., 2016), resulting in a secondary poisoning risk for these animals. Therefore, the risk for non-target small rodents from the consumption of rodenticide baits has been integrated in the revised ESD for PT 14.

Invertebrates like snails are capable of entering bait boxes and consuming rodenticide baits. Thus, animals like hedgehogs, starling or shrews feeding on contaminated invertebrates can accumulate anticoagulant rodenticides in their tissues (Dowding et al., 2010). Alomar et al., 2018 have investigated the accumulation of three anticoagulant active substances (chlorophacinone, bromadiolone or brodifacoum) in the slug *Deroceras reticulatum* exposed for a period of 5 days followed by a depuration time of 4 days in the laboratory. Furthermore, they studied the exposure of slugs to brodifacoum baits placed in bait boxes in the field. In the laboratory trial all slugs consumed baits and all three anticoagulant rodenticides could be detected in snails from the first day of exposure on. Mortality could not be observed. The decrease of bromadiolone and brodifacoum concentrations in slugs was significant during the post exposure period but not significant for chlorophacinone. The estimated elimination half-lives were 1.9 days, 2.5 days and 4.0 days for bromadiolone, brodifacoum and chlorophacinone, respectively. In the field study part, brodifacoum was detected in more than 90 % of the analysed slugs. Based on a toxicity-exposure ratio approach, the authors judged that slug consumption represents a risk of secondary poisoning for hedgehogs, shrew and European starling, with shrews being affected most seriously. Hence, this exposure route is relevant and will be considered in the risk assessment for secondary poisoning.

Secondary and tertiary poisoning may also occur, when non-target organisms like birds feed on rodenticide baits or poisoned rodents and are afterwards eaten by non-target predators or scavengers. It is well acknowledged, that this transfer of a compound along the food chain is a relevant exposure pathway for secondary and tertiary consumers but further research as a basis for a quantitative assessment is recommended.

Though similarities exist, there are differences as to the susceptibility to or tolerance of the different rodenticides among non-target mammals and birds.

Within the framework of the revision of the ESD for PT 14, the relevance of the species used for the primary and secondary risk assessment was reviewed and revised, as appropriate. Additionally, the establishment of a generic approach is attempted for the identification of focal species regarding different behaviour patterns and food habits.

The identification of generic focal species is based on the following criteria:

1. Probability to feed on rodenticide baits (primary poisoning) or on poisoned organisms (secondary poisoning) based on the respective species' foraging behaviour and its presence in areas where rodenticides are used.

2. Ratio food intake rate (FIR) / body weight (bw).

3. Monitoring of poisoning incidents/residues.

4. Relevance of species within the EFSA document on risk assessment for birds and mammals (EFSA, 2009).

In the questionnaire (Knoell, 2016a), eCAs requested a harmonisation of the procedure for assessing primary poisoning of biocides with the procedure applied for PPPs as described in the EFSA document (EFSA, 2009). Therefore the chapter on primary poisoning of this ESD has been adapted accordingly.

A summary table of the scenarios and sub-scenarios for which an assessment on primary and secondary poisoning has to be conducted is enclosed in Appendix 8.2 (Table 41).

5.2 NAET (No Acute Effect Threshold) derivation for anticoagulant rodenticides and the acute poisoning situation

The questionnaire sent to eCAs (Dr. Knoell Consult, 2016a) contained the following question regarding the $PNEC_{oral}$ derivation for the acute poisoning situation:

'The addendum for $PNEC_{oral}$ derivation of anticoagulant rodenticides (now integrated as Appendix 5 in ECHA, 2016a) proposes a qualitative approach for the acute poisoning situation, due to the lack of guidance for calculating an acute $PNEC_{oral}$. Do you consider this qualitative approach to be sufficient or should a quantitative approach be implemented in a revised ESD for PT 14, based on a $PNEC_{oral}$ for the acute situation?'

7 out of 9 eCAs answered that they would prefer a quantitative approach when assessing acute primary and secondary poisoning incidents. A proposal is therefore made here for the derivation of a $PNEC_{oral}$ for the acute poisoning situation (lethality). Since the term '$PNEC_{oral}$' is generally based on chronic effect concentrations, it is not appropriate to specify an acute threshold value. Therefore, the threshold value for the acute poisoning situation as defined here is termed 'No Acute Effect Threshold' (NAET).

The first draft CARs of the anticoagulant rodenticide active substances were screened to learn about the original approaches taken by the different eCAs. Different approaches were taken in the first draft CARs with regards to the acute poisoning situation (both primary and secondary) of birds and non-target mammals:

- The least conservative approach was applying an AF of 10 on a single dose LD_{50} for birds and mammals, respectively, to derive the NAET values for birds and mammals. The choice of an AF of 10 on a single dose LD_{50} is principally in line with the approach taken in the EFSA guidance 'Risk Assessments of Birds and Mammals' (EFSA, 2009).

- Another option was the implementation of an AF of 40 on the same LD_{50} values to derive NAET values for birds and mammals. This AF of 40 comprised of a factor of 4, which was assumed for extrapolation of a LD_0 from the measured LD_{50} value and a factor of 10 for interspecies variation.

- In one CAR, the NAET for birds was derived by applying an AF of 30, covering interspecies variation and laboratory to field extrapolation, on a single dose LD_{50} for birds. For mammals, the same AF was applied to a NOAEL from an acute oral study.

- The most conservative approach taken when deriving the NAET for birds was to apply an AF of 30 on a NOEC from a 5-days dietary study for birds. For mammals the AF of 30 was applied on a NOEC (derived from a NOAEL) from an acute oral study with mammals (single dose). The AF of 30 covers variation between species and between laboratory and field; however, no extrapolation from an acute to a chronic exposure situation.

- In the draft CARs which were published after endorsement of the addendum to the original ESD for PT 14 (Appendix 5 in ECHA, 2016a), the acute poisoning situation was addressed in a qualitative manner without deriving quantitative NAET values.

It is proposed to use the following approach for the derivation of NAET values of birds and mammals:

- Birds: Application of an AF of 30 on a NOEC from a 5-days dietary study (OECD 205)

- Mammals: Application of an AF of 30 on a NOEC from an acute oral study with mammals (single dose)

Both kinds of studies represent realistic worst-case conditions for acute poisoning situations. For birds, it could be argued that also a single dose LD_{50} could be used for NAET derivation together with an AF of 30 to align it with the derivation of the mammalian NAET. However, a reliable single-dose LD_{50} with birds may not always be available (e.g. as for difenacoum) and according to the Guidance on BPR, Volume IV: Environment Part A: Information Requirements (ECHA, 2014) for rodenticides, short-term toxicity testing with birds (avian dietary toxicity test) is to be preferred to acute oral toxicity studies. Accordingly, a reliable acute oral study may not be available for rodenticide active substances and therefore, the NOEC from a 5-day feeding study is proposed as a basis for NAET derivation.

