HUMAN EXPOSURE

TO

BIOCIDAL PRODUCTS

TECHNICAL NOTES for GUIDANCE

June 2007

This document replaces the TNsG on Human Exposure to Biocidal Products from June 2002 including the User Guidance Version 1.

This is the same document that has earlier been available on the JRC website with the date "January 2008". This was changed in September 2009 because the date of endorsement was in fact in June 2007.

This document was endorsed at the 25th meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (19-21 June 2007).

PREAMBLE

This TNsG consists of a written part (the present document), as well as a computerised database (BEAT) of exposure data (largely for occupational settings), and the consumer exposure model ConsExpo (both downloadable).

The model and database can then be installed on a computer and used to its full possibilities. The model and the database will have their own included explanations and help files.
An Excel database on use patterns is embedded in the written report.

The worked examples are indicated in the report but are described in detail in the database.

The computerised version of BEAT is available from http://xnet.hsl.gov.uk/download/ (copy this in your browser) with the password for installation: grenoble (no capital letters). An updated version of the database will be available in February 2008.

ConsExpo can be downloaded from www.consexpo.nl.

Executive Summary

This report builds upon the concepts developed in the 1998 report reference 97/505/3040/DEB/E2: Assessment of Human Exposure to Biocidal products, the Technical Notes for Guidance: Human Exposure to Biocidal Products. Guidance on Exposure Estimation (B4-3040/2000/291079/MAR/E2), and the Human Exposure to Biocidal Products (TNsG June 2002), User Guidance version 1. It replaces both these documents.

The intended readership of this guidance falls into two main groups. These are:

- Applicants, in seeking the entry of specific active substances to Annex 1, and authorisation of biocidal products, and
- Competent Authorities, in evaluating data dossiers.

Links with other guidance

The reader should be aware of Technical Guidance Documents for New and Existing Substances, which covers all chemicals. The reader may also be aware of allied guidance for the estimation of human exposure to plant protection products (agricultural pesticides – such as EUROPOEM, the best available at the moment within the EU. Other sources are the UK-POEM and BBA model). New guidance is being prepared under REACH. It is essential to follow the developments there with care to take advantage of the developments in the exposure assessment.

How to use this guidance

The reader may familiarise him or herself with the subject of this guidance by reading the chapter on general principles of the exposure assessment (Chapter 2, p. 8). After having done so, the various flowcharts form the core of this Guidance which guide the reader through the various elements that are required for the exposure assessment for each Product Type that may be relevant. Through the use of the Guidance the various databases can be searched (through hyperlinks).

In the final version of the report the computerised approaches for worker and consumer exposure assessment will be available, together with all text and databases. The computerised exposure models must each be installed separately on the computer. Worked examples for worker exposure assessment are contained in the computerised exposure database, and are implicit in the consumer exposure model.

It is expected that the databases will be updated with new information, whenever that is made available. Worked examples based on TM discussions can be added to improve the usability of the TNsG.

Recommendations

- Knowledge management of real estimates as new examples

The developed approach for assessment of human exposure is state of the art, but will need further treatment on the basis of experiences with it in practice. It is recommended to monitor the experience in practice, update examples for all product types and specific applications within Product Types for the present Technical Notes for Guidance to the extent required.

- New experiences and scientific developments

The field of human exposure assessment for biocidal products with its great variety of uses and its primary and secondary exposures, is in development in Europe and in North America. This also covers developments in research on combined exposure. This will no doubt lead to new discoveries and approaches which should be validated and incorporated into the Technical Notes for Guidance to the extent relevant. This underlines that the present Technical Notes for Guidance should be updated at regular intervals, according to scientific progress. In the computerised database many examples have been collected that may need updating and expanding with new ones based on the risk assessment process as it proceeds on EU level.

- Further development of exposure models

The BEAT (Bayesian Exposure Assessment Tool) model is a new development, which is at present not completed. The current version covers dermal exposure, but not yet inhalation exposure. Exposure data are available in several cases and in principle these exposures can be incorporated into the model. In the present project time it was, however, impossible to finalise this approach. The inhalation exposure will be assessed in a classical fashion. A further development has been initiated with the implementation of REACH, which is called the advanced exposure model, which covers inhalation and dermal exposure using both a deterministic approach based on theoretical considerations and databases of measurements. They are combined using Bayesian statistics and probabilistic modelling. The development of this high Tier tool has begun and is expected to be finished in the coming years.

- Reference exposure scenarios

A set of relevant reference scenarios is prepared for assessing secondary exposures for each product type. The actual exposure assessments for these scenarios are still in need of further development and/or refinement in several cases.

- Version control group

It is proposed to install a version control group that follows the developments in human exposure assessment, as indicated above. The group should propose updates (new data and new insights) for the Technical Notes for Guidance on a regular basis.

Contents

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 its use.

There is still a paucity of exposure data on biocides; as a consequence, various approaches are used to estimate human exposure to them. From 1998 onwards the European Union funded a series of projects to both fill this knowledge gap and establish a harmonised approach for assessing human exposure to biocides. The outcome of these projects was the publication of the Technical Notes for Guidance on Human Exposure to Biocidal Products (TNsG). The TNsG was then consolidated through the production of User Guidance (TNsG 2002).

The present version of the TNsG 2007 (this report) updates the earlier versions and replaces all relevant information, including the User Guidance.

The present version covers all Product Types and presents worked examples for each of them. This guidance takes forward and builds on the previous guidance. There is however a major change in that extensive use of a computer database is proposed. Almost all of the currently available exposure data have been brought together into one computer database. This is a significant step forward, which will require a different way of working but will enhance the exposure assessment process and contribute to the standardisation and harmonisation of exposure assessment. This updated Guidance also introduces a series of detailed ‘flowcharts’ (or decision making paths). These flowcharts will help the user to decide which is the best path to follow. Unfortunately, not all tasks that may be carried out with biocidal products are covered with suitable experimental exposure data or databases/approaches. In such cases it is up to industry to provide suitable information on exposure on which to build a risk assessment to indicate appropriate safety for humans during use.

2 General Principles of Exposure Assessment

2.1 Introduction

The fundamental concept 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.

