HUMAN EXPOSURE TO BIOCIDAL PRODUCTS (TNsG June 2002)

USER GUIDANCE version 1

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1. INTRODUCTION

Directive 98/8/EC (The Biocidal Products Directive) requires risk assessment of biocidal products before these can be placed on the European Market. The risk assessment for humans compares the toxic effects of the substance with a predicted dose. The estimation of human exposure is therefore a fundamental element of the risk assessment process and requires quantification of the levels of exposure for both users of the biocidal product and others who may be exposed following the use of a biocide.

There is a paucity of exposure data on biocides and currently various national approaches/models are used to estimate human exposure to biocides. The European Union therefore funded a project to fill this knowledge gap to establish a harmonised approach for assessing human exposure to biocides. Technical Notes for Guidance on Human Exposure to Biocidal Products (TNsG) have been produced as a result of this exercise and are available on the European Chemicals Bureau's website. The TNsG have consolidated the available exposure data/models on biocides and set out a harmonised European approach for predicting human exposure to biocidal products.

This User Guidance is intended for those who assess human exposure to biocidal products. The aim is to provide information on the general principles of human exposure assessment and practical advice for deriving quantitative exposure estimates.

The present version of the User guidance contains most relevant models presented in the TNsG, and provides detailed guidance, with worked examples, for the two product types [Wood preservatives (PT 8) and Rodenticides (PT 14)], forming the first tranch of the Biocides Review Programme. The guidance will be updated over time with the other product types as they come up for evaluation under the Biocides Review Programme.

2. GENERAL PRINCIPLES OF EXPOSURE ASSESSMENT

The fundamental concepts underlying the approach for human exposure assessment is the need to establish the full range of human exposure situations that could occur from the use of a biocidal product and to consider all routes of exposure. The exposure assessment process therefore requires determination of the patterns of use, identification of the exposed population, establishing the pathways of exposure and quantification of potential chemical intake.

2.1 Patterns of Use

Pattern of use information forms the basis of human exposure assessments and is essential to ascertain how exposure will arise and to whom it will occur. Information on the pattern of use can only be gathered through surveys or generic data from similar products. Specific information on patterns of use for many biocidal products types is fairly limited and those placing biocidal products on the market will need to conduct research into patterns of use directly with the users when actual or surrogate data are not available.

Although there is good data for some professional uses of biocidal products the pattern of use may be a seasonal, regional or local issue and Competent Authorities will need to assure the relevance of a stated pattern of use in product authorisation. Information on product use by consumers is not widely available. The instructions of the manufacturer provide information on the recommended use, and unlike professional products, the actual use may differ significantly from the instructions on the label. However, some trade associations have provided data on product uses for specific consumer product categories that may be useful for estimating exposure. These data may be found in the guidance on exposure assessment for New and Existing Substances (TGD).

The TNsG include a matrix to inform the collection of pattern of use information and also sets out default patterns of use for most of the professional and consumer biocidal products types and many of the uses that are anticipated to occur (Part 2.3.2 and 2.3.5). Competent Authorities and Approval Holders should use this information in deriving exposure scenarios for biocidal products when estimating human exposure. However, it is important to note that these are proposals made on the basis of knowledge available at the time of writing and are therefore neither complete nor exhaustive. The defaults are open to revision in the light of better information.

The pattern of use information is used to develop exposure scenarios, which are then evaluated to derive quantitative exposure estimates. The essential pattern of use information required for deriving exposure scenarios are listed in Annex 1 and include information on:

- The product (physical state, concentration, vapour pressure)
- Where and how the product will be used (location, method of application)
- By whom the product will be used (primary exposure)
- Tasks, frequency and duration for each stage of use
- Expected exposure controls
- Who else may be exposed (secondary exposure)

2.2 Exposed Populations

Humans may be exposed to biocidal products in the workplace, from the use of consumer products and indirectly via the environment. The exposure assessment process therefore requires determination of the patterns of use, identification of the exposed population, establishing the pathways of exposure, quantification of potential exposure, and estimation of systemic intake. The first step in the exposure assessment process is to determine the likelihood of exposure of the various populations to the biocidal product under consideration. If this initial screening step indicates that exposure to one or more of the human populations does not occur, no further assessment is needed and the conclusion can be mentioned in the risk assessment phase. If potential exposure has been identified, a quantitative exposure assessment will be required.

The exposed human populations can be categorised by the nature of the exposure i.e. primary exposure and secondary exposure. Primary exposure to biocidal products occurs to the individual who actively uses the products containing biocides i.e. the user. Secondary exposure occurs to non-users or bystanders; these are individuals who do not actively use the biocidal products but are indirectly exposed to biocides released during or after product use by another person (the user). It is important to note that the user of a product may be subject to both primary and secondary exposure whereas the non-user or bystander will only experience secondary exposure. Primary exposures are invariably higher than secondary exposures, however, some specific subgroups of the population may experience higher secondary exposures because of their specific behaviour (e.g. children crawling on the floor). In addition, secondary exposure can be experienced over a much longer time-period than primary exposure, particularly for persistent products.

2.2.1 Primary exposure group

The primary user group is relatively simple to identify. Primary exposure is that of the user performing the task. The user may be a professional at work or a non-professional. Professional users differ from non-professional users in a number of aspects and a distinction between the two is necessary in exposure assessments.

Professional users

The professional user is subject to worker protection legislation and has residual risk controlled through control measures which may include the use of Personal Protective Equipment (PPE) if that is necessary for the normal work. Some professional users will have limited knowledge and skills to handle hazardous biocidal products - particularly if the use of biocidal products is not routinely required in the workplace (e.g. incidental use of slimicides, insecticides, irregular disinfection, use of products containing preservatives, etc.). There are also

specialised professional users, who will probably have expert knowledge and skill in handling hazardous biocidal products and their pattern of use will show greater frequency and/or duration of use.

Non-professional users (consumers)

The non-professional user is the consumer, i.e. a member of the general public who may primarily be exposed to biocides by using a consumer product. The consumer is unlikely to take informed measures to control exposure and to exactly follow the description of use. In addition, the non-professional pattern of use is expected to show lesser frequency and/or duration of use.

The consumer exposure assessment should normally address the intended uses of the product. However, since consumers may not accurately follow instructions for use of products or articles, a separate assessment of other reasonably foreseeable uses should be made. For example, consumers will experience relatively high exposures when they use biocidal products in poorly vented indoor areas. When use under these circumstances is foreseeable, an exposure assessment for this situation should be carried out.

Another important aspect of consumer practice is the very limited use of PPE to control exposure. Consumers will not normally use PPE unless it is convincingly recommended by the manufacturer and provided with the product. As a result only typical clothing should be assumed when carrying out consumer exposure assessments.

2.2.2 Secondary exposure group

The groups at risk through secondary exposure are less easy to identify. However, the intended location of use (e.g. indoors, outdoors, industrial, residential recreational) will provide useful indicators. The location of use will help to determine the population (e.g. ancillary workers, general public, residents/children) at potential risk through secondary exposure and suggest the frequency/duration of exposure as well as their exposure routes.

Some individuals may be exposed to higher concentrations than others because of differences in their behaviour and physiological parameters. Young children, for instance, may be exposed to higher levels than adults due to their distinct (hand to mouth or crawling) behaviour and relatively lower body weights. The exposure scenarios therefore need to take such factors, specific to the exposed sub-population, into consideration.

2.3 Pathways of Exposure

Human exposure follows through any or all of three potential exposure routes: inhalation, dermal contact and ingestion. The second step in the exposure assessment process is therefore to determine the likelihood of the biocides to enter the body by being breathed in (inhalation), by passing through the skin (dermal), or swallowing (ingestion). Although not a major route of exposure, the potential of exposure to the eyes will also need to be considered, particularly when handling irritant/corrosive substances. If in this second step it is indicated that exposure via one or more of the pathways does not occur, no further assessment is needed for that route of exposure and the conclusion can be mentioned in the risk assessment phase. Where one or more routes of exposure have been identified then each will require a quantitative exposure assessment.

2.3.1 Inhalation exposure

Inhalation exposure is often a small component of total exposure to biocides but can in some cases become the predominant route of exposure (e.g. use of a volatile material in an enclosed space). Inhalation exposure is usually derived from the airborne concentration of the breathing zone of the exposed individual. It may refer to the active substance or to the product in use and is expressed as mg/m^3 as a time weighted average concentration over a stipulated period of time.

2.3.2 Dermal exposure

Exposure of and via the skin is usually a significant aspect of human exposure to biocides and can be subdivided into potential or actual dermal exposure. Potential dermal exposure is the amount that deposits on the clothes and on exposed skin over some defined period of time. The most common metric for measurement for biocides is the amount of biocide product that deposits per unit time (mg/min) or task (mg/cycle). Actual dermal exposure is an estimate of the amount of contamination that actually reaches the skin. It is dependent on the efficiency and effectiveness of clothing and is often expressed simply as a weight of biocide product on skin (mg on skin).

2.3.3 Ingestion exposure

This is the amount entering the mouth other than that which is inhaled. There are no standard methods for quantifying exposure by ingestion but it can be inferred from biological monitoring studies. It is expressed as mg per event or mg/day.

2.3.4 Systemic exposure

The estimates of exposure, via the three routes, outlined above relate to external exposure i.e. the amount of the substance ingested, the amount in contact with the skin and/or the amount inhaled. For risk characterisation purposes it is necessary to calculate internal (systemic) body burdens from these values. This conversion is based on the selection and use of a variety of physiological default values (body weight, breathing rate etc) for specific situations. In addition, absorption data for the different routes of exposure are often not available. Therefore the calculation of systemic body burdens is subject to a high degree of uncertainty and requires expert judgement. Some guidance and default values are given in Appendices IV B (Dermal absorption) and IV C (Physiological factors) of the TGD on New and Existing Substances, Human Health Assessment.

2.4 Quantifying Human Exposure

The pattern of use information is used to identify the range of possible exposure scenarios, which are then evaluated to derive quantitative exposure estimates. An exposure scenario is the set of information and/or assumptions that tell us how the contact between the person and the biocide takes place. It describes a specific use of a substance with a set of specific parameters, which characterise the biocidal product's uses and the control measures.

The exposure scenarios for exposure estimation must be well-documented, realistic and, in the absence of good data, work on reasonable worst cases. Although all exposure scenarios that are reasonably foreseeable, must be assessed, exposure as a result of accidents or from abuse does not need to be included.

2.4.1 Primary exposure scenarios

Primary exposure is experienced by professionals and non-professionals (consumers) who use/apply a biocidal product. It is related to the task and the overall exposure scenario will consist of a series of tasks that can be allocated to 3 distinct phases of use:

- Mixing & loading — Include the tasks involved in delivery and handling of bulk ready-for-use and concentrate products, dilution of concentrates and/or the introduction of product to the application apparatus/system.
- Application — Involves all uses of biocidal products, including application by hand, by hand-held tool, by dipping, by spraying, handling treated articles, and in machining. This phase of use can

	lead to the exposure of people who are present during the product application (secondary exposure).
- Post-application	Includes exposure through separately cleaning and maintaining process equipment and tools.

The contribution to each route of exposure may vary considerably between these phases with any given active substance, given that mixing and loading can reflect exposure to a concentrate, application to a dilute product, post-application to vapour or dried residue and removal to waste material (e.g. removing and disposing of a preserved coating). In practice, exposure data often relates to full-shift sampling and therefore includes all three phases of use. However, it is important to ensure that each phase of use has been accounted for in the exposure assessment.

2.4.2 Secondary exposure scenarios

Secondary exposure is all that is not primary and describes the exposure of people who receive a dose of a biocide through being present during an application task (performed by another person) or being present in places where a biocide had been applied or during use/handling of materials treated with biocidal products. These exposures can include dermal contact of contaminated surfaces, inhalation of residues in air and ingestion from hand to mouth contact. A key feature is that secondary exposure occurs without the exposed person being aware or having control over that exposure and the exposure can occur over a long time period.

A tasked based approach does not apply to secondary exposure assessments, as there are no well-defined tasks for the post use situation. Instead, a reference scenario approach is proposed for estimating secondary exposures. It is important to note that both acute (short-term) and chronic (long-term) exposure potential needs to be considered when developing secondary exposure scenarios

Reference Scenario

Using the pattern of use information, it is possible to ‘invent’ reasonably foreseeable exposure scenarios that will involve reasonable worst case for secondary exposures of adults and children through inhalation, via the skin and ingestion. These scenarios are termed “Reference Scenarios” and examples of possible Reference Scenarios are presented in Part 2 and Part 3 of the TNsG.

Reverse Reference Scenario

The reverse reference scenario can be used to determine an estimate of the maximum amount of exposure that might be acceptable and its likelihood of occurrence as a reasonable worst case. Using the relevant No Observed Adverse Effect Level (NOAEL), it is possible to compute the amount of product that would lead to that dose by a specific route. That amount can be related to the amount of exposure that is likely obtained from experimental or other data.

2.4.3 Evaluating exposure scenarios

Having established the relevant exposure scenario(s) the next step is to identify the tasks that need to be considered as well as the approximate time budgets for each task. Annex 2 sets out a format for information to produce a scenario-based time budget for use in estimating exposure. Task analysis will then lead to the identification of suitable exposure data that can be used to calculate the potential exposure for the proposed use based on the time budget information. The overall approach for assessing human exposure to biocidal products is outlined in Annex 3.

2.5 Exposure Data

In addition to the pattern of use information, which is used to describe the nature of human exposure there is a need for quantified exposure data to allow estimates of exposure to be calculated. In view of the uncertainties associated with assessing exposure in human populations, preference should always be given to obtaining good representative measured exposure data. Where this is unavailable, it will be necessary to model exposure using generic (analogous/surrogate) data or mathematical models.

Although substance specific measured data is preferred over modelled data, it could contain considerable uncertainty due to temporal and spatial variations as well as deficiencies in the quality and/or quantity of the available measured data. In such circumstances it may be very useful to compare measured data with modelled exposure estimates. This will require a critical analysis of the results and reasoned arguments to explain the similarities or differences between the two estimates. The ultimate choice of exposure estimates should be made on the basis of the robustness/representativeness of the measured and/or modelled data for the situation/use scenario/conditions under consideration. This will require substantial expert judgement and should always be based on reasoned arguments.

2.5.1 Product specific exposure data

Measured exposure data for the specific product and associated information describing these data may be available from workplace exposure assessments or dedicated monitoring surveys. The data should be accompanied by sufficient information to place the exposures in context with respect to the pattern of use and control. All data will require careful evaluation before use and should have been collected following good occupational hygiene practice; preferably applying standardised procedures, particularly with respect to sampling strategy, measurement methods and analytical techniques.

2.5.2 Generic exposure data

Generic exposure data describes measured exposure data from similar operations utilising similar biocidal products. The data is collected from exposure surveys of worker or, in the case of consumers, from simulation studies using analogous products. This data is used to develop simple (generic) database exposure models for particular product types and specific use scenarios.

Generic exposure modelling is a useful regulatory tool in this scheme because of the capability to predict the likely levels of occupational exposure of users of biocides before widespread use and for the ability to estimate the effect of changes in conditions of use on exposure. Where representative generic data and a suitable model exist modelling is the initial and often the only basis for the exposure assessment. Generic exposure models may also be used instead of or as well as exposure data for the specific product if there is significant uncertainty associated with the quality and/or quantity of this data.

The TNsG have collated the available generic models that are considered adequate for human exposure assessment to biocides. These models, for exposure assessment, are based on databases of relevant studies representative of particular biocidal use areas. Subsets of this database have been formed for generic exposure scenarios and are presented in Annex 4. It is important to note that this is not an exhaustive list of all the database models collated in the TNsG and the other database models available in the TNsG may be more appropriate in some situations.