According to ECHA (2016a), the assessment factor (AF_{oral}) takes into account interspecies variation, acute/sub-chronic to chronic extrapolation and laboratory data to field impact extrapolation. The AF of 30 proposed above, accounts for interspecies variation, lab-to-field extrapolation, as well as acute/sub-chronic to chronic extrapolation. The latter extrapolation is however, not applicable in this context as only the acute poisoning situation is concerned. Therefore, an application of an AF of 30 on a NOEC from a single dose study for mammals and on a NOEC from an avian dietary toxicity test, respectively, seems to be sufficiently conservative to cover an acute primary and secondary poisoning incident for mammals and birds.

The NOEC values from a 5-days feeding study with birds and an acute oral study with mammals should be the first choice for the NAET derivation. In case no NOEC values are available, but LC_{50}/LD_{50} values, a higher assessment factor of 300 should be employed.

5.3 Scheme for assessing the potential for primary and secondary poisoning

A tiered approach is proposed for assessing the risks through both primary and secondary poisoning.

Table 32: Tiered approach for assessing the potential for primary and secondary poisoning

Tier	Acute / chronic	Primary poisoning	Secondary poisoning
Tier 1	Acute	Risk is quantified as the ratio between the concentration of the active substance in the bait in mg/kg food (PEC_{oral}) and the no acute effect threshold for oral intake for non-target birds and mammals (NAET in mg/kg food).	Risk is quantified as the ratio between the concentration in the rodent/slug immediately after a last meal on day 5 ($PEC_{oral,rodent/slug}$ in mg/kg food (=rodent or slug)) and the no acute effect threshold for oral intake for the predator (NAET in mg/kg food). The parameters AV, PT and PD (only relevant for rodents) are by default 1. The ADME factor is by default 0. The parameters F_{rodent} and F_{slug} are by default 1.
	Chronic	Risk is quantified as the ratio between the concentration of the active substance in the bait in mg/kg food (PEC_{oral}) and the chronic predicted no-effect concentration for oral intake for non-target birds and mammals ($PNEC_{oral}$ in mg/kg food).	Risk is quantified as the ratio between the concentration in the rodent/slug immediately after a last meal on day 5 ($PEC_{oral,rodent/slug}$ in mg/kg food (=rodent or slug)) and the predicted no-effect concentration for chronic oral intake for the predator ($PNEC_{oral}$ in mg/kg food). The parameters AV, PT and PD (only relevant for rodents) are by default 1. The ADME factor is by default 0. The parameters F_{rodent} and F_{slug} are by default 0.5.
Tier 2	Acute	Risk is quantified as the ratio between the estimated daily intake of a compound (ETE in mg/kg bw/d) by generic focal species and the no acute effect threshold for oral intake for non-target birds and mammals (NAET in mg/kg bw/d). The parameters PT, PD and AV are by default 1 but can be lowered (<1) based on data.	Risk is quantified as the ratio between the concentration in a generic focal predator/scavenger species after single or prolonged exposure ($PEC_{oral\ rodent/slug\ predator}$ in mg/kg bw/d) and the no acute effect threshold for oral intake (NAET in mg/kg bw/d). The parameters PT, PD and AV (only relevant for rodents) are by default 1 but can be lowered (<1) based on data. The ADME factor is by default 0 but can be altered if data of ADME studies are available. The parameters F_{rodent} and F_{slug} are by default 1.
	Chronic	Risk is quantified as the ratio between the estimated intake of a compound ($PEC_{oral,5\text{-}d}$ in mg/kg bw) for 5 consecutive days (immediately after the last meal) and the chronic predicted no-effect concentration for oral intake for the non-target birds and mammals ($PNEC_{oral}$ in mg/kg bw/d). The parameters PT, PD and AV are by default 1 but can be lowered (<1) based on data. The ADME factor is by default 0 but can be altered if data of ADME studies are available.	Risk is quantified as the ratio between the concentration in a generic focal predator/scavenger species after single or prolonged exposure ($PEC_{oral\ rodent/slug\ predator}$ in mg/kg bw/d) and the predicted no-effect concentration for chronic oral intake ($PNEC_{oral}$ in mg/kg bw/d). The parameters PT, PD and AV (only relevant for rodents) are by default 1 but can be lowered (<1) based on data. The ADME factor is by default 0 but can be altered if data of ADME studies are available. The parameters F_{rodent} and F_{slug} are by default 0.5.

The $PNEC_{oral}$ should be calculated according to ECHA (2016a). The results of the available mammalian or avian tests used for the NAET or $PNEC_{oral}$ derivation may be expressed as a concentration in the food (mg/kg food) or as a dose (mg/kg bw/d). For tier 1 assessment, the unit of the NAET/$PNEC_{oral}$ must be mg/kg food, whereas for tier 2 it is mg/kg bw.

Correspondingly, toxicity data has to be converted if necessary according to equations 96 and 97 of ECHA (2016a). Data from animals used in the test should preferably be used for conversion, i.e. body weight and daily food intake of the test species. If these are not available, appropriate default conversion factors from ECHA (2016a, Table 24) should be taken.

A detailed description of the procedure for assessing the primary and secondary poisoning risk is given in the following chapters.

5.4 Primary poisoning

In the EFSA guidance document on the risk assessment for birds and mammals exposed to PPPs (EFSA, 2009), the primary poisoning risk assessment is generally structured in a screening step and three tiers. In the first screening step, an indicator species[1] is used along with worst-case assumptions. Substances that pass the screening step are considered to pose a low risk. Substances failing the screening step have to go to tier 1, which uses more realistic exposure estimates and generic focal non-target species[2]. In case the substance does not pass, tier 2 applies. This involves more realistic exposure scenarios and focal species[3] relevant for certain regions or crops. If substances still fail, a weight of evidence approach is applied (tier 3). Weight of evidence approach, according to the EFSA guidance, means that the risk is characterised by giving appropriate weight to each of the available lines of evidence.

The EFSA guidance document for PPPs (EFSA, 2009) includes several scenarios which are not applicable to be transferred to rodenticides, e.g. spray applications. The scenario that is most appropriate in terms of rodenticide applications is the risk assessment for treated seeds. It is clear that treated seed applications in the plant protection area are different compared to the application of cereal-based baits treated with rodenticides. However, the procedure for assessing concentrations of active substances in non-target species due to primary poisoning can basically be adopted with modifications.

In the EFSA scheme for treated seeds, no screening step is proposed, but instead the assessment starts at tier 1 using generic focal species. Although eCAs wish a harmonisation of the risk assessment procedure with reference to primary poisoning between PPPs and biocides, it is proposed to maintain a screening step (in this context called tier 1). This tier 1 step has already been an integral part of the addendum to the original ESD PT 14 (now Appendix 5 of ECHA, 2016a), however no quantitative NAET value has been defined in the addendum. Tier 1 in this revised ESD for PT 14 is the comparison of the rodenticide concentration in the food (bait) with the NAET (acute poisoning situation) and the $PNEC_{oral}$ (chronic poisoning situation)

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[1] An ‘indicator species’ is not a real species but, by virtue of its size and feeding habits, is considered to have higher exposure than other species that occur in the particular crop at a particular time. It has a high food intake rate and consumes one type of food which in turn has high residues on/in it (EFSA, 2009).