2.2 Users of Biocides

2.2.1 Professional users

The industrial (those involved in manufacturing, handling and/or packaging of actives or products in industry) or professional (those using end-products outside industry) user comes into contact with the biocidal product as a consequence of their professional life. In general the professional user is subject to national worker protection legislation (e.g. EU Chemical Agents Directive) and has residual risk controlled through control measures, which although a last line of defence, may include the use of Personal Protective Equipment (PPE). However, some workers will have limited knowledge and skills to handle hazardous biocidal products – particularly if the use of biocidal products is not routinely required in their workplace (e.g. incidental use of slimicides, insecticides, irregular disinfection and use of products containing preservatives). The exposure conditions of these users might be similar to those of non-professional users. 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 (e.g. pest control operators).

2.2.2 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 follow exactly the instructions for using the biocidal product. In addition, the non-professional pattern of use is expected to show a lower 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 ventilated 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.

2.3 Primary and secondary exposure scenarios

Primary exposure to biocidal products occurs to the individual who actively uses the biocidal products, i.e. the user. 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.
Included in this document (section 3.2) is a flowchart where this distinction can be made.

Secondary exposure is exposure that may occur after the actual use or application of the biocidal product. For professional users it is useful to make a distinction between *intentional secondary* exposure scenarios and *incidental secondary* exposure scenarios. An intentional secondary exposure scenario is any secondary exposure incurred during a worker's regular employment duties, e.g. a carpenter exposed to wood dust impregnated with a biocide. In most instances the professional users' flowchart will provide the most suitable approach for these scenarios. Incidental secondary exposure relates to any exposure not necessarily incurred during employment but resulting from the professional use of a biocide. Home laundering of contaminated work clothes is a typical example of incidental secondary exposure. In most instances these exposure scenarios are best assessed using the methodology for non-professional uses (consumers).

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 a treated carpet).

2.4 Pathways of exposure

Human exposure occurs 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 what the likelihood of the biocides entering the body by being inhaled (inhalation), absorbed through the skin (dermal), or swallowed (ingestion) is. Although not a major route of exposure, the potential for exposure of 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.

2.4.1 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 in 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. By its nature this concentration represents an assessment of

potential exposure. If respiratory protection is used an additional, actual exposure, will need to be calculated; this will take into account the effectiveness of the protection measures. Inhalation exposure ceases at the end of the work shift when exposure ends.

2.4.2 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 or gloves 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)[1] 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 effectiveness of clothing and is often expressed simply as a weight of biocide product on skin (mg on skin).

For the assessment of dermal exposure (professional and non-professional) it is estimated that the calculated external dose (mg/min x duration of exposure resulting in mg per person) will stay on the skin for the whole shift or even longer, since it is generally not possible to rely on cleaning habits as a reducing factor. This means that for daily exposure, the skin contamination remains for that day, unless thorough cleaning of the skin can be assured.

2.4.3 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. It is usually assumed that ingestion exposure in workplaces does not occur when good hygiene is assumed. This may not be true in all cases, especially when there is a regular contact between the contaminated skin and the mouth region. Unfortunately, at present there are no sound ways to estimate oral exposure to humans, unless with biomonitoring (where oral, dermal and inhalation exposure are integrated).

2.4.4 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, two approaches can be taken.

The first is to calculate the internal (systemic) body burden from these values. This conversion is based on the selection and use of a variety of physiological default values (e.g. body weight and breathing rate) for specific situations. As absorption data for the different routes of exposure are often not available, the calculation of systemic body burdens is subject to a high degree of uncertainty and requires expert judgement.
The second approach is to use route-specific external exposure data and compare that to limit values for each relevant route of uptake. These external values can be calculated from the

[1] For liquids mg/min is often used interchangeably with ul/min for water based formulations with a density close to 1. For liquids more generally, expressing dermal exposure in ul/min and using a weight/volume concentration of active substance, will avoid the need for making a correction for density.

systemic limit value (e.g. systemic AOEL (Accepted Operator Exposure Level)) using relevant absorption data for each route of uptake.
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.
The most appropriate way of assessing total systemic exposure is by biomonitoring. The interpretation, however, requires detailed pharmacokinetic information on the compound involved.

2.5 Patterns of use

Pattern of use
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 in its most general format shown below 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)

Information on the pattern of use can be gathered through surveys or generic data from similar products. Specific information on patterns of use for many biocidal product types is limited and those placing biocidal products on the market will need to conduct research into patterns of use directly with the users if actual or surrogate data are not available. A pattern of use database for all different biocidal product types is available in section 3.5. This provides defaults for duration and frequency of the different tasks for each product type for different formulation types.

Variation of frequency and duration
The frequency and duration of a task are major determinants influencing the level of exposure. The frequency of task is variable and is critical in deciding whether the exposure is chronic or acute for risk characterisation purposes. Frequency of exposure should be expressed as events per day (with precision as to how many days per year the user of biocides is exposed).
Duration of exposure should be expressed as minutes or hours per day.

The pattern of use is not universal and thus likely to show considerable variability within Member States (e.g. different user groups; professional user vs. amateur user/consumer). Also, variability in pattern of use across the EU may be based on, amongst others:

- regional differences
- climatic differences

Competent Authorities will need to ensure the relevance of a stated pattern of use, especially in product authorisation. For that purpose an overview of reasonable worst case default values has been developed, as is shown later in this guidance (section 3.5; in this section an Excel database is embedded).

Pattern of use – data requirements

In the following overview, the most important data requirements are listed.

Data requirement	**Priority**	**Comment**
Product		
- physical properties	Essential	liquid / solid / in-situ generation / particle size, aerosol, volatility
- package details	Essential	volume, material, closure, bulk delivery.
- 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		
User sector	Essential	
- 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.		

Information on the use of products by consumers is not widely available. The development of the consumer exposure model, ConsExpo, with detailed 'use patterns' and provision of default values (in factsheets) to be used, has helped to fill this gap.
The mentioned defaults for frequency and duration of exposure should serve as a starting point for exposure assessment and should be used in the absence of accurate scenario data only. Whenever more detailed information for use scenarios is available, these data should be used instead, but always on the basis of a valid argument, e.g. in case a survey been carried out.

2.6 Methods of application and tasks, and data quality

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 three 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. Secondary exposure is also included in the post-application phase.

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. Since production, formulation and removal is basically not different from general and industrial chemicals, these aspects have not been covered.

2.6.1 Criteria for quality assessment of reports concerning exposure data

This section sets out criteria to judge the quality of exposure survey and study reports. It is not acceptable to use inadequate data from inadequate reports in exposure estimation and so it is imperative that all data generated are adhering to thoughtfully-designed protocols and carefully-conducted studies.