Annex 4 gives a summary of the generic indicative exposure values derived from the available database models presented in the TNsG. Most of the larger datasets have undergone peer review; particularly with regard to the sampling methodology and analytical aspects of the study and consideration of the operational aspects in terms of their reflection of European practice for biocidal use. Most of the models relate to workplace situations and cover exposure by inhalation and skin contact. Annex 4 gives single indicative exposure values for each type of exposure which are generally 75th percentiles; for smaller datasets

90^{th}, 95^{th} or the maximum exposure have been used instead. The values presented can be found in Part 2 of the TNsG, or are calculated from the raw data.

The following general 'rules' have been applied for selection of the surrogate data in Annex 4.

1. *Moderate uncertainty. The dataset is sufficiently large and/or the variability sufficiently low that the exposure distribution can be characterised with a reasonable level of assurance. Confidence intervals* for the 75^{th} percentile are typically less than a factor of 2. For these datasets the 75^{th} percentile is proposed as an indicative exposure value.*

2. *Considerable uncertainty. The dataset is of smaller size and/or the variability greater than for datasets of moderate uncertainty. The degree of confidence in the characterisation of the exposure distribution is lower with confidence intervals for the 75^{th} percentile typically greater than 2. For these datasets the 95^{th} percentile is proposed as an indicative exposure value.*

3. *High uncertainty. The dataset is of small size and/or the variability is great. The lognormal approximation to the exposure dataset may not be verifiable and so confidence intervals based upon this assumption might be misleading. The exposure distribution is poorly characterised and so the maximum exposure value is proposed as an indicative value.*

**90% confidence intervals*

It is important to note that the rules defined above only address the sampling uncertainty associated with each data set. The use of any generic data model is also subject to scenario and extrapolation uncertainty reflecting the degree of analogy between the assessment scenario and the circumstances *represented* by the data model. The strength of this analogy requires expert evaluation and might justify the use of a higher percentile.

Generic exposure data can also be used to develop more complex computer based data models. Two computer based data models, which have relevance for assessing human exposure to biocides, are described below.

BEAT

BEAT is a Bayesian task-based exposure model, currently being developed by HSE/HSL and TNO, for assessing dermal exposure in a wide variety of circumstances. BEAT provides exposure estimates based upon the strength of analogy between an assessment scenario and multiple exposure scenarios contained within an internal exposure database. The internal database contains

full records of every data point (including multiple exposure measurements and contextual information) and can be updated as new exposure measurements become available. BEAT predicts median exposure rates to in-use biocidal formulations and also provides estimates of both exposure variability (GSD) and uncertainty. This allows a variety of exposure percentiles to be derived dependent upon the circumstances of the assessment. BEAT is useful for estimating exposures when there are insufficient *actual* exposure data or the choice of a single unambiguous generic data model is unclear. As many of the data within the BEAT database are also those presented in the TNsG BEAT might also be used more generally as an aid in selecting relevant exposure data.

EASE (model implemented in EUSES)

The EASE model (Estimation and Assessment of Substance Exposure) is a rule-based expert system that has been in use for several years to estimate personal exposure to hazardous substances in the workplace. It was developed by the UK Health and Safety Executive (HSE) to enable exposure to be assessed for European regulatory risks assessments of new and existing substances. The system uses a number of rules to predict a range of likely exposures or an "end-point" for a given work situation. The end-point ranges were derived from an analysis of data contained in the HSE's National Exposure Database. For inhalation exposure the rules incorporated into EASE encompass the physico-chemical properties of the substance (physical state, vapour pressure, type of dust) and the way in which it is used (source of substance, pattern of use, and type of control measures used). Exposure is estimated as contaminant concentration in air for the identified task (as mg/m^3), rather than 8-hour time-weighted average. For dermal exposure EASE only estimates the rate of contamination (as $microg/cm^2/day$) of the hands and forearms of the worker.

Extensive validation work has shown that EASE inhalation predictions are generally conservative and more reliable for solid aerosols compared with gases and vapours. Similar studies involving dermal exposure assessment suggest that EASE also tends to overestimate the dermal exposure by about one order of magnitude, although the average measured exposure levels appear to increase in line with the predictions from EASE.

The output ranges for exposure by inhalation are considered acceptable for exposure assessment. However, as currently implemented, the dermal routines of EASE are not recommended for use unless the hands and forearms are the only locations for skin contamination.

EASE is available from the Health and Safety Executive and is free.

2.5.3 Modelled exposures

In the absence of product specific and/or generic exposure data for a particular biocidal use/scenario Competent Authorities and Approval Holders should make use of the available mathematical exposure models for assessing human exposure to biocidal products. As in the case of generic exposure models, mathematical exposure models may also be used instead of or as well as exposure data for the specific product and generic models if there is significant uncertainty associated with the exposure estimates derived from the first two approaches.

Mathematical models are calculation routines that are based on the physico-chemical properties of a substance and the environment into which these substances are released. Although the basis for the calculation algorithm is scientific these models can be gross approximations of the real world as the full range of real variables cannot be accounted for and are therefore assigned very conservative defaults. In general few of the models have been validated against real situations. However, based on the available information to-date, the following models are recommended for use in human exposure assessment of biocides.

Droplet Simulation Model (Fraunhofer)

The Fraunhofer Institute for Toxicology and Aerosol Research has developed a deterministic model for predicting aerosol exposure during spraying.

The model calculates the airborne concentration of respirable, thoracic and inhalable size fraction of aerosols generated from the spraying of liquid products in indoor environments. The model is a short-term exposure model covering time scales typical for the release process. Long-term emissions of vapours from walls and other surfaces are not included.

It is assumed that the biocidal product is composed of a non-volatile active substance dissolved in a solvent with known volatility. The model is based on a simulation of the motion of released droplets taking into account gravitational settling, turbulent mixing with the surrounding air, and droplet evaporation. In the model a continuous space is used instead of artificially defined space compartments. The spatial distribution of the concentration is modelled explicitly.

The main input parameters are: the released droplet spectrum, the release rate, the concentration of the active substance, the spatial and temporal pattern of the release process (surface spraying against floor, ceiling, wall; room spraying, etc), the vapour pressure of the liquid, the size of the room and the ventilation rate. The path of the sprayer can be explicitly included into the model.

For surface treatment by spraying, a droplet deposition module is incorporated in the programme package. This module calculates the fraction of non-impacting droplets, which are relevant for human exposure. For room spraying the stopping distance of droplets is also taken into account.

The programme can be executed under WINDOWS 2000. The first level is an input form for the definition of general data such as room size, room ventilation rate, turbulent intensity, and nozzle and spray parameters as well as relevant parameters of the spray liquid. The second level allows for the definition of the spray and contains the results of the calculation: 1) graphical presentation of the concentration versus time curve; 2) the time integrated inhaled and deposited exposure of active substance. Initial validation work using simulated room scenarios showed that concentrations and temporal patterns were predicted with reasonable accuracy by the model.

The programme and manual (in German and English) will be available for downloading from the BAuA home page (www.baua.de) by end of 2004.

HSL 2000

The Health and Safety Laboratory (HSL, UK) has produced a basic EXCEL spreadsheet based model for residual airborne biocide concentrations for a concentration-based partly mixed single room. Adsorption and desorption are ignored, calculations relate to a temperature of 20 ^{o}C only, and uncorrected for vapour density or the presence of liquid phase. The model is appropriate for assessing secondary exposure via inhalation.

Input values are the room dimension, ventilation rate, a mixing factor, temperature, pressure, air density and viscosity (values entered), and the contaminant data (vapour pressure, molecular weight, quantity applied and the surface area). The output is an airborne concentration profile. Some validation has been done. The model's output is precautionary, over-predicting airborne concentrations by a factor of two. The model does not reproduce the effect for materials having very low volatility, or taking longer than calculations predict to reach an equilibrium concentration in real life.

The routine is available as "HSL 2000" HSL Report CM/99/19.

DEPOSITION

This is a simple arithmetical calculation routine in an EXCEL spreadsheet. The input formulae are derived from a report by Fogh and Andersson (Ann. Occ. Hyg., 44(7):532, 2000). Data for rates of deposition of particles from aerosols below 10 microns were taken from human volunteer experiment data in a report from Riso National Laboratory, Roskilde, Dk 2000.

The model is believed to be appropriate for assessing dermal exposure for both professional users (e.g. oil mist) and non-professionals (e.g. vaporised insecticide). The input values are the area available for potential dermal exposure, the deposition velocity, the airborne concentration and the exposure duration. The output is expressed as mg deposit.

CONSEXPO 3.0

The CONSEXPO (CONSumer EXPOsure models) program is being developed at the RIVM (The Dutch National Institute of Public Health and the Environment) to provide estimation routines for exposure to consumer products including pesticides.

The program is based on a modelling framework that contains the components of (1) contact, (2) exposure and (3) uptake. For each component, the user selects a model and provides its parameters. The contact component does not contain a mathematical model but specifies duration of actual use, duration of contact with the product, and frequency of use. The duration of actual use and the duration of contact might differ if actual usage is short, like using a spray, but compounds from the product fill the air around a person, causing a prolonged exposure.

The exposure component contains multiple models to estimate the concentration of compound in the medium that directly contacts the human body. These estimation models range from simple screening models to advanced models describing specific exposures. Exposure includes the inhalation, dermal, and oral routes and the software provides the possibility to model exposure through multiple routes of exposure. For the inhalation route, the advanced models include painting, evaporation, exhaust gas production, and a continuous source. For the dermal route, the models include transfer factors, contact rates and fixed volume of product. For the oral route, models include ingestion, leaching from materials into food or into the mouth and hand-mouth contact.

The uptake component estimates the amount taken up through the skin, the lungs or the gastrointestinal wall. This denotes the amount that reaches systemic circulation. If information on the fraction taken up is available, this can be specified. Otherwise, simple diffusion models can be used to estimate the fraction taken up. As an alternative, uptake can be set to 100%, in which case potential doses are calculated by the program.

Features

• Total exposure is defined from the combination of contact, exposure and uptake scenarios for each route of entry and dose measures are calculated. These dose measures contain concentration estimates, and short and long-term average doses in terms of milligram chemical per day per kilogram bodyweight.
• The program allows for stochastic parameters and each parameter can attain a normal, lognormal or uniform distribution, or an empirical distribution defined by

data. Exposure and dose distributions reflect stochastic parameters and these distributions can be depicted and percentiles can be quantified.
• The program provides sensitivity analyses for each stochastic parameter, where mean exposures or doses as function of the value of a selected stochastic parameter are depicted and analysed. Sensitive parameters will cause big differences in model outcome, while others will cause hardly any differences.

MODELS OF THE US-EPA OFFICE FOR POLLUTION PREVENTION AND TOXICS

The Office for Pollution Prevention and Toxics of the US-EPA (EPA-OPPT) maintains a series of models for exposure assessment. These models are primarily used for exposure assessments of new and existing chemicals. The consumer and worker exposure models are also useful for exposure assessment of biocides, if the expected exposure scenario matches the scenario assumed in the model.

The OPPT explicitly recognises screening tier and higher tier models. Relevant models in the screening tier are E-Fast and ChemSTEER. E-Fast contains consumer and environmental release models; ChemSTEER contains industrial and worker exposure models, and environmental release models. Relevant models in the higher tiers are MCCEM and WPEM. MCCEM models release and indoor distribution of volatile substances, WPEM models exposure to volatile substances from paint.

All the above models are available from the web site of US-EPA OPPT: http://www.epa.gov/opptintr/exposure/

US-EPA OFFICE OF PESTICIDE PROGRAMS SOPS

The Residential Exposure Assessment Work Group developed Standard Operating Procedures for Residential Exposure Assessments for the US-EPA Office of Pesticide Programs.

The objective of the SOPs is to provide standard default methods for developing residential exposure assessments for both application and post-application exposures when applicable monitoring data are limited or not available. The SOPs cover calculation algorithms for estimating dermal, inhalation, and/or incidental ingestion doses for a total of 13 major residential exposure scenarios: (a) lawns; (b) garden plants; (c) trees; (d) swimming pools; (e) painting with preservatives; (f) fogging; (g) crack and crevice treatments; (h) pet treatments; (i) detergent; (j) impregnated materials; (k) termiticides; (l) inhalation of residues from indoor treatments; and (m) rodenticides. Default values for the underlying exposure factors, such as amount used or dermal transfer factors, are specified. These defaults represent (reasonable) worst-case values.

While the SOPs provide methodologies and default assumptions for conducting screening-level residential exposure assessments for indoor and outdoor settings under FQPA, the SOPs do not preclude the use of more sophisticated methodologies (including stochastic analyses) and the replacement of default values for exposure parameters with new data.

The SOPs aim at screening tier residential exposure assessment. Each SOP provides (1) a description of the exposure scenario; (2) recommended algorithms and default values for parameters for quantifying exposures; (3) example calculations; (4) a discussions of limitations and uncertainties; and (5) references. The calculations are built around the general equation *PDR = C x CR*, where *PDR* = potential dose rate (mg/day); C = contaminant concentration in the media of interest (mg/cm^2; mg/m^3, mg/g); and *CR* = contact rate with that media (cm^2/day; m^3/day; day). Each product category and exposure route may differ with respect to the specification of the contact rate *CR*. The contaminant concentration *C* may be expressed as an in use concentration or a unit exposure.

Two versions of the document are available on the Internet. The last full version (December 1997) is available as pdf-document under:

http://www.epa.gov/oppfead1/trac/science/trac6a05.pdf

A July 1997 version as submitted to the EPA's Science Advisory Panel is very close to the December 1997 version and is available as HTML-documents under:

http://www.epa.gov/oscpmont/sap/1997/september/sopindex.htm

It is also important to note that the Science Advisory Council for Exposure, of the US-EPA, published a policy document to update many of the defaults within the SOPs (Policy number 12; February 22, 2001). The calculations and defaults described in the SOPs form the basis of the residential exposure assessment parts in the US aggregate exposure models. These models are described below.

US AGGREGATE EXPOSURE MODELS

Newly emerging exposure models are set up to accommodate aggregated residential exposure scenarios, containing multiple sources of a chemical. These models are mostly initiated in response to the demands of the Food Quality Protection Act (FQPA) in the United States. The FQPA forces legislators to account for aggregated and cumulative exposures of pesticides.
Four sets of models are available to comply with the demands of the FQPA: SHED, Lifeline, Calendex and CARES/REx. A common approach in these models is that they estimate exposure from the probability to contact a source of exposure (e.g. a product or a food item) and the exposure resulting from that contact. The incorporation of the probability of contact is new in comparison with the other models. It is included because the FQPA-initiated models sum

exposures from all potential sources of the active ingredient (treatments, products and food-items). The assumption that the probability of contact is one, i.e. a single person experiences all contacts, would result in an overestimation of exposure. All other models take a single contact, e.g. a single product use, as their basis and may therefore neglect the probability of exposure. The European Union biocides directive focuses on single products and the risks of their use. Therefore, product-based models are appropriate instead of the FQPA-initiated models.

Availability:

SHEDS is available from the US-EPA. Contacts are V. Zartarian and H. Özkaynak (US-EPA, Office of Research and Development, NERL).

Lifeline is available from the Lifeline group, 129 Oakhurst Road, Cape Elizabeth ME 04107 USA, e-mail: psprice@pipeline.com.

Calendex is available from Novigen Sciences Inc., 1730 Rhode Island Avenue NW Ste. 1100, Washington, DC 20036 UNITED STATES, info@novigensci.com or Novigen Sciences Inc. 75 Graham Road Malvern, Worcs, WR14 2HR UNITED KINGDOM, info@novigensci.co.uk.

REx is available through http://www.infoscientific.com/ where the spreadsheet can be downloaded.