[2] A ‘generic focal species’ is considered to be representative of all those species potentially at risk, i.e. it is based on ecological knowledge of a range of species that could be at risk. It has a high food intake rate and may consume a mixed diet rather than just one as for the indicator species (EFSA, 2009).

[3] A ‘focal species’ is a real species that actually occurs in the crop when the pesticide is being used. The aim of using a ‘focal species’ is to add realism to the risk assessment insofar as the assessment is based on a real species that uses the crop. It is essential that the species actually occurs in the crop at a time when the pesticide is being applied. It is also essential that this species is considered to be representative of all other species that may occur in the crop at that time (EFSA, 2009).

for oral uptake for non-target birds and mammals (see section 5.2).

The tier 1 assessment of the EFSA guidance document corresponds to the tier 2 assessment in this context. Generic focal species are defined and the estimated daily intake is compared to the NAET and $PNEC_{oral}$ acute and chronic values, respectively.

With reference to the tier 2 assessment as being proposed by EFSA, a transfer to rodenticides is not appropriate. The close relationship between applications of PPPs in certain regions/crops, and habitats of focal non-target species is not considered to apply to that extent for rodenticides. It is acknowledged, that there might be different species predominantly affected primarily if rodenticides are applied, e.g. around buildings or in open areas. Such a close interaction between the areas of use and the habitats of focal non-target species may apply to PPPs, but cannot reliably be established for rodenticides. The tier 2 assessment as described in the EFSA document is therefore not reasonable for rodenticides.

5.4.1 Relevant non-target species for assessing the potential for primary poisoning

Baits are mostly based on cereals, thus granivorous and omnivorous birds and mammals are the potentially affected non-target species. The most relevant species are therefore:

- Small non-target granivorous and omnivorous mammals and birds which fit into bait boxes or have otherwise access to baits, applied in a protected manner.

- Larger non-target granivorous and omnivorous birds and mammals, not able to enter a bait box or a protected baiting place, however feeding on spilled baits.

The original ESD PT 14 (Larsen, 2003) considered different species as being relevant, representing domestic animals (i.e., dogs as well as young pigs and adult pigs) and granivorous wildlife birds (i.e., tree sparrows, chaffinches, woodpigeons and pheasants).

Based on the proposal in the original ESD for PT 14 and information gained, the following recommendation is made for lead non-target species:

a) Shrews (*Sorex spp.*): Non-target small mammals such as shrews, wood mice (*Apodemus sylvaticus*) or yellow-necked mice (*Apodemus flavicollis*) are especially susceptible for primary poisoning as they are nearly of the same size as target rodents and thus are able to enter bait stations/boxes. Shrews have been chosen as generic focal species for primary poisoning assessment because (i) residues of anticoagulant rodenticides have been already detected in shrews (Geduhn et al., 2012), (ii) they have a high daily food intake to body weight ratio and (iii) shrews, in contrast to *Apodemus* species, are insectivore/carnivore and are thus not considered as (rodent) pest species, which is sometimes the case for wood mice or yellow-necked mouse. Although shrews are mostly insectivorous/carnivorous species, it has been reported that seeds can be an important part of the diet for some species of shrew (Saarikko, 1989).

b) Dogs (*Canis familiaris*): As indicated in Larsen (2003), dogs are more omnivorous animals compared to cats and as such become more often victims of primary poisoning. Furthermore data analyses highlighted that dogs, amongst mammals, are the most exposed species to anticoagulant rodenticides (Buckle, 2013). Therefore it is proposed to maintain dogs as generic focal species for assessing the primary poisoning risk.

c) Pigs (young/adult (*Sus scrofa*): Due to available toxicity data, pigs can be considered to be the most susceptible species among domestic animals (Larsen, 2003). Because of the lower body weight of a young pig compared to adult pigs, it is considered to be sufficient to address only the young pig in the assessment for primary poisoning.

d) House sparrow (*Passer domesticus*): House sparrows are omnivorous birds. Small seeds are included in their diet. House sparrows live close to and even inside man-made structures (Larsen, 2003). Studies have shown house sparrows feeding on baits by entering the bait stations (Elliot et al., 2014). For reason of harmonisation with the EFSA document, the house sparrow should be included as generic focal species instead of the tree sparrow, which was included in the original ESD for PT 14.

e) Chaffinch (*Fringinella coelebs*): Since house sparrows are commensals of civilization, they are considered to be of a higher primary poisoning risk compared to chaffinches. Furthermore, there is no pronounced difference in the body weight and the food consumption of chaffinchs compared to sparrows (Larsen, 2003). Therefore, chaffinches are covered by assessing the primary poisoning risk for house sparrows.

f) Woodpigeon (*Columba palumbus*): The woodpigeon is widely distributed in agricultural, forested landscapes as well as in urban landscapes (Miljøministeriet, 2010). They prefer to place their nests on or even inside man-made structures (Larsen, 2003). Depending on the season, high amounts of cereals or seeds are their main diet. Thus, pigeons are potentially highly exposed to anticoagulant rodenticides used in their surroundings. The woodpigeon is also a focal species in the EFSA document as a medium herbivorous and granivorous bird (EFSA, 2009). Therefore, it is proposed to keep the woodpigeon as a representative species for assessing the risk for primary poisoning.

g) Pheasant (*Phasanisu colchicus*): Referring to the ESD for PT 14 (Larsen, 2003), the pheasant is important to be included in the risk assessment as a representative for medium–sized granivorous birds, and could be used as a focal species for the domestic hen. Pigeons however, are cultural successors and appear more frequently in regions affected by humans compared to pheasants which need forest edges and open areas (Robertson, 1992). Furthermore, pheasants have a much higher bodyweight compared to woodpigeons, so the risk for primary poisoning for pheasants is already covered by the assessments for woodpigeons. Thus, the woodpigeon represents a worst case, covering pheasants and domestic hens.

5.4.2 Exposure scenario

5.4.2.1 Tier 1

The tier 1 assessment for primary poisoning due to rodenticides corroborates to the screening step of the EFSA guidance document. In the tier 1 assessment, it is assumed, that the whole day's food requirement of the non-target species consists of the consumption of the rodenticide. Avoidance is not considered to be relevant. Therefore, the concentration in the food is the same as the concentration of the active substance in the bait. If for example the concentration in the bait is 0.005 %, the PEC_{oral} would account for 50 mg/kg food. This PEC_{oral} is set into relation to the NAET (in mg/kg food) for the acute poisoning situation and to the $PNEC_{oral}$ (in mg/kg food) for the chronic poisoning situation.

5.4.2.2 Tier 2

If rodenticides are applied, they might be available for non-target organisms over a certain time period. This is especially true, if rodenticides are applied permanently, which is routine in certain areas (cf. section 2.3). Therefore, the exposure for primary poisoning should include the acute as well as the chronic poisoning situation.