Initially, to build a database from past studies it may be necessary to use less stringent quality criteria. However, these "barely adequate" data must - in time - be superseded by more acceptable data so that they can serve as entries into a generic data base. Inappropriate data may trigger over-conservative default assumptions.

Acceptability

Scientifically sound and well-documented state-of-the-art data are given preference over default assumptions. The conduct and reporting of study shall be in compliance with current test protocols and requirements.

Documentation is adequate when studies have been carried out in compliance with Good Laboratory Practice. Hawkins et al. (Am. Ind. Hyg. Ass. J. 53:34-41, 1992) called this *Good Exposure Assessment*, and defined this in terms of eight components. All components should be present:

- A detailed *protocol*, which bridges the study conduct and the conclusions that may be reached.
- The study should be carried out with adequate and validated equipment by committed and qualified scientific and technical staff, described in terms of *organisation, personnel, and resources*.
- A statement on the *study model* which bridges the actual observed data and the general application, be it deterministic, empirical or statistical.
- A fully described *study design*, containing all forms of data handling (sampling, chemical and statistical analysis). It is essential not only to describe what is done and how, but also to show that the procedures are adequate for reaching the study goal.
- A *quality assurance* procedure, including external audits.
- A *statement of overall uncertainty*, indicating the errors due to variables in the study and possible bias.
- All documents relevant to the study should be retained, the report indicating the absolute essential *archiving*.
- The need for *communication and confidentiality* of results, when relevant or appropriate.

In practice it is recognised that a pragmatic approach to study acceptability would have to be developed to deal with the sparse data for exposure to biocides.

Criteria

Each study submitted should be evaluated by comparison with pragmatic data acceptability criteria as set out below.
This evaluation forms the basis for the decision whether or not to include a study in the database, which study information to include and which study exposure records (data points) to include in subsets for deriving surrogate values or distributions for use in predictive models. It would also form a basis for Competent Authorities to evaluate studies submitted in support of authorisation of specific biocidal products.

To provide transparency on the individual judgements, each study should be summarised in a standardised note format. The information in this summary should contain:

- study number (unique number)
- documentation (comment on adequacy or otherwise)
- contextual information about the scenario and tasks
- database contribution (number of records)
- participants (number and definition)
- replicates (number per worker)
- time/surface/volume (relevant measure, as related to a work cycle or shift)
- equipment (and/or other relevant information)
- information, training
- engineering measures in use

- recommended (or in use) personal protective equipment
- matrix-matched recovery data (field and laboratory)
- limits of detection and quantification
- inhalation (technique and sampling media, collection efficiency, particle size, if applicable)
- dermal (body) (technique and sampling media)
- hands (technique and sampling media)
- bulk concentrate and in-use biocide concentrations
- analytical aspects (technique and documentation)
- container size/type
- formulation (type)
- activities involved
- notes (other relevant information)
- judgement (proposed decision on inclusion of exposure records to be included)
- environmental conditions
- calculations and data analysis
- plausibility analysis
- discussion of results

The pragmatic acceptance criteria are set out in the table on the next page. These are set out as essential requirements, desirable attributes and rejection criteria. For example, it is considered essential that a study report should contain a description of the aims of the work and, ideally, there should be a written protocol for the study, including a justification/ reasoning for the chosen design.

Recommended pragmatic acceptance criteria for human exposure studies

Essential requirements	Desirable requirements	Rejection criteria
Aims of survey or study strategy[2]	Protocol for study	No stated objective
Identification of the process etc.	Full details of process, task, equipment, substance in use	No process or task description, substance unidentified
Number of subjects and samples	Number of unique subjects and samples	Many replicates (few subjects, many samples)
Work environment	Workplace information	No workplace information
Product used - form, packing, site delivery	Product form etc and in-use assay	No product details
Duration of task / tasks	Full pattern of use data and work-rate	No data for use duration
Sampling methods	Sampling methods validation	No clearly stated sampling methods
Analytical outline and recovery data	Analytical method, validation, recovery, storage, detection limits	No recovery data (unless obvious)
Task sampled - task and sampling match	Sampling data linked to task data	Sampling time and task or duration mismatch,
In-use product	Bulk in-use product samples taken	Missing bulk information
M&L, application, or post-application information	M&L, application, or post-application sampling	No clear description of activity phase sampled
Controls, work clothing	Exposure controls and PPE used, laundry, etc	No data on work clothing or controls
Outline of disposal route	Detail of exposure route and recycling	No way of deducing disposal route
Data reported in full	Data reported in full	Data as summary (e.g. range and statistics)
Study date	Date	No indication

M&L: mixing and loading; PPE: personal protective equipment

[2] GLP compliance of studies into exposure to biocidal products is at the moment no generic demand in the EU, as it is in the USA and Canada. Some Member States require GLP-compliant studies for pesticides.

Expert judgement will be required to evaluate whether certain aspects of a study do not fulfil some of the essential requirements.
Studies meeting any of the rejection criteria will still be evaluated to see if they contain any useful data on any aspect of exposure, such as the pattern of use or the environment in which the product was applied.

The assessor must report on the acceptability or otherwise of studies submitted. All studies that are reported in the present document have met the criteria of acceptability, unless noted otherwise.

In addition to the general desirable study characteristics set out above there are a number of specific contextual data items that should also be documented in a study report. These are shown in the following table.

Desirable contextual human exposure data

Data item	**Desirable amount of detail to be recorded**
Emission of biocides	Either: solid/liquid aerosol, vapour, mist; spray, splash or spill
Location of biocide use	Inside or outside a building; volume of room
General ventilation	Details of general ventilation, e.g. good mechanical ventilation, poor mechanical ventilation, natural ventilation; details of weather conditions if outside
Physical properties of biocidal product	Some indication of the dustiness of solids being handled or the volatility of liquids; qualitative details of the viscosity of liquid biocidal products
Mass of product used	The total mass of product used during the task or tasks
Biocide concentration	Record of the concentration of the active biocide, both in use and before any dilution
Proportion of the task exposed to biocide	Percentage time the person is exposed (by inhalation or dermal contact) to the biocide
Time near to the source	Proportion of the task where the person is close (within 1m) to the source of the biocide
Description of the handling of the biocide	Details of the process or activity; for example, handling contaminated objects, spraying, brushing, wiping, immersion etc; details of the process, e.g. spray technology, spray pressure, nozzle diameter, etc
Process temperature	Temperature of the biocide in use
Description of local controls	Presence of local ventilation for inhalation risks, ideally with some comment on its likely effectiveness; details of any other control measures applied at the source
Housekeeping	Description of the apparent cleanliness of the area; details of any accidental splashes, spills, etc
Contaminated surfaces	Area of contaminated surfaces, concentration of biocide on surfaces, estimated personal contact rate (hands or body touches per hour) with surfaces.
Use of personal protective equipment	Type of respirator, gloves, clothing or other PPE worn while using biocide; brief description of training of people to use the equipment and administration of the PPE.
Physical activity involved with task	Categorised as: *rest* (e.g. sitting), *light* work (e.g. sitting or standing with moderate arm movements), *moderate* (walking with moderate lifting or pushing), *heavy* (e.g. intermittent heavy lifting with pushing or pulling), *very heavy* (e.g. shovelling wet sand).
Categorical (yes/no)	Inadvertent exposure of food through treatment/contamination