3. TIERED APPROACH IN HUMAN EXPOSURE ASSESSMENT

It is useful to initially conduct an exposure assessment based on realistic “worst case” assumptions and to use default values when model calculations are applied. If the outcome of the risk assessment based on worst-case exposure assumptions is that the product is “not of concern”, the risk assessment for that human population can be stopped and no further refinement of the exposure estimate is required. However, if the outcome is that a biocidal product is “of concern”, the assessment must, if possible, be refined using additional data and/or reasoned arguments based on expert judgement to allow a more informed decision. This tiered approach is a logical stepwise process to risk assessment and uses the available information to the optimum extent while reducing unnecessary requirements for human exposure surveys or studies. The three tiers described below provide an illustration of how this iterative risk assessment process might progress.

Tier 1

This is the screening tier in the risk assessment process and should be kept simple. The assessor should select the top end value from a single exposure

study or the recommended indicative value from an empirical (database) model or a worst-case estimate from a mathematical exposure model. Tier 1 estimates should be based on reasonable worst-case time budget information (i.e. frequency and duration of use) and must not take account of exposure reduction measures such as personal protective equipment.

If this exposure assessment produces an unacceptable outcome in risk assessment, a refined exposure estimate will be required.

Tier 2

The second tier in the exposure estimation process is more complex and requires further specific data and/or reasoned argument to produce a more refined exposure assessment. The exposure studies/models are used in the same way as in Tier 1 but specific data on time budgets; transfer factors and the effects of exposure reduction measures (e.g. personal protective equipment) may be used to modify the exposure assessment. However, the use of PPE by consumers should only be considered in very limited situations e.g. where gloves are to be supplied with the product. The options for exposure reduction measures and appropriate defaults are discussed in more detail in the TNsG (Part 2.2.3)

Where after this remodelling the predicted exposure is still unacceptable, then a third iteration of the exposure assessment will be required.

Tier 3

The most detailed level of risk assessment requires surveys or studies with the actual product or with a surrogate. The surveys must be representative, cover all the key tasks within the scenario and provide detailed information on patterns of use.

It should be noted that where biological monitoring is not included in the study, unless the specific scenario of the study is more representative than the generic model, simply generating further potential inhalation and dermal exposure data may not allow refinement of the exposure assessment. Obviously where no generic data, and hence a model, are available then a field study is required. Where field studies are done the OECD guidance on exposure studies should be followed and biomonitoring studies should be carried out in accordance with the Helsinki Declaration.

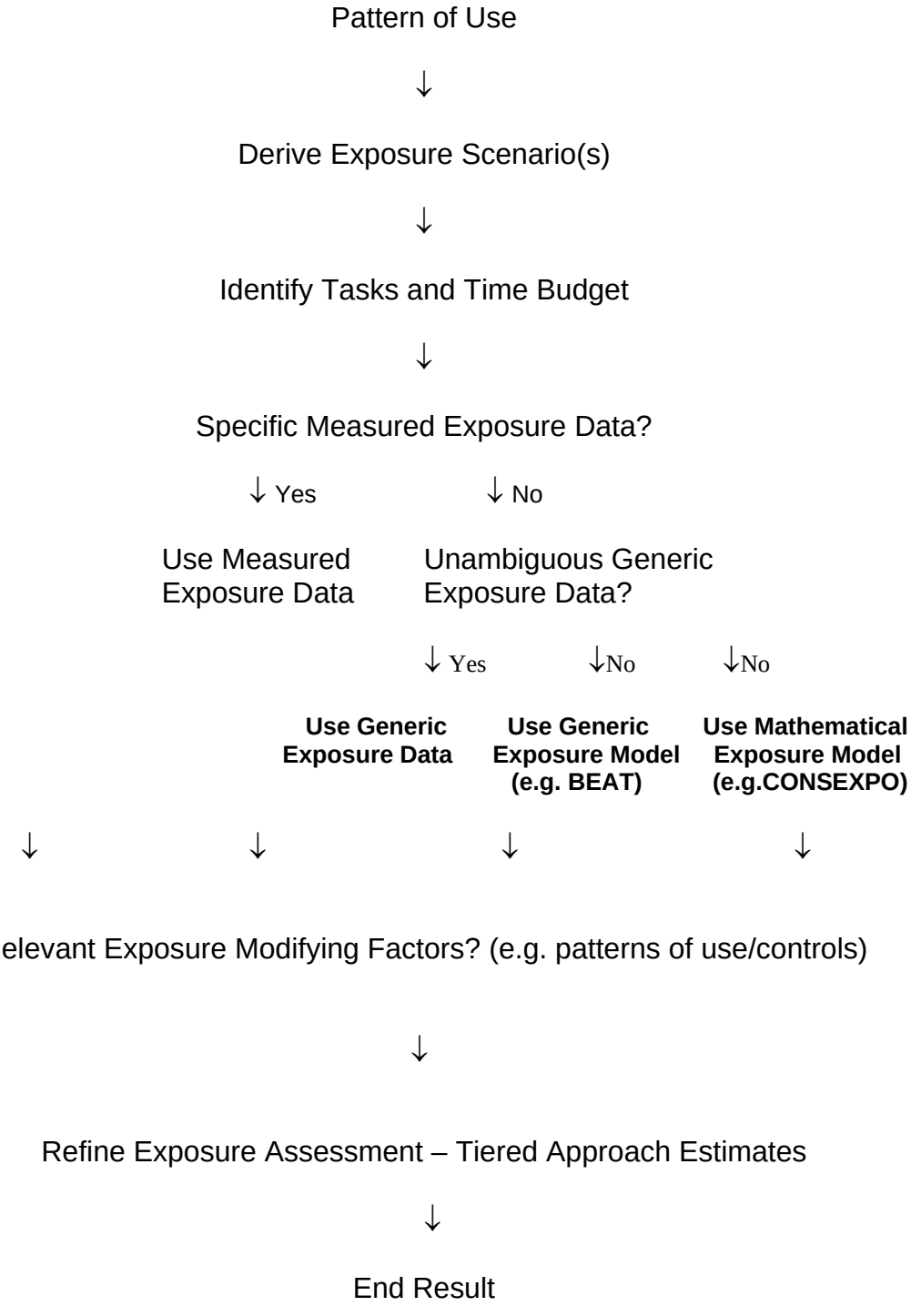
ANNEX 1: Pattern of use information required for exposure assessment

Information Required	Priority	Comment
Product		
- physical state	Essential	liquid / solid / in-situ generation / particle size, aerosol, volatility
- package details	Essential	volume, material, closure, bulk delivery, etc.
- formulation details	Essential	active substance and co-formulants
- site inventory	Desirable	amount, delivery frequency
- storage information	Desirable	
Purpose of product		
- where used	Essential	location / system treated
- description of tasks	Essential	how used, application rates
- equipment used	Essential	pressures, volumes
Use environment		
- containment	Essential	barriers to exposure, ventilation
- pattern of control	Essential	full containment, LEV, segregation, dilution ventilation
- use pattern	Essential	closed system, within a matrix, non-dispersive, wide dispersive
Mixing and loading phase		
- task	Essential	description
- frequency per task	Essential	events per day
- duration of task	Essential	event duration
- quantity used per task	Desirable	
- dilution rate	Essential	
Application phase		
- task	Essential	description, continuous / intermittent / event
- frequency per task	Essential	events per day
- duration of task	Essential	event duration
- quantity used	Essential	not always relevant
- area / volume treated	Essential	not always relevant
- timing	Desirable	seasonality etc.
Post-application phase		
- task	Essential	description, continuous / intermittent / event
- frequency per task	Essential	events per day
- duration of task	Essential	event duration
Disposal		
- task description	Desirable	e.g. strip old coatings, collect dead vermin
Primary exposure		
- mode of exposure	Essential	inhaled / via skin / ingested, by task
- proximity to exposure source	Desirable	hand / arm's length / more distant
- operators per task	Desirable	
Secondary exposure		
- population (acute phase)	Essential	include mode and likelihood of exposure
- population (chronic phase)	Essential	include mode and likelihood of exposure
- removal of product	Desirable	include mode of exposure
Data may be better expressed as ranges and likely values, rather than as single values.		

ANNEX 2: Time budget matrix for a stated scenario

Phase	**Scenario and task (minutes)**					
	Task A	Task B	Task C	Task D	Task E	Task F
Mix & Load						
Application						
Post-application						
Removal						
No of tasks / day						
Task as % of day	%					

ANNEX 3: Scheme for estimation of human exposure



ANNEX 4: Indicative exposure values

This annex contains indicative exposure values for a range of exposure scenarios that have been taken from the TNsG. The values presented here are considered to be appropriate for many situations with regard to chronic exposure but there is flexibility to use other values depending upon the specifics of an assessment. Higher percentiles (such as the 95th) may sometimes be more appropriate, especially when considering acute toxic effects. Confidence intervals are presented (where appropriate) to give an indication of the sampling uncertainty associated with each data set. The use of any generic data model is also subject to *scenario and extrapolation uncertainty* reflecting the degree of analogy between the assessment scenario and the circumstances represented by the data model. The strength of this analogy requires expert evaluation and might justify the use of a higher percentile.

Models for Mixing and Loading

Description of Exposure Model	Formulation	Indicative Exposures	Uncertainty
Professional pouring formulation from a container into a portable receiving vessel e.g. knapsack sprayer. The models are derived from data relating to mixing and loading of agricultural pesticides and cover relatively large volumes. The exposures are expressed as mg a.s./kg a.s. per operation and dermal exposure is limited to the hands. [1]*EUROPOEM II database* [2]*Mixing and loading model 5 TNsG part 2, p 137*	Granule[2]	Hands 171 mg/kg a.s. Inhalation 0.036 mg/kg a.s.	Uncertainty for hands is *high* – indicative value based on highest of 8 data. Inhalation uncertainty is *moderate;* 90% C.I. for 75th 0.02-0.06. Uncertainty is *moderate.* 90% C.I. for 75th 0.9-2.3 mg/kg a.s.
	Powder[2]	Inhalation 1.5 mg/kg a.s.	
	Liquid[1]	Hands 464 mg/kg a.s. Body 48.3 mg/kg a.s. Inhalation 0.021 mg/kg a.s.	Uncertainty is *moderate.* 90% C.I. for the 75th 278-775 (hands); 21-112 (body); 0.014-0.034 (inhalation).
Professional pouring formulation from a container into a fixed receiving vessel e.g. reservoir tank on tractor. The models are derived from data relating to loading of agricultural pesticides and cover relatively large volumes. The exposures are expressed as mg a.s./kg a.s. per operation and dermal exposure is limited to the hands only. [1]*EUROPOEM II database* [2]*Mixing and loading model 5 TNsG part 2, p 137*	Granule[2]	Hands 3.3 mg/kg a.s. Inhalation 0.24 mg/kg a.s.	Hand exposure uncertainty is *moderate.* 90% C.I. for 75th 2.1-5.4. Inhalation uncertainty is *high*, Indicative value is highest of 13 data. Hand exposure uncertainty is *moderate.* 90% C.I. for 75th percentiles 5.5-18.7. Inhalation uncertainty is *high*, Indicative value is highest of 8 data.
	Powder[2]	Hands 10.2 mg/kg a.s. Inhalation 0.66 mg/kg a.s.	
	Liquid[1]	Hands 8.0 mg/kg a.s. Body 1.95 mg/kg a.s. Inhalation 0.003 mg/kg a.s.	Uncertainty is *moderate.* 90% C.I. for the 75th percentiles are 4.9-13.0 (hands); 1.4-2.6 (body); 0.002-0.004 (inhalation).

Professional pouring liquid agricultural pesticides from various size containers into a receiving vessel. Exposure is limited to the hands and expressed as ml of in-use product per operation. *Mixing and loading model 4 TNsG part 2, p 136*	Liquid 1 litre 5 litre 10&20 litre	0.01 ml (hands) 0.2 ml (hands) 0.5 ml (hands)	Indicative values currently based upon 75th.
Non-professional pouring a solvent-based (SB) or water-based (WB) concentrate from a 1 litre container into a small bucket. Exposure is limited to the hands and forearms and expressed as mg in-use product per operation. *Mixing and loading model 2 TNsG part 2, p 134*	Liquid	SB Hand/forearm 1.7 mg/event WB Hand/forearm 3.2 mg /event	Uncertainty is *high.* Indicative exposure values based upon worst case.
Professional 'potmen' loading antifouling paints into a reservoir for airless spraying. The model covers a wide range of antifouling applications, from small through to very large vessels. Hand exposure is actual exposure inside gloves. The exposures are expressed as mg/min and mg/m^3 in-use product. *Mixing and loading model 6 TNsG part 2, p 138*	Paint	Hands actual 8.2 mg/min Hands potential 30 mg/min Body 92 mg/min Inhalation 1.9 mg/m^3	Uncertainty for actual hand exposures is *considerable.* 95th taken as indicative value. Potential hand exposure uncertainty is *high.* Indicative exposure based upon highest of 4 data. Uncertainty for body exposures is *moderate*. 90% C.I. for 75th 50-168. Inhalation uncertainty is *considerable.* 75th percentile of non-zero data taken as indicative value (≈ 84th overall).

Models for Direct Handling

Description of Exposure Model	Process	Indicative Exposures	Uncertainty
Professional intermittently handling water-wet or solvent-damp wood and associated equipment. The models are derived from data relating to industrial timber treatment using vacuum pressure plants and water-based (WB) or solvent –based (SB) liquid formulations. Hand exposure is actual exposure inside gloves. Exposure is expressed as mg/cycle and mg/m^3 in-use product. *Handling model 1 TNsG part 2, p 160*	Vacuum pressure plant (timber)	WB Hands 1080 mg/cycle Body 8570 mg/cycle Inhalation 1.9 mg/m^3 SB Hands 260 mg/cycle Body 158 mg/cycle Inhalation 0.6 mg/m^3	WB uncertainty is *moderate*. 90% C.I. for 75th; 946-1233 (hands), 6299-11660 (body), 1.4-2.6 (inhalation). SB 90% C.I. for 75th: hands 27-295 (95th used as indicative value); body 113-221 (75th used as indicative value). 19 out of 24 inhalation non-detected, indicative value median measured value (≈ 90th overall).
Professional net deployment activity – an intermittent handling of treated nets at various stages of dryness. The work includes semi-automated handling of the nets during the process of reconstructing the cages around fish farms. Hand exposure is actual exposure inside gloves. *Handling model 2 TNsG part 2, p 163*	Handling of contaminated objects	Hands 0.21 mg/min Body 7.55 mg/min	Uncertainty is *moderate*. 90% C.I. for 75th percentiles: 0.15-0.30 (hands), 4.6-12.4 (body).

Professional carrying out a range of dipping activities (including mixing/diluting formulations, handling wet articles, machine minding and loading/unloading) involving a variety of articles. The models are reflective of conditions where operatives may contact treatment fluids and wet objects and the exposures are expressed as mg/min or mg/m^3 in-use product. Hand exposure is actual exposure inside gloves. [1]*Dipping model 1 TNsG part 2, p 167* [2]*Dipping model 2 TNsG part 2, p 168* [3]*Dipping model 3 TNsG part 2, p 169* [4]*Dipping model 4 TNsG part 2, p 170*	Manual dipping in open tanks (wooden articles)[1]	Hands 25.7 mg/min Body 178 mg/min Inhalation <1 mg/m^3	Uncertainty is *high.* Models 1-3 contain only 5 data each, whilst model 4 contains 9 data. Indicative exposures are based upon maximum values.
	Manual dipping in enclosed vessels (leather)[2]	Hands 39.9 mg/min Body 178 mg/min	
	Semi-automatic dipping in open vats (fishing nets)[4]	Hands 16.7 mg/min Body 221 mg/min Inhalation 0.2 mg/m^3	
	Automated dipping (textiles)[3]	Hands 1.6 mg/min Body 23.8 mg/min Inhalation 122 mg/m^3	

Professional handling dusty powders packaged in cardboard bags of approximately 25 kg. The exposures are expressed as mg/min in-use product. The model relates to manual handling of bags containing calcium carbonate in paint factories and is appropriate for other similar powder handling situations. *Dust and soil adhesion model 3 TNsG part 2, p 181* *Sub models describing exposures resulting from the different tasks can also be found in part 2 p 181*	Weighing/scooping powder. Handling, emptying and disposal of bags.	Hands 347 mg/min	Uncertainty is *moderate*. 90% C.I. for 75th percentile is 271-441 mg/min.
Professional operator diluting and mixing disinfectant and wiping surfaces using a cloth. The exposure to the hands inside protective gloves is expressed as mg/min in-use product. [1]*Surface disinfection model 1 TNsG part 2, p 173* [2]*Surface disinfection model 3 TNsG part 2, p 175*	Dipping of cloth and wiping of surfaces with rung cloth	Hands[1] 10.3 mg/min Body[2] 87.6 mg/min Inhalation[1] 22.9 mg/m^3	Model 1: uncertainty is *moderate*; 90% C.I for 75th of hand exposures 5.4-19.6. Indicative inhalation exposure is 50th of non-zero values – approximately 80th overall. Model 3: uncertainty is *high*. Indicative body exposure based upon highest of 8 data.