FIR (food intake rate), body weight (bw), rodenticide product consumption (RPC)

In the original ESD for PT 14, the upper limit of rodenticide product taken up by young pigs and dogs has been fixed to 600 g per day, which was defined as the amount being available at maximum for amateurs in a single package. Recent BPC opinions on active substance renewals for rodenticides (https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval) propose a maximum pack size for anticoagulant rodenticides and amateur use of 1 500 g and 300 g for FGAR and SGAR, respectively. Therefore, it is proposed to keep the 600 g as a default value for young pigs and dogs.

Body weights of house sparrows, woodpigeon and shrews as well as the ratios FIR/bw have been taken from EFSA (2009).

Table 33: Generic focal species for assessing the primary poisoning risk: Ratio food intake rate (FIR) / body weight (bw) and rodenticide product consumption (RPC) / body weight (bw)

Generic focal non-target species	Body weight (bw in g)	Food intake rate / bw (g/g bw per day)	Rodenticide product consumption (RPC)/ bw (g/g bw per day)
Shrew (*Sorex ssp.*)	9.7	0.55	n.r.[1)]
Dog (*Canis familiaris*)	10000	n.r.	0.06
Pigs (young, *Sus scrofa*)	25000	n.r.	0.024
House sparrow (*Passer montanus*)	27.7	0.23	n.r.
Woodpigeon (*Columba palumbus*)	490	0.1	n.r.

[1)] n.r. = not relevant

C (corresponding to $Fc_{product}$)

The concentration of the active substance in the fresh diet (bait) has a product specific value which should be inserted accordingly.

General remarks to the parameters AV (avoidance factor), PT (fraction of diet obtained in treated area), PD (composition of diet obtained from treated area) and ADME (absorption, distribution, metabolism and excretion)

In the original ESD for PT 14 (Larsen, 2003), the parameters AV and PT are proposed to be lowered to 0.9 and 0.8, respectively as realistic worst-case values, based on EPPO recommendations (a proposal for lowering PD has not been made in the original ESD for PT 14). In the EFSA guidance, this per se reduction is, however, not integrated. The tier 1 assessment in the EFSA guidance document (corresponding to the tier 2 assessment in this case) is based on the conservative assumption that non-target birds and mammals feed entirely on rodenticides and do not avoid the baits. By default, all three parameters are 1. A refinement may involve lowering the three parameters AV, PT and PD, but only in case data are available justifying this reduction. This rationale is now also taken over for the primary poisoning assessment for biocides. This means, that lowering the default value of 1 for AV, PT and PD is only permitted if data are available providing unequivocal indications that this is justified.

The rate of absorption, distribution, metabolism and excretion (ADME) in the gastrointestinal tract of non-target birds and mammals may influence the toxicity of the active substance (EFSA, 2009). In the original ESD for PT 14 (Larsen, 2003), this factor is named ‘elimination factor’ (EL). Since the parameter comprises absorption, distribution, metabolism and excretion of a compound it is more appropriately be termed ADME factor. The ADME factor is by default 0. A general increase of the ADME factor to 0.3 as proposed in the addendum to the original ESD for PT 14 is not foreseen in the EFSA guidance document. In accordance with the EFSA guidance, also for rodenticide assessment this parameter can only be altered if data from ADME studies are available justifying this increase. Otherwise, the default factor of 0 applies.

AV (avoidance factor)

The avoidance of rodenticide baits by non-target birds and mammals is a mechanism that might reduce the exposure. Avoidance can occur by two mechanisms, i.e., due to novel or unpleasant characteristics of the food or due to sub-lethal intoxication because of previously having consumed the contaminated food (EFSA, 2009). If the latter reason is responsible for the reduced feeding (which could apply for the consumption of rodenticides), EFSA considers the implementation of a simple multiplication factor AV as not being appropriate. The factor should be set to 1 by default if no data on avoidance are available. When data have been generated unequivocally indicating avoidance to the baits, these can supersede the default value.

PT (fraction of diet obtained in treated area)

PT defines the proportion of the animals' daily diet obtained in the area controlled with rodenticides. By default it is assumed, that generic focal non-target species find all their food in the controlled area, which is in line with EFSA (2009), thus PT being 1. This is a worst-case assumption especially when taking into consideration the chronic exposure situation. The parameter PT can be lowered based on available data.

PD (composition of diet obtained from treated area)

Congruent to EFSA (2009), it is assumed by default that the complete diet of a non-target species consists of the rodenticide bait, which is expressed by PD being 1. The parameter PD can be lowered based on available data.

ADME factor

The ADME factor is the fraction of daily uptake detoxified in bodies of non-target species. Congruent to EFSA (2009), by default no absorption, distribution, metabolism and elimination of substances in the gastrointestinal tract of non-target birds and mammals is assumed to influence the toxicity of the product (ADME = 0). However, ADME studies can be used for inserting a factor >0 – 1.

Table 34: Acute primary poisoning, tier 2: Estimated daily uptake of a rodenticide compound

Parameters	Nomenclature	Value	Unit	Origin
Input				
Food intake rate / body weight	FIR/BW		[g food.g $bw^{-1}.d^{-1}$]	P (cf. Table 34)
Rodenticide product consumption / body weight	RPC/BW		[g food.g $bw^{-1}.d^{-1}$]	P (cf. Table 34)
Concentration of the active substance in the fresh diet (bait)	C		[$mg.kg^{-1}$]	S
Avoidance factor	AV	1/<1	[-]	D/S
Fraction of diet obtained in treated area	PT	1/<1	[-]	D/S
Composition of diet obtained from treated area	PD	1/<1	[-]	D/S
Output				
Estimated daily uptake of a compound	ETE		[$mg.kg^{-1}bw.d^{-1}$]	O
Calculation				
ETE = FIR/BW • C • AV • PT • PD (house sparrows, shrews and woodpigeon)				(5.1)
ETE = RPC/BW • C • AV • PT • PD (dogs and young pigs)				(5.2)

The ETE represents the $PEC_{oral,acute}$ and should be set into relation to the NAET. Note that if the NAET is calculated from a study in which the endpoints are expressed as dietary concentrations, conversion to a daily dose should be made (please refer to the section below Table 33).

For the chronic exposure, a repeated consumption of the baits over 5 days is considered. The expected concentration of an active substance in an animal for the chronic situation is the estimated intake of a rodenticide compound for 5 consecutive days ($PEC_{oral,5-d}$). In case a study is available indicating a stop-feeding-effect of target species after less than 5 meals, this can be taken into account. Dissipation and degradation rates of the active substance in the rodenticide bait could reduce the estimated daily uptake of a compound. However, rodenticides are designed for being effective for a certain time period under environmental conditions hence the stability of the product should be maintained, especially when being applied in bait boxes. Dissipation and degradation of the active substance in the rodenticide product is therefore not taken into consideration.

The factor PT might, however, gain more importance in the chronic exposure situation as especially birds may obtain their food in a variety of areas and the longer the time period, the higher the probability that locations with non-contaminated food are visited. However, by default all reduction factors (AV, PT, PD) are set to 1 and the ADME factor is 0. If suitable data are available, the parameters AV, PT and PD can be lowered. Furthermore, ADME studies can be used for inserting a factor >0 – 1.

$PEC_{oral,5-d}$ is calculated according to Table 36.