It is realised that most studies of human exposure to biocides that have previously been undertaken will not report detailed data for many of the above. However, it is considered that in the future further efforts should be made to collect such data.

2.7 Personal protective equipment and control measures

This section of the guidance introduces concepts of how to control exposure to biocides. More detail, about a framework for addressing control of exposure and factors to consider when selecting personal protective equipment is provided in Annexes 2 and 3.

When undertaking an exposure assessment the assessor should seek to ensure that exposure to a biocide is prevented or controlled. Exposure can be prevented by a variety of means, including elimination; substitution and modification of a process or substance to reduce emission or release. For biocides, with the myriad of application methods available, preventing exposure is not, in many cases, reasonably practicable. Exposure must therefore be controlled.

2.7.1 Control options

There are control options that evaluators can invoke, to abate exposure. The options to consider are:

- structure related;
- engineering;
- technical (especially for consumers);
- administrative; and
- personal.

Structure related control of exposure (applies to both residential environments and workplaces)
Structure related control means the reduction of exposure by inhalation afforded by general ventilation, e.g. opening windows.

Engineering control of exposure (applies to workplaces only)
Engineering control in the professional setting means the abatement of exposure by local exhaust ventilation (LEV) at the point of emission, or by containment in pipework or other systems from which minor emissions only are anticipated.

Technical measures for control (for consumers)
Bait boxes and child-resistant fastenings are good example here for technical measures to reduce possible exposures.

Administrative control of exposure (applies to both residential environments and workplaces, but in different ways)

Residential administrative control means the exclusion of residents from treated spaces until aerosols have dispersed and surfaces are dry. All subsequent exposure is secondary.

Workplace administrative control has several levels to consider:

- proper supervision and training of workers; and
- procedural plans, event planning (such as accidental spill procedures) and permits to work.

‘Safe systems of work’, ‘emergency procedures’ and ‘permits to work’ mean that hazardous biocides can be used with minimum risk. For example, the risk is likely to be high in operations such as maintenance, and a ‘permit to work’ is needed. The permit sets out the steps to assure that situations are made safe before work starts, remains safe, and includes standby rescue and recommissioning procedures.

Personal control of exposure (applies to both residential environments and workplaces, but in different ways)

The personal approach refers to the use of personal protective equipment (PPE), which can be defined as '*all equipment (including clothing affording protection against the weather) which is intended to be worn or held by a person and which protects them against one or more risks to their health or safety*'. The user, taking specific steps to limit inhalation and skin exposure, uses PPE as a means of abatement of primary exposure. PPE is relevant to primary exposure only. The impact of the use of PPE as part of the exposure assessment is complicated and needs to address:

- proper functioning, i.e. designed and tested to result in reproducible, quantifiable reduction of exposure; and
- proper use, i.e. wearers use PPE according to guidelines to ensure adequate protection under conditions of use.

Non-professionals and the residential environment

While non-professionals may wear overalls, gardening or kitchen gloves, or even a dust mask, such usage cannot be assured and **must not** be assumed in exposure estimation. For example, non-professional users wearing sandals and shorts when applying antifoulants to leisure craft is the rule, rather than the exception in warm weather. At most, a user may be expected to wear a long shirt, long trousers and footwear, irrespective of any label stipulation. For inhalation exposure, no exposure reduction should be assumed

Professionals and workplaces

Workers are covered by additional regulatory control mechanisms and, as a consequence there is more chance that, if needed, PPE will be used at work. In many cases PPE should be supplied and used at work wherever there are risks to health and safety that cannot be adequately controlled in other ways.

Default values

Our current knowledge for estimating reduction factors through the wearing of adequate PPE/RPE, in an appropriate way, is incomplete. Agreeing the meaning of the terms 'adequate' and 'appropriate' is also a long way off. A paper by Gerritsen-Ebben et al. (2007)[3] investigated current views and facts on the use of default values for the estimation of the effectiveness of PPE in exposure reduction in the registration processes for biocides; this paper is commended to the reader. Whilst we can acknowledge there are difficult issues, a way forward, to ensure a consistent and transparent approach to the selection of protection factors, is required. Tables 1 and 2 below pull together current thoughts on default values that should be used in exposure calculations.

[3] Gerritsen-Ebben MG, Brouwer DH, and Hemmen van JJ , Effective Personal Protective Equipment (PPE): Default setting of PPE for registration purposes of agrochemical and biocidal pesticides, TNO Report V7333 (2007).

Table 1: Overview of 'Assigned Protection Factors' for filtering devices
(British standard, American standard and German standard)

Mask type	**Filter type**	**BS 4275**	**ANSI Z88.2**		**BGR 190**
Filtering half masks	FFP1	4			4
	FFP2	10			10
	FFP3	20	**10**		30
Half or quarter mask and filter	P1	4			4
	P2	10			10
	Gas	10	10		30
	GasXP3	10	10		30
	P3	20	**10**		30
Filtering half masks without inhalation valves	FMP1	4			
	FMP2	10			
	FMGasX	10	10		
	FMGasXP3	10			
	FMP3	20	**10**		
Valved filtering half masks	FFGasXP1	4			
	FFGasX	10	10		
	FFGasXP2	10			
	FFGasXP3	10	10		
Full face masks and filter	P1	4			4
	P2	10			15
	Gas	**20**	100		400
	GasXP3	20			
	P3	**40**	100		400
Powered filtering devices incorporating helmets or hoods	TH1 all types	**10**	100		5
	TH2 all types	**20**	100		20
	TH3 (semi)hood/ blouse	**40**	1000		100
Power assisted filtering devices incorporating full, half or quarter masks	TM1 (all types)	**10**	50 (Half face)	100 (full face)	10
	TM2 (all types)	**20**	50 (Half face)	100 (full face)	100
	TM3 (half face) particle, gas or combined filters	**20**	50		
	TM 3 (full face) gas or combined filters	**40**	1000		500

Assigned Protection Factors (APF) for different designs of RPE are well documented and have been introduced, with general acceptance, to quantify effectiveness of RPE. In Table 1 the bold typed numbers are the default values to be used.