Models for Hand Held Tool Application

Description of Exposure Model	Application Method	Indicative Exposures	Uncertainty
Professional washing and wiping floors using a mop, bucket and wringer. E.g. hospitals and schools. Mixing and loading is not included and the task durations are between 10-40 mins. Exposure data is for the body (no hand data) and is expressed as mg/min in-use product. *Surface disinfection model 2 TNsG part2, p 174*	Mopping	4.50 mg/min (body)	Uncertainty is *high*. Indicative exposure is maximum of 6 data.
These two models relate to Professional treating soil by watering and subsoil by injection. The tasks include mixing and loading and the exposure is expressed as mg/min and mg/m3 in-use product. Hand exposure is actual exposure inside gloves. *Subsoil treatment model 2 TNsG part 2, p 177*	Watering can	Hands 48.8 mg/min Body 38.2 mg/min Inhalation 4.15 mg/m^3	Uncertainty is *high.* Indicative exposures based upon the highest of 4 data.
	Sub-soil injection	Hands 8 mg/min Body 25.8 mg/min Inhalation 0.57 mg/m^3	Uncertainty is *moderate.* 90% C.I. for 75th: 5.1-12.6 (hands), 18-37(body), 0.4-0.8 (inhalation).
In-situ application of wood preservatives with brush. These models relates to a Non-professional painting: 1. Rough wooden joists and the underside of floor boards, overhead indoors, with water based product (includes decanting). *Consumer product painting model 1 TNsG part 2, p 200* 2. Brushing sheds and fences, outdoor (direct from can). *Consumer product painting model 3 TNsG part 2, p 202*	1. Brushing	Hands/forearms 150 mg/min Legs/feet/face 35.7 mg/min Inhalation 3.1 mg/m^3	Uncertainty is *moderate.* 90% C.I. for 75th: 116-193 (hands), 21-60 (legs), 1.9-5.1 (inhalation).
	2. Brushing	Hands 5.91 mg/min Body 16.9 mg/min Inhalation 1.63 mg/m^3	Uncertainty is *moderate.* 90% C.I. for 75th: 3.7-9.4 (hands), 7.3-39.2 (body). Indicative exposure based upon 50th of non-zero values (80th overall, 9 zero inhalation exposures out of 15).

Non-professionals brushing and roller painting antifouling paint on underside of small boats, outdoor (direct from can or paint tray). Hand exposure is actual exposure inside gloves or on gloves. *Consumer product painting model 4 TNsG part2, p 203*	Brushing and roller	Gloved hands 76.6 mg/min Protected hands 18.5 mg/min Body 50.8 mg/min Inhalation 0.05 mg/m^3	Uncertainty for hand exposures is *high.* Indicative exposure is highest value out of 9 data for protected hands and out of 2 data for gloved hands. Uncertainty for body and inhalation exposures is *moderate.* 90% C.I. for 75th: 28-91 (body), 0.035-0.07 (inhalation).

Models for Spray Application

Description of Model	Application Method	Indicative Exposures	Uncertainty
Professional mixing and loading liquids and powders in compression sprayers or dusting applicators, and applying indoors and outdoors in overhead or downward direction. This model relates to insecticide application to various surfaces and articles in domestic and public (e.g. schools, nursing homes, restaurants, hospitals) areas. The model may also apply to other operations involving application via hand-held compression sprayers. Hand exposure is actual exposure inside gloves. *Spraying model 1 TNsG part 2, p 143* *Another model (model 10) describing exposures resulting from low pressure spraying of insecticides can be found in part 2 p 156*	Hand-held low pressure (1-3 bar) spraying Medium/coarse spray Spot, crack and crevice and broadcast applications	Hands 10.7 mg/min Hands (potential) 181 mg/min Body 92 mg/min Inhalation 104 mg/m^3	Uncertainty is *moderate*. 90% C.I. for 75th: 5.8-19.8 (hands), 64-132 (body). Indicative exposure for inhalation based upon 50th of non-zero data (≈ 85th overall) Uncertainty for potential hand exposures is *high.* Indicative exposure based upon maximum of 5 data.
Professional mixing, loading and applicating liquids in reservoir for powered spray application indoors and outdoors, in overhead and downward direction. This model relates to application of remedial biocides to structural timbers and masonry in industrial, recreational and residential settings. The model will also apply to other operations involving application using a pump-pressurised sprayer. Hand exposure is actual exposure inside gloves. *Spraying model 2 TNsG part 2, p 146*	Hand-held medium pressure (4-7 bar) spraying Medium/coarse spray Broadcast application	Hands 7.8 mg/min Hands (potential) 273 mg/min Body 222 mg/min Inhalation 76 mg/m^3	Uncertainty is *moderate*. 90% C.I. for 75th: 4.3-14.3 (hands), 134-368 (body), Indicative inhalation exposure is 75th of non-zero values (≈ 80th overall) 90% C.I. 45-128. Uncertainty for potential hand exposures is *high.* Indicative exposure based upon maximum of 6 data.

Professional spraying viscous solvent-based liquids outdoors, in overhead and forward direction. This model relates to high-pressure spraying of antifouling paints to ships. The model is equally applicable to many high-pressure paint-spraying operations. Hand exposure is actual exposure inside gloves. *Spraying model 3 TNsG part 2, p 149*	Hand-held high pressure (>100 bar) airless spraying Medium/coarse spray Broadcast application	Hands 2.04 mg/min Body 250 mg/min Inhalation 17.3 mg/m^3	Uncertainty is *moderate*. 90% C.I. for 75th: 0.86-4.97 (hands), 152-410 (body), 7.5-40 (inhalation).
Professional disinfection of slaughterhouses and meat processing industry by overhead and downward spraying or foaming. Exposures include mixing and loading, as well as application. The mixing and loading was done manually or by using automated dosing systems. *Spraying model 9 TNsG part 2, p 159*	Various techniques	Hands 2300 mg/min Body 4900 mg/min Inhalation 3600 mg/m^3	Inhalation uncertainty is considerable; indicative exposure is based upon the 95th percentile. Uncertainty for hand exposures is *high.* Indicative value is based upon the highest of 9 exposures. Uncertainty for body exposures is *moderate*. 90% C.I. for 75th percentile is 2650-9070.
Professional application of amenity herbicides at ground level using a controlled droplet wand applicator. Hand exposures are actual exposures inside gloves. *Fogging and misting model 1 TNsG part 2, p 183*	Controlled droplet applicator	Hands 0.12 mg/min Body 13.8 mg/min Inhalation 0.26 mg/m^3	Uncertainty for hand exposures is *moderate,* 90% C.I for hand exposures 0.06-0.25. Uncertainty for body and inhalation exposures is *high*. Indicative values based upon highest of 12 data.
Non-professional spraying liquid ready for use product indoors, in overhead direction. This model relates to powered application of wood preservatives to joists and underside of floorboards. The model may apply to other pump-pressurised operations in an overhead direction. *Consumer spraying and dusting model 3 TNsG part 2, p 197*	Hand-held medium pressure spraying Medium/coarse spray	Hands/forearms 176 mg/min Legs, feet & face120 mg/min Inhalation 115 mg/m^3	Uncertainty is *moderate.* 90% C.I for 75th are 117-265 (hands), 85-170 (legs), 79-168 (inhalation).

Non-professional spraying liquid ready for use product outdoors, in forward and downward direction. This model relates to powered application of wood preservative to solid and lattice fences. *Consumer spraying and dusting model 3 TNsG part 2, page 197*	Hand-held medium pressure spraying	Hands/forearms 144 mg/min Legs, feet & face 84 mg/min Inhalation 6.5 mg/m^3	Uncertainty is *high.* Indicative exposures based upon maximum of 6 data.
Non-professional surface spraying insecticide, indoors, on soft furnishings, carpets, skirting boards and shelves with dust applicators trigger sprays and aerosol cans. The models are derived from the following simulated volunteer studies: 1. Includes crack and crevice treatment for ants in a kitchen (skirting, shelves, horizontal laminate floors) using a fine powder (45% of particles less than 75 microm) and broadcast flea treatment (carpet) using coarse granules (95% of particles greater than 180 microm). 2. Crack and crevice insecticide treatment (skirting, shelves, horizontal/vertical laminate surfaces) using a ready for use liquid spray. 3. Broadcast treatment of small room (sofa, skirting dining chairs and carpet) using liquid spray. *Consumer spraying and dusting model 2 TNsG part 2, p 197*	1.Hand-held flexible duster	Hand/forearm 2.73 mg/min Legs/feet/face 2.74 mg/min Inhalation 2.47 mg/m^3	Uncertainty is *moderate.* 90% C.I. for 75th are 1.9-3.9 (hands), 1.7-4.4 (legs), 1.5-4.2 (inhalation).
	2.Hand-held trigger spray	Hand/forearm 36.1 mg/min Legs/feet/face 9.7 mg/min Inhalation 10.5 mg/m^3	Uncertainty is *moderate.* 90% C.I. for 75th are 26-50 (hands), 7.6-12.4 (legs), 9.0-12.2 (inhalation).
	3. Pre-pressurised aerosol spray can	Hand/forearm 64.7 mg/min Legs/feet/face 45.2 mg/min Inhalation 35.9 mg/m^3	For hands and inhalation uncertainty is *moderate.* 90% C.I. for 75th are 37-114 (hands), 31-43 (inhalation). Uncertainty for legs is *high* – highest exposure out of 6 used.

Non-professional space spraying insecticide in a small sealed room with trigger sprays, pumped sprayers and aerosol cans. The models are derived from simulated volunteer studies involving the discharge of the sprayer into the air on four consecutive occasions. Each discharge took six seconds and the user remained in the room for the next 30 seconds before exiting Liquid. It is important to note that application and dwell times are critical determinants of exposure in such scenarios and the data presented in these models are a reflection of the specific scenarios used in the experiments. *Consumer spraying and dusting model 1 TNsG part 2, p 194*	Hand-held trigger sprayer	Hand/forearm 136 mg/min Legs/feet/face 42.4 mg/min Inhalation 90.2 mg/m^3	Uncertainty is *moderate.* 90% C.I. for 75th are 95-194 (hands), 22-82 (legs), 69-118 (inhalation).
	Hand-held pumped spray	Hand/forearm 98.4 mg/min Legs/feet/face 22.7 mg/min Inhalation 76.3 mg/m^3	Uncertainty is *moderate.* 90% C.I. for 75th are 36-271 (hands), 19-28 (legs), 65-90 (inhalation).
	Aerosol can	Hand/forearm 156 mg/min Legs/feet/face113 mg/min Inhalation 234 mg/m^3	Uncertainty is *moderate.* 90% C.I. for 75th are 114-214 (hands), 83-153 (legs), 175-312 (inhalation).

Models for Fogging Applications

Description of Model	Application Method	Indicative Exposures	Uncertainty
Professional applying insecticide at waist level, indoor, using cold (ULV) or thermal foggers. The models are based on simulation studies using professional operators in realistic building settings. Hand exposure is actual exposure inside gloves. [1]*Fogging and misting model 2 TNsG part 2, p 185* [2]*Fogging and misting model 3 TNsG part 2, p 186*	Cold (ULV) fogging[1]	Hands 0.20 mg/min Body 21.8 mg/min Inhalation 70.2 mg/m^3	Uncertainty is *moderate.* 90% C.I. for 75th are 0.03-0.05 (hands), 11-43 (body), 49-102 (inhalation).
	Thermal Fogging[2]	Hands 0.33 mg/min Body 1.13 mg/min Inhalation negligible	Uncertainty is *high.* Indicative exposures based upon maximum of 4 data.

Model for Metal Working Fluids

Description of Model	Process	Indicative exposures	Uncertainty
Professionals at companies ranging from multinationals to small independent engineering workshops handling mineral oils, semi-synthetic oils and synthetic fluids. *Metal working fluids model 2 TNsG part 2, p 188*	Tool making and other metalworking operations.	Oil-based Inhalation 2.18 mg/m^3 Water-based Inhalation 0.33 mg/m^3	Uncertainty is *moderate.* Data set contains over 300 personal samples. Indicative exposure values represent 75^{th}.

ANNEX 5: Confidence intervals for percentiles of exposure distributions

The correct selection and use of exposure percentiles in a risk assessment is essential in order to avoid excessive conservatism whilst also providing reassurance that highly exposed workers are incorporated into the assessment. As uncertainty increases with small datasets it is generally the case that a higher percentile such as 90th, 95th or maximum exposure value will be used in place of a more moderate one such as a 75th percentile. Alternatively, a confidence interval may be calculated for a percentile to indicate the level of precision in the value and this supplementary information considered when making the assessment.

Assuming that a sample of *n* exposure measurements has a lognormal distribution with a geometric mean of exp (μ) and a geometric standard deviation of exp (σ) then an estimate of the *p*th percentile is given by:

$$\exp \{ \mu + z_p \sigma\}$$

Where z_p is the *p*th percentile from a standardized normal distribution N(0,1). For example, $z_{75} = 0.6745$, $z_{90} = 1.2816$.

An approximate standard error of log(*p*) can be calculated as:

$$\sqrt{\sigma^2 n^{-1} + z_\alpha{}^2 \sigma^2 (2n)^{-1}}$$

1-α% confidence intervals for exposure percentiles can then be calculated using the following formula:

$$\exp\left(\mu + z_p \sigma \pm z_{\frac{\alpha}{2}} \sqrt{\sigma^2 n^{-1} + z_p{}^2 \sigma^2 (2n)^{-1}} \right)$$

Example

A sample of size 10 with geometric mean 20 and GSD 5 has a 75th percentile of exp{log(20) + 0.6745 $\times$ log(5)} = 59.2.

The standard error of the log 75th percentile is (log(5)^2/10 + 0.6745^2 $\times$ log(5)^2 / 20)$^{0.5}$ = 0.56.

A 90% confidence interval for the 75th percentile is then given by exp(log(59.2) $\pm$ 1.6449 $\times$ 0.56) e.g. 23.6 to 148.7.

Often, rather than assuming a lognormal distribution, an empirical estimate of a percentile will be taken directly from the ranked exposure data. In these cases an approximate 90% confidence interval for the percentile is given by:

Lower endpoint: $p / \exp\left(1.6449\sqrt{\sigma^2 n^{-1} + z_p{}^2 \sigma^2 (2n)^{-1}}\right)$

Upper endpoint: $p \times \exp\left(1.6449\sqrt{\sigma^2 n^{-1} + z_p{}^2 \sigma^2 (2n)^{-1}}\right)$

Tables 1 and 2 give the multiplicative values required to obtain a 90% confidence interval for a 75th and 95th percentile of a variety of geometric standard deviations and sample sizes. For example for an empirical 75th percentile of 100 mg min^{-1} from a dataset of 50 measurements with a GSD of 6 a 90% confidence interval for the percentile is 63 mg min^{-1} (100 /v1.59) to 159 mg min^{-1} (100v×v1.59). Confidence intervals become wider (less certain) with greater exposure variability and narrower with increasing sample size.