Table 35: Chronic primary poisoning, tier 2: Expected concentration of an active substance in a non-target animal immediately after the 5th meal (PECoral,5-d)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Estimated daily uptake of a compound	ETE		$[mg.kg^{-1}\ bw.d^{-1}]$	Cf. Table 35
ADME factor	ADME	0/>0	[-]	D/S
Number of days the not-target species is consuming rodenticide baits	n	1 to 4[1)]	[d]	D
Output				
Expected concentration of an active substance in the non-target species on day 5 immediately after the 5th meal	$PEC_{oral,5\text{-}d}$		$[mg.kg^{-1}\ bw]$	O
Calculation				
$PEC_{oral,5\text{-}d} = (\sum_{n=1}^{4} ETE \bullet (1 - ADME)^n + ETE)$				(5.3)

[1)] In case a study is available indicating a stop-feeding-effect of target species after less than 5 meals, n can be adapted

The $PEC_{oral,5\text{-}d}$ in mg active substance.kg^{-1} bw should be set into relation to the $PNEC_{oral}$ expressed as daily dose (see section below Table 33).

According to section 3.5.5.1 a risk assessment for primary poisoning by gaseous formulations is not considered to be reasonable.

5.5 Secondary poisoning

The secondary poisoning risk for non-target birds and mammals consuming rodents is forced by behavioural changes of poisoned target organisms, making them an easier prey for predators compared to non-poisoned rodents. In the original ESD for PT 14 (Larsen, 2003), a procedure is defined for assessing the risk for non-target animals, ingesting poisoned target organisms. This procedure has been revised as described below. In addition, a quantitative approach is provided to assess the secondary poisoning risk for non-target birds and mammals when consuming poisoned snails.

5.5.1 Relevant non-target species for assessing the potential for secondary poisoning

Pets such as cats and dogs that live in close contact with human beings are at risk of being poisoned with rodenticides if they prey on poisoned rodents around buildings where rodenticides are used. Other predatory mammals such as foxes, polecats, stone martens, stoats, racoon dogs and weasels may be at risk because they often search for prey around farms, gardens, parks or other areas where rodents may be controlled.

Raptors such as common kestrels, common buzzards, red kites, tawny owls, barn owls and eagle owls are bird species that prey on living rodents. They often hunt around or not far away from human settlements or in areas where rodents are controlled due to their pest status. Though such birds of prey do not eat rodenticides, their risk of being victims of secondary poisoning through poisoned prey animals has to be evaluated. Also scavenger birds such as *corvidae* (e.g. crows and allies) and *laridae* (gulls) and other birds such as buzzards and kites which scavenge as well may be at risk for secondary poisoning.

The accumulation of anticoagulant rodenticides in invertebrates has been reported by several authors (a summary is given in Alomar et al., 2018). The diet of many mammals (e.g. hedgehogs, shrew) and birds (European starling) in Europe consists of slugs, so this is an important route for anticoagulant transfer in predators.

Based on their feeding habit, the relevant species for secondary poisoning are:

- Predatory mammals or birds that feed on poisoned target rodents and which especially search for prey in areas where rodents may be controlled (e.g. red kite (*Milvus milvus*), barn owl (*Tyto alba*), common kestrel (*Falco tinnunculus*), red fox (*Vulpes vulpes*), weasel (*Mustela nivalis*)).

- Predatory mammals or birds that feed on poisoned non-target organisms ((e.g. red kite (*Milvus milvus*), barn owl (*Tyto alba*), common kestrel (*Falco tinnunculus*), red fox (*Vulpes vulpes*), weasel (*Mustela nivalis*)). This route for secondary poisoning will not be dealt with separately in this revised ESD as it is considered to be covered by the risk assessment for predatory mammals and birds that feed on poisoned target rodents. Rodenticide concentration in non-target species can be assumed to be in the same order of magnitude compared to concentrations in target species. However, it is acknowledged, that this exposure route may affect other predatory species compared to those mentioned above, e.g., snakes.

- Omnivorous/insectivorous/carnivorous mammals and birds that mainly feed on invertebrates (e.g. slugs) that have taken up rodenticides and which especially search for prey in areas where rodents may be controlled (e.g. shrew).

- Scavenger birds that mainly feed on carrion and which especially search for carcasses in areas where rodents may be controlled (e.g. crows).

The original ESD PT 14 (Larsen, 2003) considered different species representing raptors (i.e., barn owls, kestrels, little owls and tawny owls) as well as mammalian predators (i.e., foxes, polecats, stoats and weasels).

In the framework of the revision of the original ESD for PT 14 (Larsen, 2003), the relevance of these species was reviewed. Additionally, the establishment of an approach was attempted for the identification of generic focal species regarding different behaviour patterns and food habits.

Based on the information gained, the following animals are selected as generic focal non-target species:

a) Barn owl (*Tyto alba*): Barn owls are bird species that almost exclusively prey on rodents, particularly voles, shrews and wood mice (Buckle, 2013, Geduhn et al., 2016, Glue, 1972). They often nest in houses and artificial nest boxes (Petty, 1994) and hunt close to human settlements or in areas where rodents may be controlled (Larsen, 2003). Anticoagulant rodenticides were found in more than 50 % of the investigated barn owls (Dowding et al., 2010, Shore et al., 2013; Geduhn et al., 2016) and the amount of detected anticoagulant residues has been rising steadily from 1980 to 2011 (Walker et al., 2013). The barn owl is called a long-term sentinel referring to PBMS (Predatory Bird Monitoring Scheme, Walker et al., 2010). Thus, the barn owl functions as a generic focal species for secondary poisoning for all the other owls used in the former ESD (Larsen, 2003).

b) Common Kestrel (*Falco tinnuculus*): Common kestrels prey on rodents, mainly common voles and shrews (Yalden et al., 1979, Fiuczynski, 1960). They often hunt close to human settlements or in areas where rodents may be controlled due to their pest status (Larsen, 2003). Kestrels are highly affected by anticoagulant rodenticides (Koivisto et al., 2016, Dowding et al., 2010). Referring to the Predatory Bird Monitoring Scheme (PBMS) report (Walker et al., 2010), kestrels are considered as species of concern, with a similar diet as the barn owl but, for unknown reasons, with a greater assimilation of residues.

c) Carrion crow (*Corvus corone*): Crows often nest close to human settlements or in areas where rodents may be controlled. They often feed on carrions and are therefore potentially at risk of being poisoned secondarily with rodenticides (Erikson & Urban, 2004). Researchers killed unpoisoned water voles and showed that carrion crows took two thirds of all the carcasses (Montaz et al., 2014). Thus, it seems likely that carrion crows are generic focal species for being poisoned with rodenticides (Montaz et al., 2014).