Compared to respiratory protection, determination of APFs for protective clothing and gloves is much more complex. This is in part due to the multi-compartment origin of dermal contamination and the effect of workers' behaviour. The assessment of protective properties for PPE (including gloves) relies on laboratory test data on penetration, permeation rates and break-through times. Hand exposure inside protective gloves is common. The mechanisms for this are:

- permeation through the glove fabric;
- penetration of the glove (drips, flaws, worn gloves); and
- human factors (taking gloves off, contaminating the hands, then putting the gloves back on).

Table 2: Currently assigned default protection factors[4]

Descriptor	Default protection factor
Use of LEV	
Use of containment	
Clothing penetration (only for dry substances*) – for a non-professional wearing: long-sleeved shirt and trousers or skirt with shoes; no gloves worn (central tendency)	50 % protection
Wearing protective gloves	90 % protection
Wearing dry* cotton coveralls	75 % protection
Wearing 'impermeable' coveralls	95 % protection

* Only for dry substances. Dry is introduced here, since wet cotton coveralls will offer little or no protection.

2.8 Active substance and systemic absorption

For an exposure assessment, one almost always will not consider an active substance, but a product containing an active substance. This may be a liquid or a solid. The concentration may be given in percentage (for a solid) or as w/w or w/v for liquids. One should take care to interpret these values appropriately.

Say the active substance concentration in the in-use product is 0.56 % w/v. This means there is 0.56 g of active substance in 100 ml of in-use product.
If the density of the in-use product is 0.8 g/ml then, 100 ml of in-use product weighs 0.8 x 100 = 80 g of in-use product.
Consequently, for 0.56 g of active substance in 100 ml (i.e. in 80 g) of in-use product then in 1 g of in-use product there is 0.56 ÷ 80 = 0.007 g of active substance.
Thus, there is 0.007 x 100 = 0.7 g of active substance in 100 g of in-use product. This is equivalent to a concentration of 0.7 % w/w active substance in the in-use product.

[4] It is recommended to await the results of the development of guidance for Risk Management Measures (RMMs) under REACH, since for the development of 'safe' Exposure Scenarios, RMMs are essential, and thus their alleged protective effectiveness.

An important further issue is to deal with absorption for each relevant route of uptake. This again is not so much relevant for the active substance, but for the product of choice containing the active substance.
For inhalation, the absorption is usually taken as 100 %, when no further details are known. The same may hold for dermal absorption, although in this case the actual absorption may in practice be much lower and will also depend on the concentration in use. This may vary appreciably between concentrates and in-use dilutions.

2.9 Secondary exposure scenarios

Introduction
For each Product Type, likely secondary exposure scenarios have been listed below in Table 3.
The Table presented is an overview of possible secondary exposure scenarios that might be considered when doing risk assessments for specific biocidal products in view of their uses within a certain Product Type. The list is by no means exhaustive and does not contain the possible pattern (duration and frequency) of exposure, nor contains a possible approach for assessing the exposure levels.

It is suggested to use these scenarios to cover the most relevant secondary exposure that may occur using products per Product Type. It is further suggested, for practical reasons to use only one or two of the most relevant scenarios for each product. This is not to say that there may not be more than two relevant scenarios.

A detailed overview of exposure scenarios to children is given in RIVM report 320005001 / 2004 (Non-food products: How to assess children's exposure?). This report also contains some help in assessing the levels of exposure using ConsExpo.

Table 3: Possible (non-exhaustive) list of secondary scenarios per Product Type (only positive relations are indicated: †).

Product type	**Secondary scenario**	**Route(s) of exposure**	**Exposed population(s)**		
			Professionals	Non-professionals	
				Adults	Children
Disinfectants & general biocidal products					
1: Human hygiene products skin disinfectants	None proposed				
2: Private area and public area disinfectant • private area • professional cleaning • medical equipment • swimming pools • air conditioning • chemical toilets • laundries • waste	Swimming in swimming pool/fountain water Contact with treated surfaces, equipment or materials Re-entry	Dermal, Oral, Inhalation Dermal, Inhalation Dermal, Inhalation	† † †	† †	† †
3: Veterinary hygiene products • domestic animals (feet, udder) • animal housing • milking equipment	Re-entry	Dermal, Inhalation	†		
4: Food and feed area disinfectants • agriculture • food-processing industry • food retail shops	Residues in food Touching treated surfaces Re-entry	Oral Dermal Dermal, Inhalation	† †	†	†
5: Drinking water disinfectants • waterworks • private use	Residues in drinking water	Oral, Dermal, Inhalation (showering)		†	†

Preservatives					
6: In can preservative • detergents (laundry, surface, dishwash) • water based paint, dyes, ink • polishes, lubricants	Paint trays and application equipment (brushes, rollers) left in room where product is being applied	Dermal, Inhalation		†	†
	Person comes into contact with wet treated material	Dermal		†	†
	Food is placed directly onto surface that has just been cleaned and is still wet	Ingestion		†	†
	Mouthing of treated paper and paint chips				
7: Film preservatives • paints • plastics • sealants, fillers & other products	Person entering and staying in room that has just been painted	Inhalation, Dermal		†	†
	Person comes into contact with wet adhesive/sealant (not commonly used)	Dermal		†	†
	Mouthing of treated objects	Ingestion			†
8: Wood preservative • industrial processes • surface treatment	Sawing/sanding of treated wood	Inhalation, Dermal	†	†	
	Mouthing of treated woods (chips)	Ingestion			†
	Playing on treated wood structures	Dermal			†