Table 1: Scaling factors to obtain a 90% confidence interval for a 75th percentile with a variety of sample sizes and GSDs

		Geometric standard deviation								
		2	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***
Sample size	***5***	1.75	2.45	3.10	3.71	4.31	4.88	5.45	5.99	6.53
	10	1.49	1.88	2.22	2.53	2.81	3.07	3.31	3.55	3.77
	20	1.33	1.56	1.76	1.93	2.08	2.21	2.33	2.49	2.56
	50	1.20	1.33	1.43	1.51	1.59	1.65	1.71	1.76	1.81
	100	1.13	1.22	1.29	1.34	1.39	1.43	1.46	1.49	1.52

Table 2: Scaling factors to obtain a 90% confidence interval for a 95th percentile with a variety of sample sizes and GSDs

		Geometric standard deviation								
		2	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***
Sample size	***5***	2.19	3.45	4.78	6.15	7.55	8.99	10.45	11.93	13.44
	10	1.74	2.40	3.02	3.61	4.18	4.72	5.25	5.77	6.28
	20	1.48	1.86	2.19	2.38	2.75	3.00	3.23	3.45	3.67
	50	1.28	1.48	1.64	1.78	1.90	2.00	2.10	2.19	2.27
	100	1.19	1.32	1.42	1.50	1.57	1.63	1.69	1.74	1.79

HUMAN EXPOSURE TO WOOD PRESERVATIVES (Product Type 8)

1. INTRODUCTION

Wood preservatives include products used for the preservation of wood or wood products by the control of wood-destroying or wood-disfiguring organisms. The product-type can be divided into ***preventive products*** for treating structural timber/wood products before use and ***curative products*** for surface treatment of timber in-situ. The products are supplied in a variety of formulations: solvent-based or water-based products, ready-for-use or as concentrates for dilution, and as pastes.

The TNsG on Human Exposure to Biocidal Products has consolidated the available information on human exposure to wood preservatives to help inform assessors in carrying out exposure estimations for operators and others. This includes information on ***the pattern of use*** and ***results from exposure surveys*****.** The pattern of use information for wood preservative products and proposed defaults for use in exposure assessments are presented in Table 1. The generic database models derived from the exposure surveys, including indicative exposure values, can be found in Annex 4 of the User Guidance.

Additional information on processes and use of wood preservatives can be found in the OECD Emission Scenario Documents for Wood Preservatives guidance document (available through the ECB site (www.ecb.jrc.it/biocides).

2. PREVENTIVE WOOD PRESERVATIVE PRODUCTS

This type has been taken to cover all preventive treatments, including the use of anti-sapstain products. Typically timber will be treated with either water- or solvent-based formulations in industrial premises using:

-vacuum-pressure plant (water-based formulations)
-double-vacuum plant (solvent or water-based formulations)
-deluge / flood spray plant (water-based formulations)
-mechanical or manual dipping (water or solvent-based formulations)

Professionals undertake preventive treatments in industrial plant and will experience primary exposure. Non-professionals do not undertake industrial timber pre-treatment, however, they do treat timber before use by dipping or painting. There is very little information about patterns of use for preventive products used by non-professionals, though models are available for assessing exposure from the use of wood preservatives at home (fences, sheds).

Primary exposure will be predominantly via the dermal route as a result of direct contact with the surface of treated timber and through contact with ancillary equipment and contaminated process plants. Dermal exposure may also arise from the spread of contamination into areas such as control rooms

and from secondary sources such as previously contaminated overalls and gloves.

Professionals will wear coveralls, protective footwear, and gloves and may use eye and face protection. Respiratory protective equipment is often provided where solvent-based products are used. Non-professionals may wear coveralls and gloves, however such usage cannot be assured and must not be assumed in exposure estimation. At the most, a non-professional may be expected to wear a long shirt, long trousers and footwear, irrespective of any label stipulation.

Preserved wood is not placed on the market until it is dry. The wood is suitable for indoor or outdoor use and so the exposed population for secondary exposure will be adults using preserved timber in construction, children playing on preserved timber structures and infants chewing preserved timber off-cuts.

3. CURATIVE WOOD PRESERVATIVE PRODUCTS

This type has been taken to cover all curative treatments. The products are applied to interior and exterior structural timber and to wooden articles (fences, sheds, seating) in a wide range of industrial, recreational, and residential settings by low-medium pressure (1-7 bar) spraying, brushing and trowel or caulking tool.

Solvent or water-based products are supplied as concentrates for dilution on site, or ready for use. Professional products are normally obtained from wholesalers in containers up to 25 litres. Retail outlets supply non-professional products in 1 to 10 litre cans. Both professionals and non-professionals can undertake most of the processes. However, some products are restricted to professional users.

Many professional activities require considerable site preparation, and the use of preservative is less than half the time spent at the job. The job involves mixing, loading and application and done as a single scenario. Non-professionals would experience “unique event” exposure for remedial work – the job being done once and not repeated, though there may be more than one site in the home that is treated.

Primary exposure will be predominantly via the dermal route as a result of deposition of aerosols and through contact with ancillary equipment and contaminated surfaces. Dermal exposure may also arise from secondary sources such as previously contaminated overalls and gloves.

Professionals will wear coveralls, protective footwear, and gloves and may use eye and head protection. Where solvent-based products are used, they should wear respiratory protective equipment (RPE). Non-professionals may wear coveralls and gloves, however such usage cannot be assured and must not be assumed in exposure estimation. At the most, a non-professional may be expected to wear a long shirt, long trousers and footwear, irrespective of any label stipulation.

The exposed population for acute secondary exposure will be adults and children re-entering treated sites and coming into contact with surfaces which are still wet. Chronic secondary exposure will be to inhalation of volatilised residues by adults and children in treated buildings.

Table 1. Exposure scenarios for wood preservatives and default values for pattern of use in exposure assessments

Primary Exposures	Process/Task	Use Pattern	Secondary Exposures
Professional user Pre-treatment of timber in industrial premises	Mixing and loading	3 Operations/day	Acute - adult cutting and sanding treated wood (consumer) - infant chewing preserved timber off-cuts Chronic - adult cutting and sanding treated wood (professional) - adult/infant inhaling volatilised residues indoor - children playing on preserved timber structures
	Vacuum pressure	Range = 0 - 12 cycles per day (180 mins/cycle) Default (median) = 3 cycles per day (540 mins) Wood absorbs 150 litres of preservative per m^3	
	Double vacuum pressure	Range = 0 – 12 cycles per day (60 minutes/cycle) Default (median) = 6 cycles/day (360 mins) Wood absorbs 10-50 litres of preservative per m^3	
	Deluge	120 Minutes	
	Dipping	Range = 11 – 162 mins/batch (1 batch per day) Default (median) = 30 minutes/batch Wood absorbs 0.2 litres per 4 m^2 fence panel	
Professional user Remedial (curative) timber treatment in situ	Mixing and loading	3 Operations/day	Acute - not relevant Chronic - adult/infant inhaling volatilised residues
	Spraying	Range = 6 – 100 mins/application (2 applications per day) Default (median) = 40 mins/application	
	Spreading paste	30 minutes (application rate = 1 kg/m^2)	
Non-professional Remedial (curative) timber treatment in situ.	Spraying	40 minutes/day (1 to 2 times per year)	
	Brushing	Range = 76 – 241 mins/day (1-2 days per year) Default (median) = 155 minutes day	

4. PRIMARY EXPOSURE ASSESSMENTS

4.1 Vacuum-Pressure and Double-Vacuum Impregnation

Vacuum and pressure plant are operated on a cyclical basis. Professional workers in industrial plant typically work 8-10 hours a day, at least five days a week. Sites normally have one or two workers engaged in preservation, and one or two treatment vessels.

Product delivery is as kegs of concentrate paste, or as liquid concentrate in Industrial Bulk Containers (IBC) or by tanker. Any dilution of concentrates is done in industrial plants and other than incidental exposure in connecting and disconnecting transfer lines, exposure is normally not foreseen. Incidental exposure is contact with product inside protective gloves and on taking off protective gloves.

Application includes all stages in preservation, from loading the treatment vessel to stacking the treated wood to dry. The job entails a cycle of loading, waiting, unloading and removal of treated timber to storage. Fresh and treated wood is usually moved using lift trucks, however, the operators are closely involved with handling restraining straps and treatment machinery, in maintaining the door seals of treatment vessels, in removing fallen wood and sawdust sludge. Each treatment vessel will have a maximum 3 or 6 cycles of treatment in any day. The proposed default cycle times are for vacuum pressure operations, 3 per day, 3 hours per cycle and for double vacuum (oscillating pressure) operations, 6 per day, 1 hour per cycle default. Professionals spend only a fraction of their time using wood-preservatives; other jobs and paperwork all take time. Some "accelerated fixation" processes take longer, so indicating fewer treatments per day.

Post-application exposure, for professionals, constitutes system maintenance and exposure in recycling or disposal will be similar to post-application exposure. Non-professional post application exposure is all secondary exposure through using preserved wood.

Table 2. Primary exposure for professional operator during vacuum-pressure treatment. Industrial pre-treatment of timber with a water-based formulation containing 2% active substance

[*Handling model 1, TNsG Part 2, p 160* (includes application and post-application exposures)]

Product	**Units**	**Tier 2**
active substance	%	2.0%
Potential body exposure		
clothing type		cotton coverall
indicative value	mg/cycle	8570
Duration	cycles/day	3
potential dermal deposit	mg	25710
clothing penetration	%	10
actual dermal deposit [*product*]	mg	2571
Hand exposure		
gloves worn		yes
indicative value	mg/cycle	1080
duration	cycles/day	3
actual hand deposit [*product*]	mg	3240
Total dermal exposure		
product	mg	5811
active substance	mg	116
Exposure by inhalation		
indicative value	mg/m^3	1.9
duration	min	540
inhalation rate	m^3/min	0.021
inhaled volume	m^3	11.34
mitigation by RPE	value	none
inhaled [*product*]	mg	21.5
active substance	mg	0.43

Exposure during mixing and loading operations is considered to be negligible as automated dilution by pumping transfer means exposure would be accidental.

The Tier 1 assessment is obviously an unrealistic situation and therefore in the Tier 2 assessment the realistic exposure estimate is given, which assumes 10% penetration of the typical clothing worn by operators (TNsG part 2.2.3D). Tier 2

could be further refined by building in mitigation factors for other PPE such as impermeable coveralls, RPE etc.

Calculation of systemic body burdens is associated with a high degree of uncertainty and requires expert judgement. To derive a systemic dose from the above estimate appropriate information is required concerning uptake (skin, inhalation, studied route) and physiological parameters like body weight or breathing rate. If specific information is not available, appropriate defaults might be used. Some guidance and default values are given in Appendices IV B (Dermal absorption) and IV C (Physiological factors) of the TGD on New and Existing Substances, Human Health Assessment.

To derive a systemic dose from the above estimate appropriate defaults for uptake (skin and inhalation) and body weight are required. For example assuming inhalation absorption of 100%, skin absorption of 10% and a body weight of 60 kg give a systemic dose from Tier 2 of:

$$\text{Systemic dose} = \frac{10\%\ (\text{total dermal exposure}) + 100\%\ (\text{inhalation exposure})}{60\ \text{kg body weight (bw)}}$$

$$= \frac{11.6 + 0.43}{60} = 0.2\ \text{mg/kg bw/day}$$

Table 3. Primary exposure for professional operator during double vacuum-pressure treatment. Industrial pre-treatment of timber with solvent-based formulation containing 2% active substance

[*Handling model 1, TNsG Part 2, p 160* (includes application and post application exposures)]

Product	**Units**	**Tier 2**
active substance	%	2.0%
Potential body exposure		
clothing type		cotton coverall
indicative value	mg/cycle	158
duration	cycles/day	6
potential dermal deposit	mg	948
clothing penetration	%	10
actual dermal deposit [*product*]	mg	95
Hand exposure		
gloves worn		yes
indicative value	mg/cycle	260
duration	cycles/day	6
actual hand deposit [*product*]	mg	1560
Total dermal exposure		
product	mg	1655
active substance	mg	33
Exposure by inhalation		
indicative value	mg/m^3	0.6
duration	min	360
inhalation rate	m^3/min	0.021
inhaled volume	m^3	7.56
mitigation by RPE	value	none
inhaled [*product*]	mg	4.5
active substance	mg	0.1

Exposure during mixing and loading operations is normally considered to be negligible as automated dilution by pumping transfer means exposure would be accidental.

A systemic dose can be derived in the same way as indicated for vacuum pressure treatment above.

4.2 Dipping and Deluge

Dipping and deluge processes are operated on a batch basis. Professional workers typically work 8-10 hours a day, at least five days a week.

Dipping processes are supplied in 200 l drums or by tanker. Solvent-based products are ready for use; water based products are supplied as concentrates. These are diluted in process plant, or as ready-for-use solutions. Exposure during the connection and disconnection of transfer lines would be incidental. However, there may be significant potential for exposure to the hands if there is manual loading of wood preservative tanks.

Professionals spend only a fraction of their time using wood-preservatives and it is assumed that operators would spend 30 minutes dipping, once a day. Application includes all stages in preservation, from loading the treatment vessel to immersing articles and stacking them to dry. Professional post-application exposure constitutes system maintenance and exposure in recycling or disposal will be similar to post-application exposure. Non-professional post application exposure is all secondary exposure through using preserved wood/articles.

Generic exposure models are available for the professional dipping of wooden articles (e.g. fences, window frames) and these have been used to estimate exposure of operators applying wood preservative by dipping. Non-professionals may also carry out dipping and this model could be used for assessing such scenarios as long as appropriate assumptions were made with regards to amount of product handled/ container size and the options for exposure control.

During the deluge process, timber is passed through an enclosed tunnel in which the preservative is applied to it from various types of spray jet. Operator exposure should be low during this process and be predominantly due to residues from handling freshly sprayed timber. There is no generic model data for the deluge process; however, it is considered that the professional dipping model would be a good approximation in assessing exposure from the deluge process.

Table 4. Primary exposure for professional operators during dipping operations. Industrial pre-treatment of timber using water-based or solvent-based formulations containing 2% of active substance

[*Mixing and Loading model 3, TNsG Part 2, p 135*. This covers the potential for exposure during manual mixing and loading operations

Dipping model 1, TNsG Part 2, p 167 (includes application and post application exposures)]

Product	**Units**	**Mixing and loading**	**Dipping**
active substance	%	10%	2.0%
Potential body exposure			
clothing type			none
indicative value	mg/min	ND	178
duration	min/day		30
potential dermal deposit	mg		5340
clothing penetration	%		100
actual dermal deposit [*product*]	mg		5340
Hand exposure			
gloves worn		yes	yes
indicative value	mg/event	20 mg/kg/a.s.	25.7
duration or (amount handled)	min/day	20 kg a.s./day	30
actual hand deposit [*product*]	mg	400	771
Total dermal exposure			
product	mg	-	6111
active substance	mg	400	122
Exposure by inhalation			
indicative value	mg/m^3	0.005 mg/kg a.s.	1
duration or amount handled	min/day	20 kg a.s./day	30
inhalation rate	m^3/min	-	0.021
inhaled volume	m^3	-	0.63
mitigation by RPE	value	-	none
inhaled [*product*]	mg	-	0.63
active substance	mg	0.1	0.01

This can involve the use of automated or manual mixing and loading operations

The dipping estimate above is a Tier 1 estimate. A more realistic estimate would need to be derived as shown in the examples of the Tier 2 estimates for vacuum pressure treatment. To derive a systemic dose the same aspects need to be considered as indicated for vacuum pressure treatment above.