d) Red fox (*Vulpes vulpes*): The red fox is a general feeder with a high percentage of rodents in its diet. Red foxes especially feed on small mammals (Dell'Arte et al., 2007). Additionally, they are well adapted in living in urban and semi-urban environments (Harris & Baker, 2001, Vuorisalo et al., 2014). This combination makes them vulnerable for secondary poisoning with rodenticides. Many studies show residues in the red fox (e.g., Berny et al., 1997). A recent study showed the highest anticoagulant rodenticides concentration in a red fox (920 µg brodifacoum /kg body weight) compared to all the other investigated species. This fox was found dying in a garage (Koivisto et al., 2016). Jacquot, M. et al. (2013) have monitored the red fox population in the Doubs Department in France to document the impact of bromadiolone used to control outbreaks of the water voles in grassland (use as a PPP). Relative fox densities obtained from 2004-2009 were related to treatments during the years 2003–2008. It could be observed that bromadiolone applications had an impact on the red fox population. Abundance of foxes was reduced significantly in areas with extensive rodenticide use. The red fox is therefore an important mammal for secondary poisoning and it is proposed to keep it as generic focal species.

e) Weasel (*Mustela nivalis*): The weasel is also a largely affected non-target species since its main diet consists of 80 % small rodents. Several studies (Elmeros et al., 2011, Koivisto et al., 2016) have shown high concentrations of anticoagulant rodenticides in weasels (up to 1610 µg/kg ww). The latest monitoring study showed higher anticoagulant rodenticides concentrations in stone martens (which forage in more urban habits) compared to weasels. But still, weasels have to be considered as a worst-case species because they feed on rodents more frequently compared to stone martens and additionally, the weasel is the smallest of the mustelids with a body weight of only 47 g. Stone martens weigh about 1300 g (Dierks, 2002). Thus, the weasel has a very high FIR/bw ratio (Larsen, 2003) which makes it a generic focal species, representing the mustelids. A secondary poisoning risk for polecats (*Mustela putorius*) and stoats (*Mestela erminea*) needs therefore not to be assessed.

f) Domestic cat (*Felis silvestris catus*): Domestic cats may feed on small mammals. Thus there is a high risk of being poisoned secondarily by rodenticides. As domestic animals, they are the second most exposed species following dogs (Buckle, 2013), however the routes for exposure are different. Whereas dogs are vulnerable due to the direct consumption of baits, cats are prone due to the consumption of poisoned rodents. Anticoagulant rodenticides residues were found in 100 % of the investigated cats (Koivisto et al., 2016).

g) Shrews (*Sorex spp.*): Non-target small mammals such as shrews are susceptible for secondary poisoning via the consumption of invertebrates (slugs) containing rodenticides. Rodent baiting with brodifacoum baits in plastic bait boxes revealed 90 % of the slugs collected during and afterwards the campaign to contain remains of the anticoagulant (Alomar et al., 2018). Therefore, the food chain contaminated slug - shrew will be considered.

h) European starling (*Sturnus vulgaris*): According to Alomar et al., (2018), the European starling is also at risk due to its diet consisting of slugs. The calculation for invertebrate consuming birds is optional, since the exposure of predatory birds represents already the worst case.

5.5.2 Exposure scenario

5.5.2.1 Tier 1

The EFSA guidance document does not include a methodology for quantifying the secondary poisoning risk of non-target species.

Therefore, the methodology as described in the original ESD for PT 14 (Larsen, 2003) and the addendum to it (Appendix 5 in ECHA, 2016a) has been adopted including some modifications. These mainly refer to the differentiation between the acute and the chronic secondary poisoning situation as well as the integration of the food chain contaminated slug – shrew/starling.

The tier 1 assessment of secondary poisoning is based on the concentration in the predators or scavengers food, i.e. poisoned rodents and slugs. For the acute secondary poisoning situation, the concentration of the rodenticide within the rodent and slug immediately after a last meal on day 5 has to be calculated. Congruent to the original ESD for PT 14 (Larsen, 2003), it is assumed that rodents consume food equivalent to 10 % of their body weight. The parameters PT, PD and AV, which are relevant for calculating the concentration in the rodent, are by default 1. Larsen (2003) has proposed three PD factors (0.2, 0.5 and 1) accounting for different amounts of rodenticide baits being taken up by rodents. A PD factor of 1 is defined to represent the realistic worse case and this value is therefore recommended to be used. The ADME factor is by default 0. The values for PT, PD and AV and ADME can be adapted based on data. The reduction factors are not considered to be applicable for calculating the concentrations in slugs. It is assumed, that the non-target animals consume 100 % of their daily intake on poisoned rodents ($F_{rodent/slug}$ = 1).

Slugs like *Deroceras reticulatum* have a body weight of 40–1 000 mg (Frank & Marone, 1999; Alomar et al., 2018). Slugs are quite voracious and can consume between 25 % (Rheinland Pfalz, 2010) and 40 % (http://www.hortipendium.de/Schnecken) of their body weight per night. Sometimes, even 50 % is reported. For the risk assessment, it is assumed that slugs consume rodent baits corresponding to 40 % of their body weight.

For the first tier of the chronic secondary poisoning assessment, the predators or scavengers are exposed for a longer period of time to rodents or slugs that have been exposed for 5 days. The daily food intake of the predator/scavenger is assumed to consist of 50 % poisoned rodents (F_{rodent} = 0.5) or 50 % of poisoned snails (F_{snail} = 0.5) and 50 % uncontaminated food, which is in accordance to the recommendation of the original ESD for PT 14 (Larsen, 2003) and also in line with the assumptions in ECHA (2016a), that for secondary poisoning 50 % of the diet originates from the local environment.

Table 36: Acute and chronic secondary poisoning, tier 1: Predicted environmental concentration of an active substance in food (rodent, slug) of a predator/scavenger

Parameters	Nomenclature	Value	Unit	Origin
Input				
Food intake rate / body weight rodent	FIR/BW_{rodent}	0.1	[g food.g bw^{-1}.d^{-1}]	D
Food intake rate / body weight slug	FIR/BW_{slug}	0.4	[g food.g bw^{-1}.d^{-1}]	D
Concentration of the active substance in the fresh diet (bait)	C		[mg.kg^{-1}]	S
Avoidance factor	AV	1	[-]	D
Fraction of diet obtained in treated area	PT	1	[-]	D
Composition of diet obtained from treated area	PD	1	[-]	D
ADME factor	ADME	0	[-]	D
Number of days, the rodent /slug is consuming rodenticide	n	1 to 4[1)]	[d]	D
Fraction of poisoned rodents in predators' diet	F_{rodent}	1/0.5[2)]	[-]	D
Fraction of poisoned slugs in predators' diet	F_{slug}	1/0.5[2)]	[-]	D
Concentration in food (rodent) after one day	$C_{food,\ rodent}$		[mg.kg^{-1} food.d^{-1}]	O
Concentration in food (slug) after one day	$C_{food,\ slug}$		[mg.kg^{-1} food.d^{-1}]	O
Output				
Predicted environmental concentration of an active substance in food (=rodent) of a predator/scavenger	$PEC_{oral,rodent}$		[mg.kg^{-1} food]	O
Predicted environmental concentration of an active substance in food (=slug) of a predator/scavenger	$PEC_{oral,slug}$		[mg.kg^{-1} food]	O
Intermediate calculation				
$C_{food,\ rodent} = FIR/BW_{rodent} \cdot C \cdot AV \cdot PT \cdot PD$				(5.4)
$C_{food,\ slug} = FIR/BW_{slug} \cdot C$				(5.5)
Calculation				
$PEC_{oral,rodent} = (\sum_{n=1}^{4} Cfood,rodent \cdot (1-ADME)^n + Cfood,rodent) \cdot F_{rodent}$				(5.6)
$PEC_{oral,slug} = (\sum_{n=1}^{4} Cfood,slug \cdot (1-ADME)^n + Cfood,slug) \cdot F_{slug}$				(5.7)