9: Fibre, leather & polymerised materials • textiles • leather • paper • rubber and polymerised materials	Wearer of sport/outdoor clothing, which has been treated	Dermal		†	†
	Cleaning out of tanks used to house hides before tanning process	Dermal	†		
	Worker is exposed during restoration work to a property that has cavity wall insulation	Inhalation	†		
	Library archivist working with books that have been treated for storage under moist conditions	Dermal	†		
	Mouthing of treated materials	Oral			†
10: Masonry preservative	Maintenance worker is undertaking remedial work to building that has recently been treated with preservative	Dermal	†	†	
	(skin) contact with treated surfaces	Dermal, Oral			†
11: Liquid cooling and systems and processing • once-trough systems	Biocide is added to wet cooling system, passer by is exposed to biocide due to windage	Inhalation	†	†	†
• recirculating systems	Contact with treated water (decorative fountains)	Dermal, Oral, Inhalation		†	†
12: Slimicides • wood and paper pulp • oil extraction / fuel storage	Cleaning out tanks that have been used to store pulp	Dermal	†		
	Mouthing of treated paper/carton (chips)	Oral			†

13: Metal working fluids	Transfer of machined metal from lathe to storage area	Dermal	†		
Pest control products					
14: Rodenticides	Collecting/contact with (old) bait	Dermal, Inhalation	†	†	†
	Collecting/contact with dead rodents	Dermal	†	†	†
		Oral	†	†	†
15: Avicides	Taking treated grain	Oral			†
16: Molluscicides	Contact with treated surface	Oral, Dermal		†	†
	Picking grains				†
17: Piscicides	Swimming in water treated with piscicides	Dermal, Oral		†	†
18: Insecticides, acaricides and products to control other anthropods • sprays • gases • flypaper • paints • decoy boxes • powders	Collecting strips/cassettes, impregnated mats, -papers, -stickers	Dermal, (Inhalation)	†	†	†
	Re-entry of treated spaces	Inhalation	†	†	†
	Crawling on treated surfaces	Dermal, Oral			†
19: Repellents and attractants	Mouthing of repellents	Oral			†
• on skin	Re-entry treated spaces	Inhalation, Dermal	†	†	†
• not directly on skin	Touching treated surfaces	Dermal	†	†	†
Other biocidal products					
20: Preservation of food or feedstocks	Contact with (intentionally or unintentionally) treated fibres	Inhalation, Dermal	†	†	†
	Dietary ingestion	Oral		†	†

21: Antifouling products • vessels • nets and cages	Abrasion/removal of paint Contact with treated surfaces	Inhalation, Dermal Dermal	† †	† †	 †
22: Embalming and taxidermist fluids	Handling treated corpses, body parts/organs	Dermal, Inhalation	†	†	
23: Control of vertebrates/vermin	Pickup and removal of contaminated animal carcasses Taking treated grain	Dermal Oral	†	†	† †

2.10 Reverse reference scenarios

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 realistically likely, as determined by common sense from experimental or other data. A worked example is provided in chapter 5.

2.11 Suitability of exposure data sources

Any data source that describes relevant exposures can be used in the exposure assessment, when the detailed descriptions of the circumstances (contextual information) of the data source is available. The main criterion is the similarity in the tasks being considered. Good data are thus representative and robust, i.e. covering a reasonable large sample for the full range of circumstances. One might have a suitable exposure model or database with measurements at hand that cover similar scenarios. One might even have a series of measurements for the scenario to be assessed. The combination of all this information should really be done at expert level, covering all relevant parameters and circumstances, i.e. contextual information.

Another important issue is the combination of tasks, since human exposures are distributions, not single values. But single values must be drawn from the distributions in order to estimate exposures where no directly relevant data exist.
Distributions of human exposure data are commonly accepted as being approximately log-normal.

Exposure estimates for a single procedure can be reasonably estimated by a percentile from the data distribution. However, if the procedure is done several times, simple addition of percentile values can show gross deviations in the final estimate, especially with high or low percentiles.

This argument applies to:

- summing the data for several daily treatment cycles
- summing the data for the inhalation and dermal exposure routes
- adding the phase of use estimates
- combining primary and secondary exposure, and
- aggregate exposure from all sources of the particular chemical.

Example:

Exposure in applying a product has a data set with a geometric mean of 20 units and a geometric standard deviation at 2.5. For a single application, the data distribution shows the following percentiles:

50^{th} 20
75^{th} 37
95^{th} 82

For four applications, simple multiplication gives

50^{th} 80
75^{th} 148
95^{th} 328

But the percentiles for the distribution, properly combined, are:

50^{th} 103 (the simple multiplication gives 20 % under-estimate)
75^{th} 147
95^{th} 241 (the simple multiplication gives 30 % over-estimate).

Simple addition of percentiles for the routes, phases and cycles of exposure, exposure times or amounts used, and cumulative exposures, has the clear potential to provide an unacceptable estimate of exposure. The assessor needs to take great care to avoid gross errors in combining exposure.

An alternative to extracting values from data distributions is to use the entire data distribution in a probabilistic assessment. This is of particular importance for estimating combined exposure. The probabilistic estimation technique is currently not fully integrated in the risk assessment process (for more details see Ann. Occup. Hyg. 45 Suppl. 1, 2001).

2.12 Selection of indicative exposure values

The following general 'rules' are presented for selection of indicative exposure values from available exposure data (see Annex 5).

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. 90 % 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 90 % 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, or else none whatsoever.*

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.

2.13 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 arguments 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 section 2.7.

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[5] should be followed and biomonitoring studies should be carried out in accordance with the Helsinki Declaration.

2.14 Transfer coefficients

During direct contact with various materials that may have been treated with biocidal products, transfer may occur to the skin. This due to the fact that the biocidal product may be dislodgeable, i.e. can be removed from the surface. There are many variables that affect these transfer processes (see also ConsExpo). In Annex 6 a list is compiled that gives some ideas about possible transfer coefficients.

[5] OCDE/GD(97) 148 (OECD, Paris, France, 1997

3 Procedure and Format for Exposure Estimation

3.1 Exposure data

A collection of exposure data is provided either in a database or described in summary format in Annex 1. Since data for handling rodenticides are not or hardly covered, an alternative approach is presented in Annex 4.

3.1.1 Generic exposure data

Generic exposure data describes measured exposure data obtained from similar operations utilising similar biocidal products. The data are collected from exposure surveys of workers 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 its ability to predict the likely levels of occupational exposure of users of biocides and 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 these data.

In this latest version of the TNsG the available generic data models that are considered adequate for human exposure assessment to biocides have wherever possible been incorporated into an electronic database (see section 5). This is intended to simplify the process of identifying suitable data and allow for more regular updating of the guidance. Some other exposure data that are considered useful for human exposure assessment to biocides are presented in Annex 1.

3.1.2 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.