4.3 Low to Medium Pressure Spraying

Solvent or water-based products are supplied as concentrates for dilution on site, or ready for use. Professional products are normally obtained from wholesalers in containers up to 25 litres. Retail outlets supply non-professional products in 1 to 10 litre cans.

Given the need for site preparation, professional operators are likely to be exposed no more than twice per day and no more than a few times a week. Exposure to an individual product on a regular basis is foreseeable only on large remedial projects. The duration of spraying ranges from 6 to 100 minutes; median 40 minutes. Non-professionals could also spend 40 minutes spraying, one day per year. Generic exposure data are available for both professional and non-professional in situ treatment of timber with wood preservatives using a hand-held sprayer and these have been used in the following exposure assessments. Although, only Tier 1 exposure assessments are presented below, the same approach for exposure refinement, as adopted in the examples above, can be applied to these examples. The default clothing for professionals would be cotton coveralls allowing 10% clothing penetration. For non-professionals it would be reasonable to assume shorts and shirt as typical clothing and to allow 50% penetration through these clothes.

Table 5. Primary exposure for professional and non-professional users spraying remedial (curative) wood preservatives using water-based or solvent-based products containing 2% active substance

[*Spraying model 2, TNsG Part 2, p 146*

Consumer spraying and dusting model 3, TNsG Part 2, p 197]

Product	**Units**	**Professional**	**Non-professional**
active substance	%	2.0%	2.0%
Potential body exposure			
clothing type		none	none
indicative value	mg/min	222	120
duration	min	40	40
potential dermal deposit	mg	8880	4800
clothing penetration	%	100	100
actual dermal deposit [*product*]	mg	8880	4800
Hand exposure			
gloves worn		yes	no
indicative value	mg/min	7.8	176
duration	min	40	40
actual hand deposit [*product*]	mg	312	7040
Total dermal exposure			
product	mg	9192	11840
active substance	mg	184	237
Exposure by inhalation			
indicative value	mg/m^3	76	115
duration	min	40	40
inhalation rate	m^3/min	0.021	0.021
inhaled volume	m^3	0.84	0.84
mitigation by RPE	value	none	none
inhaled [*product*]	mg	64	97
active substance	mg	1.28	1.94

Both the professional and non-professional estimates above are Tier 1 estimates. A more realistic estimate would need to be derived as shown in the examples of the Tier 2 estimates for Vacuum pressure treatment (for the non-professional

50% penetration through clothing is assumed as shown in the brushing example below). The systemic dose can be derived in the same way as indicated for vacuum pressure treatment above.

4.4 Brushing

The pattern of use information indicates that both professional and non-professionals would spend sessions of up to 150 minutes painting once or twice a year. Generic exposure models are available for non-professional users applying wood preservative to fencing panels/sheds by brush and have been used to estimate exposure from brushing in the example below. Although no models are available for professional treatment of timber using a brush, it is proposed that the non-professional model should also be used to estimate exposure of professional operators applying wood preservatives by brush.

Table 6. Primary exposure for Non-professional during brush painting of fence with water-based or solvent-based formulations containing 2% active substance

[*Consumer product painting model 3, TNsG Part 2, p 202*]

Product	**Units**	**Tier 1**	**Tier 2**
active substance	%	2.0%	2.0%
Potential body exposure			
clothing type		None	shirt/shorts
indicative value	mg/min	16.9	16.9
duration	min	155	155
potential dermal deposit	mg	2620	2620
clothing penetration	%	100	50
actual dermal deposit [*product*]	mg	2620	1310
Hand exposure			
gloves worn		no	no
indicative value	mg/min	5.9	5.9
duration	min	155	155
actual hand deposit [*product*]	mg	915	915
Total dermal exposure			
product	mg	3535	2225
active substance	mg	71	45
Exposure by inhalation			
indicative value	mg/m^3	1.63	1.63
duration	min	155	155
inhalation rate	m^3/min	0.021	0.021
inhaled volume	m^3	3.26	3.26
mitigation by RPE	value	None	none
inhaled [*product*]	mg	5.3	5.3
active substance	mg	0.11	0.11

4.5 Pastes

Paste wood preservative products can be applied as remedial treatments in a variety of ways e.g. brush, trowel, caulking tool, palette knife and by gloved hand. Potential exposure is by the dermal route and it is assumed that the application phase for pastes would normally be around 30 minutes. Following contact of a

paste product with the skin, residues would be wiped off on clothing shortly after contact had occurred. In this scenario, it is unlikely that much of the product/active substance would be left on the skin.

There are no generic data for application of pastes and it is considered that exposure from use of wood preservative pastes will not give exposures greater than those observed for application of liquid formulations via brushing (101 - 1380 mg/day). In addition, a reverse reference scenario has been used to estimate the amount of exposure required to exceed an acceptable level (60 g).

Reverse reference scenario

Primary exposure of professional and non-professional remedial treatment of timber using wood preservative pastes by brush, trowel, caulking gun and gloved hand. Solvent-based ready for use formulation containing 0.5% active substance.

There are no generic data for application of pastes. In the absence of generic data, it is considered that the potential for human exposure to pastes would be less than the potential for exposure to liquid wood preservatives by brushing.

Another option is to assess the maximum exposure to the active substance, which would allow for an acceptable 'Margin of Safety/Exposure' (MOS/MOE) based on an appropriate NOAEL (the MOE will be used). A similar reasoning can be put forward using the AOEL as a starting point.

The maximum amount of active substance can be calculated by dividing the NOAEL by the appropriate MOE. Assuming an NOAEL of 50 mg kg^{-1} d^{-1} and a MOE of 100, the maximum amount of active substance is given by:

$$NOAEL/MOE = 50/100 = 0.5 \text{ mg } kg^{-1} d^{-1}$$

If dermal absorption is10%, to exceed a MOE of 100, active substance contamination would need to exceed:

$$0.5 \text{ mg } kg^{-1} d^{-1} \times 10 = 5 \text{ mg } kg^{-1} d^{-1}$$

Although in many cases the MOE is 100, the value of the MOE should always be considered first, and not to be taken 100 as default.

Comment: the above correction for dermal absorption is only correct if in the study the NOAEL is derived for an absorption through the used route of uptake is 100%. If the study were a dermal study, then there should not be a correction for dermal absorption.

If the operator weighs 60 kg then, to exceed a MOE of 100, contamination with active substance would need to be over

$$5 \text{ mg } kg^{-1} d^{-1} \times 60 \text{ kg} = 300 \text{ mg } d^{-1}$$

As the maximum concentration of active substance in the ready-for-use paste formulation is 0.5% w/w, then the weight of paste product containing 300 mg active substance that is acceptable to come into contact with skin will be:

$$300/0.5 \times 100 = 60000 \text{ mg} = 60 \text{ g}$$

5. SECONDARY EXPOSURE ASSESSMENTS

Secondary exposure occurs during or following biocide application and results from adventitious contact with the pesticide itself or treated surfaces. The exposed population is anyone in the environment who may:

- inhale residual aerosols (sprays only, during or immediately after application);
- inhale vapourised biocide from deposits (any application); dermal contact deposits (both recently applied and dried);
- ingest dislodged deposits (inadvertently by adults, for example during smoking or eating/drinking; ingestion of dislodged deposits by infants).

There is an almost limitless number of possible scenarios, which could be modelled. For every 'worst case' there will be several 'realistic worst cases' with lower exposure, and multitudes of cases with low (though prolonged) exposure. Consequently, there are no clear rules to estimate secondary exposure, which needs consideration on a structured case-by-case basis and must consider the potential persistence of the active substance and its mode of use.

In the following examples, selected **'reference scenarios'** are used to estimate a realistic worst-case exposure (based on default value calculations and stated assumptions) and to put other potential exposures into context. A risk assessment based on such a plausible scenario would indicate the acceptability of risk for secondary exposure. Two time-referenced scenarios are needed i.e. the acute phase (e.g. during or immediately after application of the biocide); and the chronic phase (long-term exposure from residues resulting from the biocide application).

The probability of the acute scenario occurring cannot be predicted with accuracy and may be very low. Conversely, depending upon the persistence of the pesticide, the probability of the chronic scenario occurring is likely to be high. Events giving rise to acute exposures lower than for the reference scenario will occur more frequently, and exposures could occur through scenarios that have not been envisaged. High secondary acute exposures are conceivable - these depend on the degree of misuse of the product and the inventiveness of the user - but they may not be reasonable.

5.1 Reference Scenarios for Preventive Products

Preserved wood is not placed on the market until the product is dry. The product is suitable for indoor or outdoor use. The *reference scenarios* modelled are as follows:

Acute phase reference scenarios

Adult - cutting and sanding treated wood (non-professional)

Infant - chewing wood off-cut

Chronic phase reference scenarios

Adult - cutting and sanding treated wood (professional)

Adult - inhalation of volatilised residues indoors

Child - playing on playground structure outdoors

Infant - playing on weathered structure and mouthing

5.2 Reference Scenarios for Curative (Remedial) Products

In the case of curative wood preservative products, it is assumed that occupants and other bystanders will be excluded from the treatment areas during application and until surfaces are dry. Thus secondary exposure for occupants following use of these products will be mainly due to chronic exposure.

Acute phase reference scenarios

Not relevant

Chronic phase reference scenarios

Adult/infant - inhalation of volatilised residues indoors

5.3 Acute Reference Scenarios

Scenario 1*: Adult (non-professional) sanding (powered sander) wooden posts (4 cm x 4 cm x 2.5 m) for one hour. The posts have been treated with 2% wood preservative solution by the double vacuum process*.

Inhalation exposure

Product in outer 1 cm layer of posts = 50 litres/m^3 (Default, see Table 1)

Volume of wooden post = 0.004 m^3 (4 cm x 4 cm x 2.5 m)

Active Substance in post = 0.004 m^3 x 50 litres x 2% = 4 g per 4000 cm^3 wood = 1.0 mg/cm^3 wood dust

Inhalation rate 1.25 m^3/hour

If the inhalation exposure were to be 5 mg/m^3 (equal to the occupational exposure limit for wood dust), the Inhalation exposure = 5 mg/m^3 x 1.25 m^3 = 6.25 mg.

Assuming a wood density of 0.8 g/cm^3; 6.25 mg of wood dust is equivalent to:

0.00625/0.8 = 0.008 cm^3

Inhalation exposure to the active substance by inhalation is then given by:

0.008 cm3 x 1.0 mg/cm3 = 0.01 mg.

Dermal exposure (hands)

Active substance residue on surface = 1 mg/cm^2

Hand surface area = 420 cm^2

Assume 20% of hand (84 cm^2) contaminated at 100% of surface concentration Dermal exposure = 1 mg x 84 = 84 mg

***Scenario 2**: Infant picks up and chews wood off-cut (4 cm x 4 cm x1 cm), which has been treated with 2% wood preservative solution by the double vacuum process*.

Volume of wood off-cut = 16 cm^3 (4 cm x 4 cm x 1 cm)

Active substance in outer 1 cm outer layer = 1.0 mg/cm^3 wood (Scenario 1)

Active substance in off-cut = 16 mg

Assuming 10% extraction of active substance by chewing then:

Ingestion exposure = 1.6 mg active substance per event

5.4 Chronic Reference Scenarios

***Scenario 1**: Adult (professional) sanding (powered sander) wooden posts (4 cm x 4 cm x 2.5 m) for one hour. The posts have been treated with 2% wood preservative solution by the double vacuum process*.

See acute reference Scenario 1 for calculation.

***Scenario 2**: Adult and infant inhale volatilised residues from treated wood installed indoors or from remedial in situ treatment of wood indoors. Assume a moderately ventilated room and residence time of 18 hours/day with an adult*

inhaling 18.5 m^3 air and an infant inhaling 4 m^3 air. As a worst-case inhalation exposure is taken as 1% of the saturated vapour pressure of the active substance (mol. wt. 326), which in this example is taken as 0.03 Pa.

1 atmosphere = 101,325 Pa

Airborne concentration = (0.03 x 1/100)/101325 = 0.003 ppm

At 25 °C, the concentration in mg/m^3 is given by:

(mol. wt. x ppm)/molar volume of gas = (326 x 0.003)/22.44 = 0.04 mg/m^3

Inhalation exposure (adult) = 0.04 mg/m^3 x 18.5 m^3 = 0.74 mg

Inhalation exposure (infant) = 0.04 mg/m^3 x 4 m^3 = 0.16 mg

***Scenario 3**: Child playing on playground structure outdoors. The structures are made of wood, which has been treated with wood preservative and there is prolonged and repeated contact of wood with hands.*

Active substance residue on surface = 0.01 mg/cm^2 (gross assumption)

Hand surface area = 200 cm^2

Assume 20% of hand (40 cm^2) contaminated at 100% of surface concentration
Dermal exposure = 0.01 mg x 40 = 0.4 mg

***Scenario 4**: Infant playing on and mouthing weathered structure. The structure is made of wood, which has been treated with wood preservative and there is prolonged and repeated contact with the wood.*

Active substance residue on surface = 0.01 mg/cm^2 (gross assumption)

Hand surface area = 200 cm^2

Assume 20% of hand (40 cm^2) contaminated at 100% of surface concentration

Dermal exposure = 0.01 mg x 20 = 0.4 mg

Assume 100% ingestion of surface deposit on 5 x 10 cm^2 of wood
Ingestion exposure = 0.01 mg x 50 cm^2 = 0.5 mg

HUMAN EXPOSURE TO RODENTICIDES (Product Type 14)[1]

Rodenticides are used for rodent control and in most cases are formulated as ready-for-use products. For special purposes, some concentrates are available and some rodenticides are formulated as tracking powders. It is a general rule that rodenticides are formulated and kept in such a way that humans and non-target animals should not be exposed. Nevertheless, one should consider primary exposure which occurs to the applicator and also secondary exposure to other individuals (e.g. bystanders, including children) that may occur during, or after application from unwanted contact with residues of the formulation.

To estimate human (primary and secondary) exposure to rodenticides, it is necessary to have information on the formulations to be used, their use scenarios and the time budget for the use scenarios. Furthermore, it is necessary to have some information on the levels of exposure for the - or similar - products/formulations used in similar or related scenarios, otherwise these data will have to be collected.
The following compiles general information on these variables. This is to give some guidance on how levels of inhalation, oral and dermal exposure (where relevant) for use of specific products/formulations can be assessed for human risk in registration procedures.

Formulation types
The following formulation types and equipment are considered relevant for rodenticidal products:
- Wax blocks
- Pellets
- Impregnated grain and maize
- Edible gels
- Bait boxes
- Contact powders
- Liquid baits (mainly aqueous solutions)
- Liquid concentrates (mainly in organic solvents)
- Fumigation pellets (e.g. generating phosphine gas)
- Gasses.

These formulation types may be used in various scenarios. The following gives some information required for the assessment of the use of formulation types in these possible scenarios.

- Bait boxes/stations

[1] Frequent use is made of Human and Environmental Exposure Scenarios for Rodenticides – Focus on the Nordic Countries (J. Lodal and O.C. Hansen), TemaNord 2002: 575.

These boxes/stations, especially when tamper-proof, are used to prevent contact by humans with the rodenticidal product. Several constructs are available, such as merely hiding the rodenticide under a cover, to prevent or at least diminish contact after placing, or placing the rodenticide in a pipe, long enough to prevent contact with the bait. More elaborate enclosed bait boxes, which have holes for the rodents to enter, are available.
Boxes/stations should be placed in such a way that others, such as children and non-target animals, cannot reach the bait. However there will often be some contamination of the bait boxes' surroundings with rodenticide from spillage caused by the rodents, or due to the rodents' contaminated urine, faeces and carcasses.