1) In case a study is available, indicating a stop-feeding-effect of target species after less than 5 meals, n can be adapted

2) F_{rodent} and F_{slug} = 1 for acute and 0.5 for chronic secondary poisoning

For the acute assessment, the $PEC_{oral,rodent/slug}$ (calculated with F_{rodent} or F_{slug} = 1) has to be set into relation to the NAET (in mg/kg food, see section below Table 33) for birds and mammals. For the chronic assessment, the $PEC_{oral,rodent/slug}$ (calculated with F_{rodent} or F_{slug} = 0.5) has to be set into relation to the $PNEC_{oral}$ (in mg/kg food) for birds and mammals.

5.5.2.2 Tier 2

In the Tier 2 assessment of secondary poisoning, the expected concentration in generic focal predators and scavengers after single or prolonged exposure (PEC_{oral}) is compared to NAET or $PNEC_{oral}$ related to the daily dose. Food intake rates and body weights are listed in the following table.

Table 37: Acute and chronic secondary poisoning, tier 2: Ratio food intake rate (FIR) / body weight (bw) for generic focal species being secondarily exposed to poisoned rodents

Generic focal non-target species	Prey	Body weight (g)	Daily mean fresh food intake (g)	Food intake rate / body weight (g/g bw per day)
Barn owl (*Tyto alba*):	rodent	294[1)]	72.9[1)]	0.25
Kestrel (*Falco tinnunculus*)	rodent	209[1)]	78.7[1)]	0.38
Carrion crow (*Corvus corone*)	rodent	570[1)]	162.2[1)]	0.28
Red fox (*Vulpes vulpes*)	rodent	5700[1)]	569.0[1)]	0.10
Weasel (*Mustela nivalis*)	rodent	63[1)]	24.7[1)]	0.39
Domestic cat (*Felis silvestris catus*)	rodent	4000[2)]	200[2)]	0.05
Shrew (*Sorex ssp.*)	slug	9.7[3)]	n.r.	0.55[3)]
European starling *(Sturnus vulgaris)*	slug	80[4)]	50[4)]	0.63

1) DEFRA (2002)

2) National Research Council of the National Academies (2001). Value calculated based on a cat's daily maintenance energy requirement of 60 kcal/kg bw. A mouse contains approximately 30 kcal. Assuming a mouse bw of 25 g, this results in 200 g fresh mouse diet.

3) cf. Table 34

4) Alomar et al. (2018)

The rodents and slugs are assumed to consume the baits on five successive days, and are caught by the predator or scavenger immediately after the last meal on day 5. In case data is available indicating the termination of feeding of rodents after a previous meal, the number of days with bait consumption can be adopted, correspondingly. For the acute poisoning situation, the factor F_{rodent} /F_{slug} is 1, for the chronic situation the factor is 0.5. The values for PT, PD and AV are by default 1 but can be adapted based on data. The ADME factor is by default 0 but can be superseded by a value >0–1 if data from ADME studies are available.

The $PEC_{oral,rodent/slug}$ which is used as an input parameter in Table 39 has the unit mg/kg bw. It is calculated according to Table 37, however the unit there is given in mg/kg food since the calculation refers to tier 1. Since the food is represented by the rodent or slug, the result of tier 1 in mg/kg food can also be expressed as mg/kg bw for tier 2.

Table 38: Acute and chronic secondary poisoning, tier 2: Predicted environmental concentration of an active substance in a predator

Parameters	Nomenclature	Value	Unit	Origin
Input				
Predicted environmental concentration of an active substance in food (=rodent) of a predator/scavenger	$PEC_{oral,\ rodent}$		$[mg.kg^{-1}bw]$	O (Table 37)
Predicted environmental concentration of an active substance in food (=slug) of a predator/scavenger	$PEC_{oral,\ slug}$		$[mg.kg^{-1}bw]$	O (Table 37)
Food intake rate / body weight	FIR/BW		$[g\ food.g\ bw^{-1}.d^{-1}]$	P (Table 38)
Output				
Predicted environmental concentration of an active substance in a rodent predator	$PEC_{oral\ rodent\ predator}$		$[mg.kg^{-1}bw.d^{-1}]$	O
Predicted environmental concentration of an active substance in a predator	$PEC_{oral\ slug\ predator}$		$[mg.kg^{-1}bw.d^{-1}]$	O

Calculation

$$PEC_{oral,\ rodent\ predator} = FIR/BW\ PEC_{oral,rodent} \quad (5.8)$$

$$PEC_{oral,\ slug\ predator} = FIR/BW\ PEC_{oral,slug}$$

6 Further research

In the framework of the revision of the ESD for PT 14, the following knowledge gaps and areas for further research have been identified.

- Tertiary poisoning of non-target birds and mammals may occur due to the consumption of secondary poisoned non-target birds and mammals. This bioaccumulation route is known but has not been an integral part of the original ESD for PT 14 and is also not integrated in this revised ESD for PT 14. Further research is necessary for establishing an assessment procedure.

- Grey squirrels may also belong to rodents that need to be controlled. This ESD for PT 14 does not include grey squirrels as a target species. If identified as such, further research is necessary for establishing an assessment procedure.

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8 Appendix

8.1 Release fractions

The following table is a summary of the release fractions (direct or indirect) for the scenarios/sub-scenarios of the original and the revised ESD for PT 14. Darker grey blocks indicate newly introduced scenarios/sub-scenarios and/or revised or new emission factors.

Table 39: Release fractions for direct and indirect release for the scenarios

Scenario	Sub-scenario	Release fraction for direct release (revised ESD / original ESD)			Release fraction for indirect release (revised ESD / original ESD		Rationale
		Soil	Sewer	Air	Soil	Sewer	
Sewer system	Section 3.3.4 All sub-scenarios	- / -	0.4 / 0.3	- / -	- / -	0.6 / 0.6	Since flushing away of baits is a relevant route for emissions, it is proposed to increase the direct release by 10 % compared to the original ESD for PT 14, resulting in a revised fraction of the direct release ($F_{release\text{-}D,sewer}$) of 0.40.