- Pellets, impregnated grain and maize

These formulations may be used indoors and outdoors and can be applied to larger surfaces which are not enclosed. They may also be placed directly into rodent burrows/holes with a spoon or small shovel. The burrows/holes may be covered to prevent access by children, for example. Again the surroundings of these places may be contaminated with the rodenticide from spillage by the rodents and with their contaminated urine, faeces and carcasses.

- Contact powders

Contact powders (tracking powders) may be used indoors and outdoors. Rodents pick up the powder on their feet which is then consumed during grooming. Consequently, the concentration of rodenticide in contact powders is much larger than in food baits. In view of the possible exposure of humans and others, the treated areas should be covered.

- Liquid concentrates

These formulations are used for preparation of poisonous food items; for use in relatively dry situations, they may also be used for preparation of poisonous drinking solutions. There may be some contamination of the surrounding areas from spillage by the rodents and their contaminated urine, faeces and carcasses.

- Fumigation

Fumigation pellets (usually generating phosphine gas) are used for control of rodents (e.g. water voles in water banks). After full reaction the pellet remains are relatively harmless. The phosphine gas will enter the air compartment above the treated holes. Therefore, to increase the gas's effectiveness, burrows/holes are generally closed with some sort of a plug (grass, stone or paper).

Rodenticides may be applied to open waste dumps in case of population outbreaks of rodents.

Frequency of events/cycli and overall duration per day

The data presented here have largely been gathered in the Nordic countries[1]. The tables below summarise the most relevant information available for primary and secondary exposures for professionals and non-professionals (such as house holders). The information is compiled for the application phase. The amount mentioned is of the formulated product.
Better, more realistic, data may be presented in the risk assessment process for specific active substances in formulated products, but these should always be argumented and substantiated.

Exposure information and exposure models
Exposure to rodenticides occurs when humans handle rodenticidal products, come into contact with a contaminated surface or other residues (e.g. carcasses, faeces), or inhale gasses (or aerosols) containing the active substances. Estimation of the level of exposure (either by inhalation, through the skin or by ingestion) can be from actual monitoring data or derived from predictive models. These models are either based on actual data or on theoretical considerations, which in themselves may or may not be partly based on actual measurement data.
'TNsG Human Exposure to Biocidal Products – Guidance on Exposure Information (June 2002)' contains few models that are suitable for purpose, with specific exception of instances related to the exposure of non-professionals when placing baits (pages 276 and 277 in Part 2), and the mixing/loading scenarios.
A theoretical approach is taken in the frequently mentioned 'Human and Environmental Exposure Scenarios for Rodenticides', largely based on the TGD, which may be used when actual measured data, if available, are insufficient or inconclusive.

Application duration and frequency[1]

Professional	Formulation	Amount per application	Duration	Event frequency	Days per year
Application	Wax blocks	250 g	5 min	Normal 4/d* Worst case: 8/d	Normal: 55 Worst case: 220
	Pellets, impregnated grain	150-400 g	5 min	Normal 4/d** Worst case: 16/d	Normal: 55 Worst case: 220
	Powder	250 g	10 min	Normal 2/d*** Worst case: 4/d	Normal: 55 Worst case: 110
	Liquid conc.	100 g	5 min	Normal 2/d*** Worst case: 4/d	Normal: 55 Worst case: 110
	Fumigation pellets,	200 g/ha $	30 min	Normal 8/d Worst case: 16/d	Normal: 25 Worst case: 55

*: 2 visits, 2-4 applications. **: 2 visits, 2-8 applications, ***1-2 visits, 2 applications, $: cf. footnote[$]

Non-professional	Formulation	Amount	Duration	Frequency	Days per year
Application	Wax blocks	20-40 g	<5 min	1/d	Normal: 1 Worst case: 20
	Pellets, impreg. grain	25-50 g	<5 min	Normal:1/d Worst case: 2/d	Normal: 1 Worst case: 20

The placing of baits was not in the original paper, but should be added; in the TNsG it is assumed that 2 bait stations are positioned 4 times a year, with 40 g bait per station.

For the use phase, the information can be compiled as follows.

[$] It should be noted that plant protection is not included in the Biocide Directive but in the Plant Protection Directive (EC 1991). However, the protection of water embankments and dikes from voles are included. Value modified due to apparent error (0.5 -1 kg/field).

Duration and frequency of the use phase[1]

Professional	Formulation	Amount per application	Duration	Event frequency	Days per year
Use	Wax blocks	250 g	<5 min	Normal 1/ 7d Worst case: 1/d	Normal: 110 Worst case: 220
	Pellets, impreg. grain	150-400 g	<5 min	Normal 1/ 2 d* Worst case: 16/d	Normal: 110 Worst case: 220
	Powder	250 g	<5 min	Normal 1/d Worst case: 1/d	Normal: 24 Worst case: 110
	Liquid conc.	100 g	<5 min	Normal 1/d Worst case: 4/d	Normal: 45 Worst case: 110
	Fumigation pellets	200 g/ha §	30 min	Accidental worst case: 16/d	Accidental worst case: 110

*: 2 visits, 8 applications. §: cf. footnote

Non-professional	Formulation	Amount per application	Duration	Event frequency	Days per year
Use	Wax blocks	20-40 g	<5 min	Normal: 1/d Worst case: 1/d	Normal: 1 Worst case: 20
	Pellets, impreg. grain	25-50 g	<5 min	Normal:1/d Worst case: 1/d	Normal: 1 Worst case: 20
	Powder	250 g	<5 min	Normal 1/d Worst case: 1/d	Normal: 1 Worst case: 20
	Liquid conc.	100 g	<5 min	Normal 1/d Worst case: 1/d	Normal: 1 Worst case: 20
	Fumigation pellets	200 g/ha §	30 min	Accidental	Accidental

§: cf. footnote

Below, theoretical models are presented (with some default values that could be used; some default values and approaches are different from the ones presented in that document, but basically their approach is taken[1]).

[PLEASE NOTE THAT SOME DEFAULT VALUES ARE NOT CONSIDERED CONSENSUS VALUES, WHERE OTHERS ARE. FOR THIS REASON SOME OF THE DEFAULT VALUES MAY VERY WELL BE REPLACED BY MORE APPROPRIATE VALUES OVER TIME. CURRENTLY SOME OF THEM MAY BE WORST CASE OR EVEN NOT REALISTIC]

The scope covers human exposure resulting from:

- Application of rodenticides by professionals and non-professionals.
- Post-application, i.e. from the use of rodenticide products and from contact with the product (e.g. residential exposure including indoor air contamination, contact with the product during use).

- Disposal (including handling of surplus formulated product, burning/incineration, dumping, empty containers, dead rodents (carcasses) disposal).

Inhalation exposure

Exposure concentration in air is higher in confined spaces such as indoor rooms. Therefore, and in agreement with worst case and realistic worst case concepts, the scenario covers indoor use of rodenticides. Both professionals and non-professionals are expected to be exposed under such conditions.

An equation for volatile substances and airborne particles was developed. It is assumed that the substance is released as vapour, gas, or airborne particles, and the room is filled immediately and homogeneously with the substance. Ventilation of the room is assumed to be absent. For indoor use, the default living room size is 50 m^3. In the house there will of course be smaller room sizes (see TGD).

The concentration in the inhaled air (C_{inh}) after using an amount Q_{prod} of the product is then:

$$C_{inh} = \frac{Q_{prod} \times Fc_{prod}}{V_{room}} \quad (mg/m^3)$$ *Equation 1*

C_{inh}	Average concentration in inhaled air	mg/m^3	
Q_{prod}	Amount of undiluted product used	mg	
Fc_{prod}	Weight fraction of active substance in the product		
V_{room}	Volume of the room (living room)	m^3	(Default: 50 m^3)

Since this guidance only relates to external exposure, the formula (eq. 2) is only presented for clarification purposes with examples (see annex).

For the direct surroundings of the person, one might use a value of 2 m^3 (but only for a short period of exposure) as a means to estimate the potential inhalation exposure when for instance applying a fumigant.

The resulting inhalation intake of the active substance might be calculated as:

$$A_{inh} = \frac{F_{resp} \times C_{inh} \times Q_{inh} \times T_{contact}}{BW} \times N_{event} \quad (mg/kg\,BW/day)$$ *Equation 2*

A_{inh}	Amount of active substance inhaled/respired		mg/kg BW/d
F_{resp}	Inhalable or respirable fraction of product		(Default : 1)
C_{inh}	Average concentration in inhaled air	mg/m^3	
Q_{inh}	Ventilation rate of adult	m^3/hour	(Default: 0.021 m^3/min; 1.25 m^3/h, 20 m^3/d)
$T_{contact}$	Duration of exposure	hours	
N_{event}	Number of events		(usually per day)
BW	Body weight	kg	

Fumigation

$$Elocal_{air} = \frac{Q_{prod} \times (1 - F_{ret}) \times (1 - F_{disin})}{Temission_{fogging}} \quad (kg/day)$$ *Equation 3*

$Elocal_{air}$	Local emission to air during episode	kg/d	
Q_{prod}	Amount used	kg	
F_{ret}	Fraction of retention in goods		(Default: 0.02)
F_{disin}	Fraction of disintegration		(Default: 0.001)
$Temission_{fogging}$	Number of emission days	days	(Default: 1)

If the default values are used, the resulting emission to air would be 98% of the applied amount.

Dermal exposure by a non-volatile active substance

A non-volatile active substance (e.g. vapour pressure < 10 mPa) contained in a medium. The concentration in the product as it is used can be calculated from the following equation:

$$C_{der} = \frac{C_{prod}}{D} = \frac{Q_{prod} \times Fc_{prod}}{V_{prod} \times D} \quad (mg/cm^3)$$ *Equation 4*

C_{der}	Average concentration of active substance in product on skin	mg/cm^3	
C_{prod}	Average concentration of substance in undiluted product	mg/cm^3	
D	Dilution factor. If dilution results in a 1% dilution, then D is the reciprocal: D = 1/0.01 = 100		Default: 1
Q_{prod}	Amount of undiluted product used	mg	
Fc_{prod}	Weight fraction of active substance in the product		
V_{prod}	Volume of undiluted product	cm^3	

The total amount to which the skin is exposed is thus given by:

$$A_{der} = C_{der} \times V_{appl} = C_{der} \times TH_{der} \times AREA_{der} \quad (mg)$$ *Equation 5*

A_{der}	Amount of active substance on skin	mg	mg/event, mg/d, mg/kg
C_{der}	Average concentration of substance in product on skin	mg/cm^3	
V_{appl}	Applied volume of product in contact with skin	cm^3	
TH_{der}	Thickness of layer of product in contact with skin	cm	(Default: 0.01 cm)
$AREA_{der}$	Surface area of exposed skin	cm^2	

Dermal exposure by a volatile active substance

A volatile rodenticide could e.g. be a substance with a vapour pressure above 10 mPa contained in a medium.

As a worst case approach, the evaporation of the compound is neglected and the algorithms presented for dermal exposure by non-volatile substances are to be used. At the risk characterisation stage, the area of skin involved and the known or derived dermal absorption of the product/substance will be taken into account. The balance between evaporation and skin permeation (dermal absorption) will determine the dermal exposure.

Oral exposure

Oral exposure may take place if after handling rodenticides a person is not aware of dermal contamination of e.g. hands. If the hands are not properly washed before e.g. eating, drinking or smoking, the person may directly or indirectly transfer the substance to the mouth. These considerations should be known to

the professionals and to a lesser extent to non-professionals. However, studies have shown that both groups may forget these elementary rules of hygiene.
Oral exposure from ingestion of the non-respirable fraction of inhaled airborne particulates may arise from handling of rodenticides. The average concentration of active substance in the product swallowed is calculated from:

$$C_{oral} = \frac{C_{prod}}{D} = \frac{Q_{prod} \times Fc_{prod}}{V_{prod} \times D} \quad (mg/cm^3)$$ *Equation 6*

C_{oral}	Average concentration of active substance in product	mg/cm^3	
C_{prod}	Average concentration of substance in undiluted product	mg/cm^3	
D	Dilution factor. If dilution results in a 1% dilution, then D is the reciprocal: D = 1/0.01 = 100		Default: 1
Q_{prod}	Amount of undiluted product used	mg	
Fc_{prod}	Weight fraction of active substance in the product		
V_{prod}	Volume of undiluted product	cm^3	

If an undiluted product is ingested or dilution unknown, the default dilution (D) is 1.

The oral intake is then given by:

$$A_{oral} = \frac{V_{appl} \times F_{oral} \times C_{oral} \times N_{event}}{BW} \quad (mg/kg\,BW/day)$$ *Equation 7*

A_{oral}	Amount of active substance ingested	mg/kg BW/d	
V_{appl}	Volume of product in contact with mouth	cm^3	
F_{oral}	Fraction of V_{appl} that is ingested		
C_{oral}	Average concentration in product	mg/cm^3	
N_{event}	Number of events		(usually per day)
BW	Body weight	kg	

Total exposure
If a consumer is exposed to active substances of rodenticides via different routes, the contribution of each route to the total uptake can be summed up. The summation is done for each time scale separately (acute and sub-chronic) after correction for the relevant bioavailability (degree of absorption).

The exposure assessment in the TNsG is task-based. This approach is also taken in the Nordic document[1] for the following phases (application, use phase and disposal).

Application phase

Based on use patterns major handler exposure scenarios were identified (application phase):

- Placing of bait packs
- Loading of bait boxes or bait stations with grain bait, bait pellets or food based bait from larger containers
- Breaking paraffinised slabs, cakes and block into pieces and placing the pieces in bait stations
- Securing large paraffin blocks at bait stations in sewers
- Applying bait by hand.

Dermal aspects

The dermal exposure is related to formulation, i.e. less when handling wax blocks or pellets than powders. Handling includes fastening and placing of wax blocks, dispense of impregnated grain, pellets and other solid formulations, pouring of liquid concentrates and drinking poisons and, finally, handling of dust blower. The exposure may extend from spills and splashes on hands and forearms to larger areas being exposed. Assuming that exposure to larger body parts than hands and forearms should be categorised as accidents, the scenario is restricted to these body parts, although spills to hands and forearms could also be seen as accidents, with a possibly higher frequency. The surface area of hands and forearms are estimated to approx. 2000 cm^2 (hands: 840 cm^2).

Inhalation aspects

The inhalation of vapours is usually considered negligible due to the low vapour pressure observed in most rodenticides (except for fumigants).

Exposure to and inhalation of dust is possible when application of contact powder takes place with dust blower. This is, however, not a likely/desirable scenario for non-professionals. Exposure is possible from application indoors and outdoors when the application takes place directly into the rat hole.

Inhalation of particulates can also result in oral ingestion.

Use phase

The use phase is the period when the biocidal product is waiting to be consumed by the target organism. This means that no primary exposure of humans is intended and should not take place. However, secondary exposure of bystanders may take place. This could be a human working or living in the treated area, e.g. farmers and their family, personnel working in storage rooms where the rodenticides are applied.

In the use phase the rodenticides will usually be confined to areas with a minimum of human access, i.e. rat holes, burrows. Bait-boxes in private and industrial areas are assumed locked off to prevent contact. Tracking powder is assumed dispersed in areas without direct access of humans. Drinking poisons

are assumed kept in a controlled manner, e.g. by automatic drinking dispenser to avoid contact by non-target animals.
The duration and frequency suggested is mainly based on professionals and non-professionals attending the feeding stations and replacing/adding new baits.

In spite of regulations etc., it is in the use phase in which the largest number of bystanders (e.g. workers unknowing of the rodenticide application, children, non-target animals like dogs and cats) etc. are exposed. Usually accidentally or by mere curiosity.
Human exposure in the use phase could be accidental touching, to dust being formed by stepping on and crushing pellets, rodenticides falling out of bait box not properly fixed or placed in an improper place.

Disposal
By inspection of rat holes, bait boxes, drain and sewerage, professionals usually decide when to stop the local campaign. Excessive amounts of wax blocks, grain and powder will be swept up with a broom and reused or collected for disposal. Normally, the same person applies the rodenticide and collects residues and empties containers for disposal. Larger residues must be delivered to a local reception station for chemical waste (hazardous waste). Empty packaging and insignificant residues of baits will often be discarded together with normal household refuse. Duration of exposure may be taken as 5-30 min once a day, once a year.

Non-professional users will usually discard empty packaging and excessive amounts of mice grain, pellets and wax blocks together with the household refuse. This is, however, an undesirable/inappropriate scenario. Duration of exposure may be taken as 5 min once a day, once a year.

The disposal scenario should include handling of carcasses, which may have residues of the active substances on the skin or having bled on the floor. However, it appears that dead rats and mice often are swept up with a broom together with other refuse.
Brooming as a means to clean up may give rise to dust containing the active substance.

EXAMPLES FOR TASK-BASED EXPOSURE SCENARIOS

[PLEASE NOTE THAT SOME DEFAULT VALUES ARE NOT CONSIDERED CONSENSUS VALUES, WHERE OTHERS ARE. FOR THIS REASON SOME OF THE DEFAULT VALUES MAY VERY WELL BE REPLACED BY MORE APPROPRIATE VALUES OVER TIME. CURRENTLY SOME OF THEM MAY BE WORST CASE OR EVEN NOT REALISTIC]

Wax blocks

Application

One wax block, typically of 250 g, is usually enclosed in a feeding box (bait box) during one application. The active ingredient varies between 0.0025% and 0.01%. The professional has typically 4 applications a day, 55 days a year. The worst case is 8 applications a day, 220 days a year. The non-professional typically performs one application a year (1 block of 20 g). The worst case for non-professionals is 1 application 20 days a year (20 blocks) (see tables).

Inhalation

The inhalation exposure when the professionals are placing the wax blocks is considered to be negligible due to the active substance embedded in a matrix (a solid, non-volatile formulation). The vapour pressures for most rodenticides are below 10 mPa and considered of low volatility. Since aerosol and airborne particles are not expected, this part may be excluded for this scenario.

Dermal

Dermal exposure may occur when handling and fastening the wax blocks. Assuming no gloves are used, the worst case exposure in the application phase is estimated to fingertips (about 30 cm^2) with a layer of default thickness (0.01 cm) resulting in a total $30 \times 0.01 = 0.3$ cm^3 of the application substance. The standard wax block is about $12 \times 5 \times 4 = 240$ cm^3, thus the exposure is 0.125% of the volume. 0.125% of the weight of 250 g is then 312.5 mg of the block rubbed into the skin. With an active ingredient content of e.g. 0.005%, this leads to an exposure of 0.016 mg active substance per event.

Oral

For oral exposure, it is assumed that the amount rubbed off onto the fingertips potentially may reach food items, cigarettes etc. and thereby get into mouth contact or even get sucked on (e.g. by children). The scenario assumes that fingertips are exposed and that about 10% of that amount may be rubbed off on items that may get into oral contact.

For the non-professional the oral exposure would be the same as for the professional.

Use phase

In the use phase, the human exposure of professionals is to be considered when inspection of the bait box is performed and/or a new wax block is placed. The exposure when replacement of the wax block is performed is the same as in the application phase.

In case uncertainties exist as to whether the substance in the use phase may have reached air at concentrations that could be hazardous by inhalation or dermal uptake, the maximum achievable concentration in air can be estimated from the vapour pressure and the Ideal Gas Law. This is substance-related, e.g. for brodifacoum the maximum achievable concentration in air would be 0.028 mg/m^3.

For non-professionals, the exposure in the use phase of blocks is considered to be negligible when bait boxes are used (which is the normal case). If no bait box is used there is a risk of ingestion by children or non-target animals.

For example, poison specialists estimate that a child would consume up to approx. 5 grams in one bite. The "eating child" scenario assumes one bite to be sufficient for the child or for parents to intervene.

Disposal

Uneaten wax blocks and residues are swept up with broom, reused or disposed of. Usually larger amounts of empty packaging are collected for major disposals as hazardous waste. Minor amounts are usually included in household refuse. The experience is that 70 to 90% of the wax blocks are removed by the target organisms, i.e. 10% to 30% are left for disposal. Using the average value 20% means that 50 g for professionals and 4 g for non-professionals have to be disposed of per control operation/event. Professionals are assumed to refill the bait box and only remove/clean it at the end of a control operation.

Removal and cleaning of the bait box may result in exposure.

Inhalation

Inhalation exposure may occur during the use of broom sweeping. In an extreme case it is assumed that the substance (residue amount 50 g; 0.005% a.s.) is released as airborne particles and that it is performed indoors in a standard room of 50 m^3. One should further note, however, that this scenario is unlikely indoors.

The concentration in the inhaled air (C_{inh}) is then:

$$C_{inh} = \frac{Q_{prod} \times Fc_{prod}}{V_{room}} \quad (mg/m^3)$$ Equation 1

C_{inh} = 50000 $\times$ 0.00005 / 50 = 0.05 mg/m^3.

Dermal
Dermal exposure may also be the result of cleaning with broom sweeping and collecting the accumulated residues/refuse. The amount equal to application is assumed.

Oral
Oral exposure could be the result if hands, face and clothes are not cleaned after the disposal and cleaning task.

Impregnated grains and pellets

Application phase

These formulations are used directly in rat holes or in feeding stations. The grain and maize are placed in the rat holes by a small pipe. Pellets in bait boxes are poured directly from bag or by tool (spoon, shovel, etc). The concentration of active substance in the products varies between 0.0025% and 0.01%. In a typical application by professionals, 250 g is used in bait stations and 150 - 400 g is applied to rat holes. Non-professionals typically use 25 g per application (see tables).

Inhalation

Inhalation exposure of rodenticides formulated as impregnated grain and maize is likely by inhalation of dust when the formulations are mechanically handled. It is assumed that from the substance (400 g, a.s. 0.01%) 1 % is released as dust/airborne particles and for calculation purposes it is performed indoors in a room of 50 m^3.

The concentration in the inhaled air (C_{inh}) is then:

$$C_{inh} = \frac{Q_{prod} \times Fc_{prod}}{V_{room}} \quad (mg / m^3)$$ Equation 1

C_{inh} = 400000 × 0.01 x 0.0001 / 50 = 0.008 mg/m^3

Dermal

Dermal exposure is possible as a result of direct contact without gloves or insufficient covering of the skin during application of dusty formulations. Dusty formulations have the ability to spread/wander during handling, and the exposure of hands and forearms are used in the scenario.

The total amount to which the skin is exposed estimated by the following equation:

$$A_{der} = \frac{Q_{prod} \times Fc_{prod}}{V_{prod} \times D} \times TH_{der} \times AREA_{der} \quad (mg)$$ Equation 8

Assuming that 400 g (cf. above) with 0.01% a.s. and density 0.5 g/cm^3 gets into contact with hands and forearms (2000 cm^2) then:

A_{der} = (400000 × 0.0001 / 400 / 0.5 × 1) × 0.01 × 2000 = 1.0 mg.

Oral
Oral exposure is possible if hands and face are not washed/cleaned after the application, e.g. via contact to food items or by smoking. Residues from clothes may also be transferred to objects that may get into contact with mouth.
For oral exposure, it is assumed that the amount rubbed off onto the fingertips potentially may reach food items, cigarettes etc. and thereby get into oral contact.

Use phase
Attending bait boxes normally involves re-filling or reapplication of the product and therefore handled during the application phase scenario (previous scenario).
In the use phase bystanders, e.g. children, may get into contact with the impregnated grain or pellets. For instance, inclusion of household mouse-poison into bait boxes of cardboard may not prevent a child from contact. Poison specialists estimate that a child would consume up to approximately 5 grams in one bite. The "eating child" scenario assumes a small handful of grain or pellets to weigh approximately the same.

Disposal
Uneaten pellets and impregnated grain and their residues are swept up with broom, reused or disposed of. Usually, larger amounts of empty packaging are collected for major disposals as hazardous waste. Minor amounts are usually included in household refuse. It is the experience that 50 to 60% of the impregnated grain and pellets are removed by the target organisms and 5 to 10% by non-target animals, 10% to 20% is left for disposal. Using the average value, 15% means that 40 g for professionals and 4 g for non-professionals have to be disposed of per control operation/event. Professionals are assumed to refill the bait box and only remove and/or clean up at the end of a control operation.

Inhalation
Inhalation exposure is potential during the use of broom sweeping due to the fact that although the products are solid, powder may be released from their surfaces by mechanical handling.
It is assumed that the substance (residue amount 40 g) is released for 1% as airborne particles and for a worst case situation it is performed indoors in a standard room of 50 m^3.
The concentration in the inhaled air (C_{inh}) is then (equation 1):

C_{inh} = 40000 x 0.01 $\times$ 0.0001 / 50 = 0.0008 mg/m^3.

Dermal
Dermal exposure may also be the result of cleaning with broom sweeping and collecting the accumulated residues/refuse. The amount equal to application is assumed.

Oral

Oral exposure could be the result if hands, face and clothes are not cleaned after the disposal and cleaning task. For oral exposure, it is assumed that the amount on the fingertips potentially may reach food, cigarettes or other items and thereby gets into mouth contact.

Contact powders

Application phase

Application of contact powders is mainly performed outdoors and to a minor degree indoors at limited spaces where only rats are expected to be active. The powder is usually blown directly into the burrows by dust blowers. Typically, 250 g of product with 0.15% a.s. is used per application.

Inhalation

Inhalation exposure may be expected for the professionals doing the application. The use of dust blower is expected to increase the air concentration considerably. An estimate of the inhalation exposure is suggested at 5% of the applied amount if no respiratory protection equipment is used.

The concentration in the inhaled air (C_{inh}) is then:

$$C_{inh} = \frac{Q_{prod} \times Fc_{prod}}{V_{room}} \quad (mg/m^3)$$ Equation 1

C_{inh} = 250000 × 0.05 × 0.0015 / 50 = 0.375 mg/m^3

Dermal

Dermal exposure is possible from direct contact without gloves or insufficient covering of the skin during application of the dusty formulation. An estimate of the dermal exposure is suggested at 1% of the applied amount without protection.

The total amount to which the skin is exposed is estimated by the following equation:

$$A_{der} = \frac{Q_{prod} \times Fc_{prod}}{V_{prod} \times D} \times TH_{der} \times AREA_{der} \quad (mg)$$ Equation 8

Assuming that 1% of 250 g (cf. above) with 0.15% a.s. and a density of 0.38 g/cm^3, gets into contact with hands and forearms (2000 cm^2) then:

A_{der} = (250000 × 0.01 × 0.0015 / 250 / 0.38 × 1) × 0.01 × 2000 = 0.114 mg

Oral

Oral exposure is possible if hands and face are not washed/cleaned after the application, e.g. via contact to food items or by smoking. Residues from clothes may also be transferred to objects that may get into contact with mouth.

Use phase

During the use phase, contact may occur if the application areas are not covered sufficiently or persons are unaware of the nature of the dust or by curiosity get into contact with it, e.g. children.

Assuming that bystanders get into contact with the applied powder, the exposure may resemble the scenario of dermal contact, i.e. using the values in the calculation example.

Disposal

Outdoors, the powder is usually left in the rat burrows. Indoors, removal by brooming may disperse the dust into the air resulting in inhalation and dermal and even oral exposures.

Inhalatory exposure and dermal exposures are estimated at 1% of the residual amount, assuming 50% residues still present.

Liquid concentrates

Application phase

The liquid concentrates are used in application to drinking water or feed. Ready-to-use formulations of rodenticides can be applied as a drinking poison. Liquid concentrates are applied with a dose dispenser directly to the feed and mixed on location (e.g. apple pieces). The normal amount used is 100 g/application event with a frequency of 2 to 4/day.

The drinking poison can be applied in a bowl or in a more closed system ("drinking automat"). If applied in a bowl, there must be no risk of presence of non-target organisms, including humans. Drinking poisons are "ready-to-use" liquids with a concentration of active ingredient of 0.005% (bromadiolone) or 0.03% (coumatetralyl).

In the application phase of the drinking poison, the most probable exposure risk is dermal exposure from splashes on hands and/or forearms when pouring the liquid.

When using the liquid formulation to poison pieces of apples, the concentration of the solution is 0.25% active ingredient. Again the most probable risk of exposure during mixing and loading is dermal, especially when the apple pieces are mixed with the liquid, and to a minor extent by inhalation of aerosols.

Dermal

Dermal exposure is possible from direct contact without gloves or insufficient covering of the skin during application of the liquid formulation. The US-EPA has estimated the exposure from splashes during mixing and application to be about of 6 ml/event to the hands.

The total amount to which the skin is exposed is estimated by equation 8:

$$A_{der} = \frac{Q_{prod} \times Fc_{prod}}{V_{prod} \times D} \times TH_{der} \times AREA_{der} \quad (mg)$$

Assuming 100 g (cf. above) with 0.005% a.s. and the density 1 g/cm^3, the substance is diluted to a concentration of 0.01%. The amount of substance that may get into contact with hands (840 cm^2) from a splash exposure of 6 ml is:

A_{der} = (100000 × 0.00005 / 6) × 0.0001 × 840 = 0.07 mg

One might also use the mixing/loading scenario models for exposure estimates for this scenario.

Oral
Oral exposure is possible if hands and face are not washed/cleaned after the application. Residues from clothes may also be transferred to objects that may get into contact with the mouth.

Use phase
In the use phase, the task is usually inspection and re-application if necessary. Inspection may cause dermal exposure if manual control of e.g. drinking automats is necessary. Re-application is considered as application phase.

Disposal
Disposal of residues and cleaning of bowls etc. may cause dermal exposure.
Assuming 30% of the 100 g (cf. above) with 0.5% a.s. is left for disposal. The substance was diluted to a concentration of 0.01%. The amount of substance that may get into contact with hands (840 cm^2) from a splash exposure of 6 ml is:
A_{der} = (30000 $\times$ 0.005 / 6) $\times$ 0.0001 $\times$ 840 = 2.1 mg.

One might also use the mixing/loading scenario models for exposure estimates for this scenario.

Pellets for fumigation

Application phase

Pellets for fumigation evolve, depending on temperature and humidity, the phosphine gas from 1 to 2 hours after application. This reduces the risk of human exposure. During normal application of the pellets, the worker is protected with special gloves.

Pellets for fumigation are used as a rodenticide to protect water embankments and dikes from the burrowing activities of voles.

One pellet aluminium phosphide (57%) weighs 0.6 g and evolves 0.2 g phosphine. Usually, the application is performed by means of a delivery tube connected to the metal container holding the formulated substance. The pellets are inserted directly into the burrows by the apparatus either through the vole hill or through holes made to the vole's gallery system. Two to three pellets are applied for each 2 to 3 meter of the vole's gallery. The duration for application averages 30 minutes and is normally performed 8 times per day or as worst case 16 times per day, i.e. 4 or 8 hours respectively.

The concentration phosphine in the inhaled air using a very rough calculation scenario assuming the gas is developed immediately and the breathing zone volume (homogeneous and outdoors) is set to 50 m^3, then for 3 pellets:

C_{inh} = 3 x 200 $\times$ 1 / 50 = 12 mg/m^3

The dermal exposure is estimated to be negligible as no contact should take place with the substance during application.

Use phase

Exposure during the use phase is considered accidental and in the worst case would be the same as in the application phase.

The phosphine gas is heavier than air and the main part is estimated to remain in the soil. Within a few days, the residues of the applied aluminium phosphide will be aluminium hydroxide and the evolved phosphine gas will be transformed into phosphates.

Disposal phase

The disposal phase only concerns the cleaning of the connection tube as the pellets are left in the ground. The tube which may have dust from the pellets on the inside is recommended submerged into water.