Scenario	Sub-scenario	Release fraction for direct release (revised ESD / original ESD)			Release fraction for indirect release (revised ESD / original ESD		Rationale
		Soil	Sewer	Air	Soil	Sewer	
In/around buildings	Section 3.4.4.1 Outdoor use: Direct emissions to soils if rodenticides are placed around buildings on unpaved ground	0.01 (bagged baits, drinking trough) 0.05 (loose baits) / 0.01	- / -	- / -	0.9 / 0.9	- / -	The release fraction for indirect emissions to soil has been taken over from the original ESD for PT 14 ($F_{release\text{-}ID,soil}$ = 0.9). Compared to the original ESD for PT 14 the direct release was enhanced by 4 % (now $F_{release\text{-}ID,soil}$ = 0.05 instead of 0.01) for loose baits (without being bagged) in bait stations. For bagged baits (bagged baits covers bagged blocks, bagged pastes and bagged grain, bagged pellets and other bagged formulations) and drinking trough the direct release fraction is kept at 0.01.

Scenario	Sub-scenario	Release fraction for direct release (revised ESD / original ESD)			Release fraction for indirect release (revised ESD / original ESD		Rationale
		Soil	Sewer	Air	Soil	Sewer	
In/around buildings	Section 3.4.4.2 Indoor use: Rats poisoned indoors are dying outside buildings (emissions to soil)	- / -	- / -	- / -	0.5 / -	- / -	This route for emissions has not been accounted for in the original ESD for PT 14. However, it is considered to be relevant. According to 96 % of the TSRs (44 positive of 46 answers), spilled baits outdoors are not observed when baits have been applied indoors. Therefore direct emissions to the outdoor soil have not been considered. Emissions to soil occur only indirectly, i.e. via rat carcasses, urine and faeces. A default value of 50 % indirect release ($F_{release-ID,soil}$ = 0.5) is proposed based on expert judgement. The indirect release fraction is assumed to be lower compared to outdoor applications (section 3.4.4.1, $F_{release-ID,soil}$ = 0.9) since indoor rat abatement should result in a greater portion of poisoned rats dying inside buildings instead of dying outside buildings, compared to outdoor baiting.

Scenario	Sub-scenario	Release fraction for direct release (revised ESD / original ESD)			Release fraction for indirect release (revised ESD / original ESD		Rationale
		Soil	Sewer	Air	Soil	Sewer	
Open areas	Section 3.5.4.1 Loose solid baits directly applied into rodent burrows	0.25 / 0.25	- / -	- / -	- / -	- / -	The release fraction for direct emission to soil has been taken over from the original ESD for PT 14 ($F_{release-D,soil,appl}$) 0.05 for emissions during the application and 0.20 for emissions during the use ($F_{release-D,soil,use}$). Indirect emissions to soil are not considered to be relevant, since dead rodents as well as excrements are assumed to be distributed over a large area, so that soil concentrations arising from indirect emissions are assumed to be negligible.

Scenario	Sub-scenario	Release fraction for direct release (revised ESD / original ESD)			Release fraction for indirect release (revised ESD / original ESD		Rationale
		Soil	Sewer	Air	Soil	Sewer	
	Section 3.5.4.1 Solid baits applied in bait boxes	0.01 (bagged baits) 0.05 (loose baits) / -	- / -	- / -	- / -	- / -	For direct emissions to soil ($F_{release\text{-}D,soil}$) a fraction of 0.01 (bagged baits) and 0.05 (loose baits) is proposed congruent to the fraction used for outdoor baiting of buildings and direct emissions to soil. Different from the 'outdoor baiting of buildings' scenario indirect emissions to soil are negligible, since the area inhabited by rodents is too large to become indirect emissions (via rat carcasses, urine and faeces) a relevant source for soil contamination.
	Section 3.5.4.2 Gassing formulations	0.99 / 0.99	- / -	0.01 / 0.01	- / -	- / -	The release fractions for direct emission to soil ($F_{release\text{-}D,soil}$) and air ($F_{release,air}$) have been taken over from the original ESD for PT 14.

Scenario	Sub-scenario	Release fraction for direct release (revised ESD / original ESD)			Release fraction for indirect release (revised ESD / original ESD		Rationale
		Soil	Sewer	Air	Soil	Sewer	
Waste dumps	Section 3.6.4	0.01 (bagged baits) 0.05 (loose baits) / -	- / -	- / -	0.9 / 0.9	- / -	The release fraction for indirect emission to soil ($F_{release\text{-}ID,soil}$ = 0.9) has been taken over from the original ESD for PT 14. This value is in line with the default value for indirect emissions for the outdoor use of rodenticides around buildings. For reasons of consistency with the 'outdoor use of rodenticides around buildings' sub-scenario the revised ESD for PT 14 also considers the direct release to soils ($F_{release\text{-}D,soil}$ = 0.01 (bagged baits) and 0.05 (loose baits).
Bank slopes	Section 3.7.4	- / -	0.4 / -	- / -	- / -	- / -	For direct rodenticide emissions to the drainage channel ($F_{release\text{-}D,water}$) a release fraction of 0.4 is proposed, congruent to the release fraction for direct emissions in sewer systems. Indirect emissions are not considered in this context as these are assumed to be of minor importance compared to direct emissions.

8.2 Scenarios relevant for the assessment of primary and secondary poisoning

The following table is a summary of the scenarios and sub-scenarios, for which the primary and secondary poisoning risk needs to be assessed.

Table 40: Relevant scenarios for assessing primary and secondary poisoning

Scenario	Sub-scenario	Formulation	Primary poisoning	Secondary poisoning	Secondary poisoning via environmental emissions
Sewer systems	All	All	Not relevant	Relevant but not for the food chain contaminated invertebrate – non-target mammal or bird	Relevant but in case only rainwater sewers have to be assessed the food chain earthworm - non-target mammal or bird is not relevant
In/around buildings	Outdoor use	Solid bait formulation	Relevant	Relevant	Relevant but not for the food chain fish - non-target mammal or bird
		Drinking trough	Relevant	Relevant	Relevant but not for the food chain fish - non-target mammal or bird

Scenario	Sub-scenario	Formulation	Primary poisoning	Secondary poisoning	Secondary poisoning via environmental emissions
In/around buildings	Indoor use	Gassing formulations	Not relevant	Not relevant	Not relevant
		Contact formulations	Not relevant	Relevant but not for the food chain contaminated invertebrate – non-target mammal or bird	Relevant but not for the food chain fish - non-target mammal or bird
		Drinking trough	Not relevant	Relevant but not for the food chain contaminated invertebrate – non-target mammal or bird	Relevant but not for the food chain fish - non-target mammal or bird
		Solid bait formulation	Not relevant	Relevant but not for the food chain contaminated invertebrate – non-target mammal or bird	Relevant but not for the food chain fish - non-target mammal or bird
Open areas	Gassing	Gassing formulations	Not relevant	Not relevant	Not relevant
	Burrow baiting	Solid baits	Relevant	Relevant	Relevant but not for the food chain fish - non-target mammal or bird
	Use of bait stations	Solid baits	Relevant	Relevant	Relevant but not for the food chain fish - non-target mammal or bird
Waste dumps/landfills	Use of bait stations	Solid baits	Relevant	Relevant	Relevant but not for the food chain fish - non-target mammal or bird
Bank slopes	Burrow baiting or use of bait stations	Solid baits	Relevant	Relevant	Relevant but not for the food chain earthworm - non-target mammal or bird

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