3.2 Schematic guidance for human exposure to biocidal products

In this chapter the procedure for assessing the exposure is detailed, making use of all available information that is required for doing so. The approach chosen to consider quickly and appropriately the essential information is through the use of flowcharts, which are indicated below. By selecting the right boxes, one may through hyperlinks reach the area of choice.
The flowchart covers professionals and non-professionals and will guide you to the relevant use patterns and the main software tools. Worked examples for professional exposure for each Product Type are available for quick reference.

In the factsheets for consumer exposure in ConsExpo (see also section 3.3), default values for dermal exposure are mainly based on generic exposure data. Therefore, when the appropriate scenario is in the ConsExpo factsheets, for dermal exposure, there is no need to check for generic exposure data.
However, for inhalation exposure the approach between ConsExpo and the generic exposure data is fundamentally different. Therefore it is recommended to review the ConsExpo scenario, and use the scenario with appropriately adjusted values. In addition, exposure should also be calculated with a suitable generic database (when available). Both results should be compared, and based on the available information the most appropriate outcome should be used for risk characterisation.

Figure 1: Identifying users and exposure scenarios

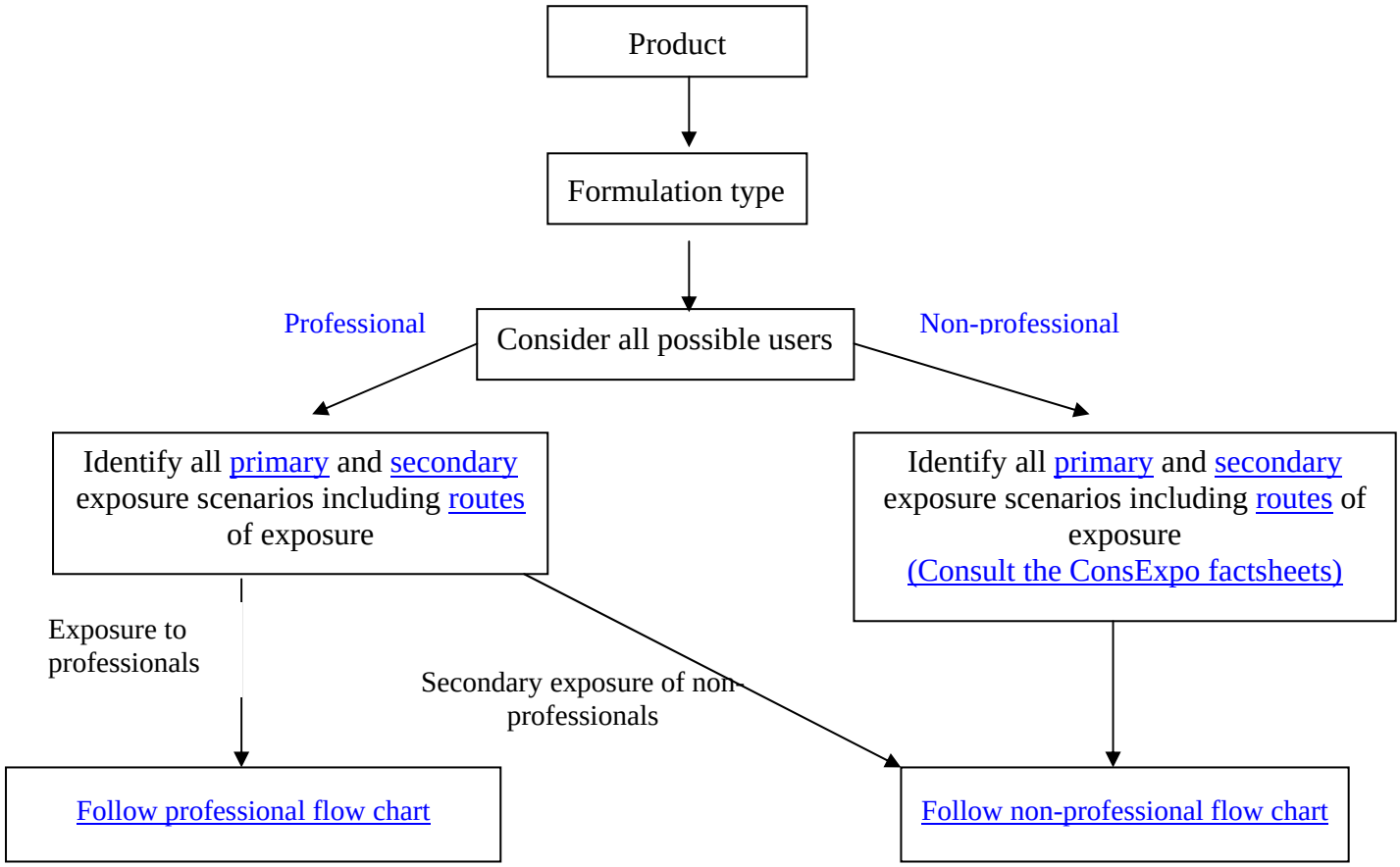


Figure 2: Flow chart for primary exposure to professional users

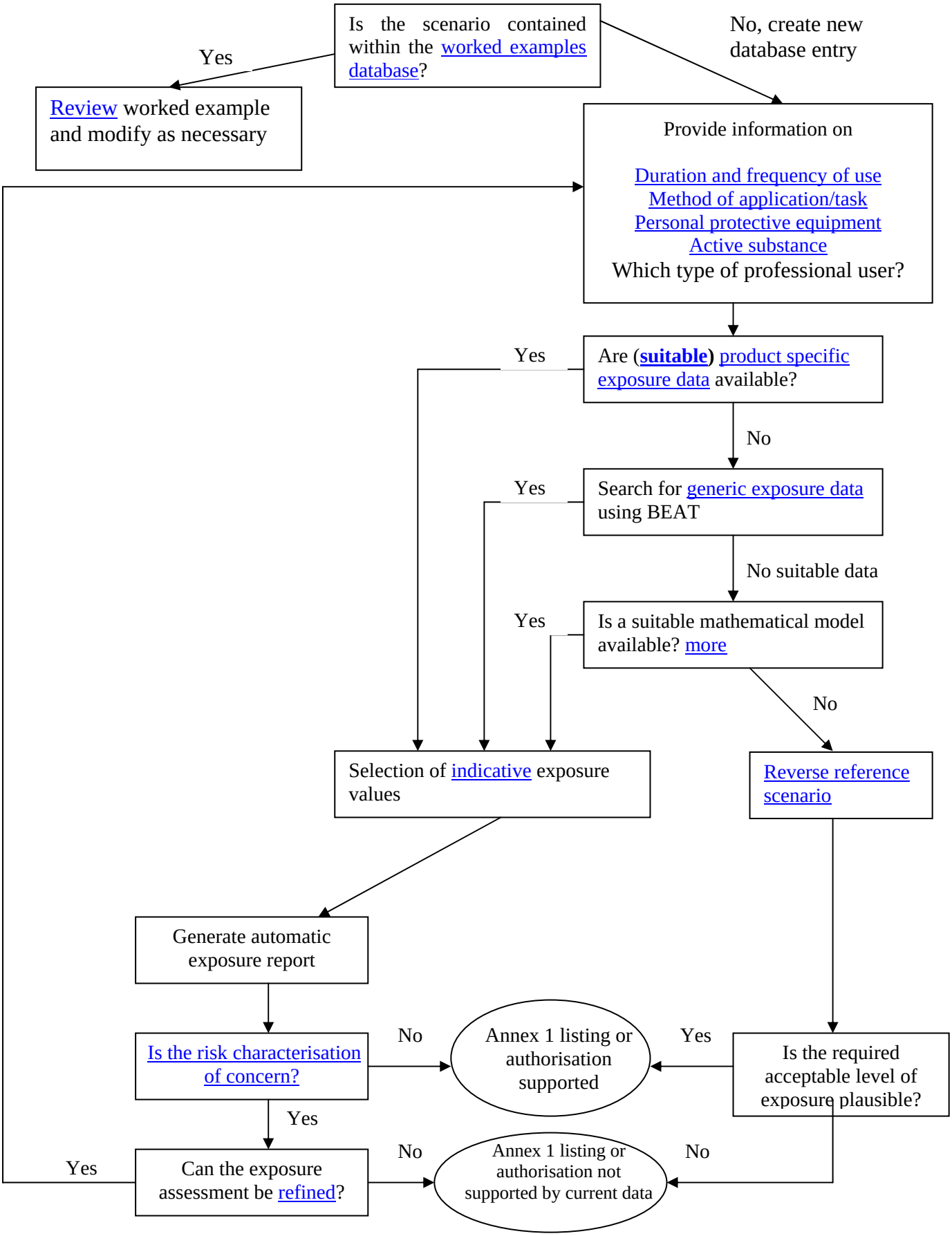


Figure 3: Reviewing worked examples for professionals

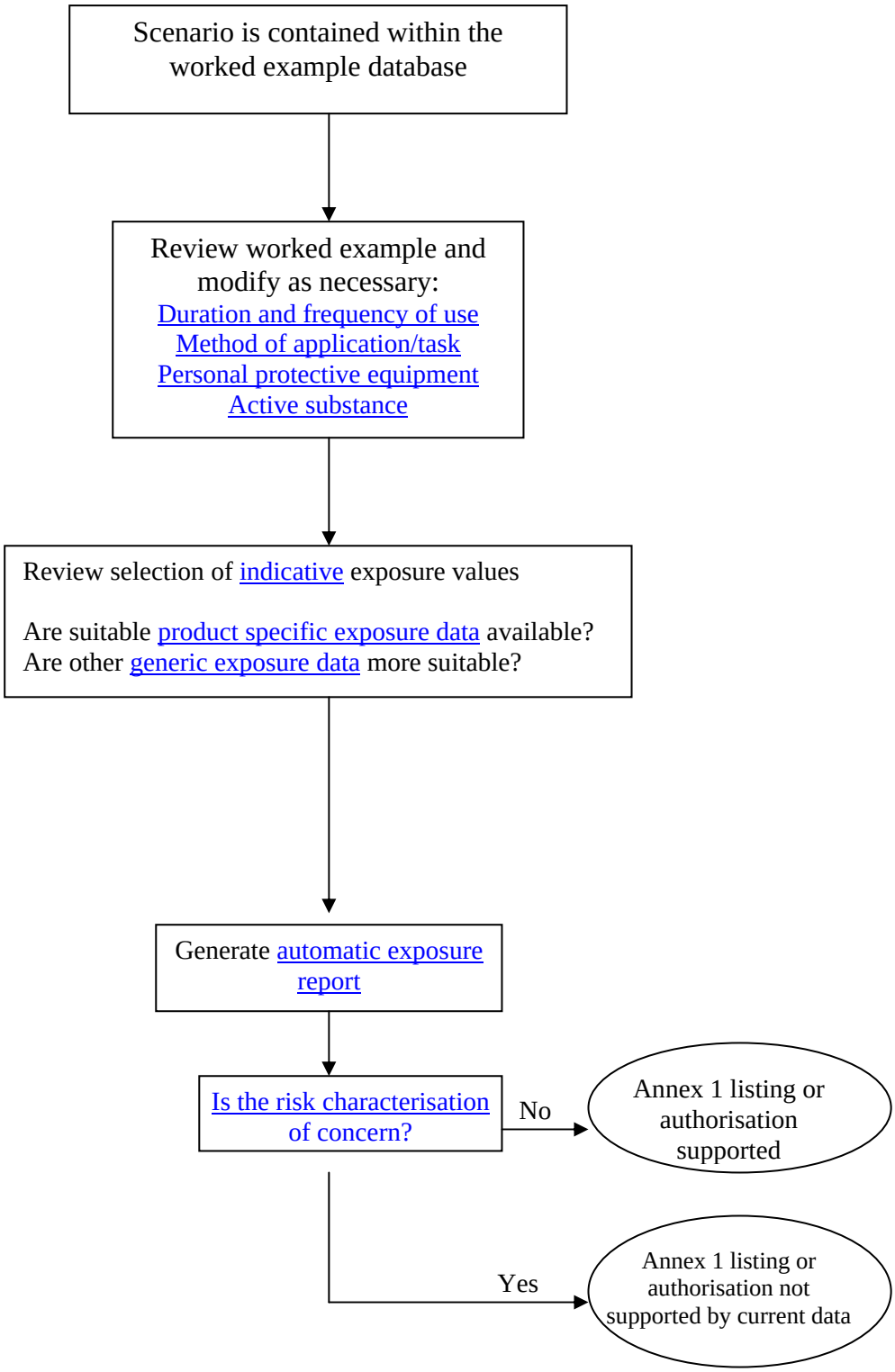
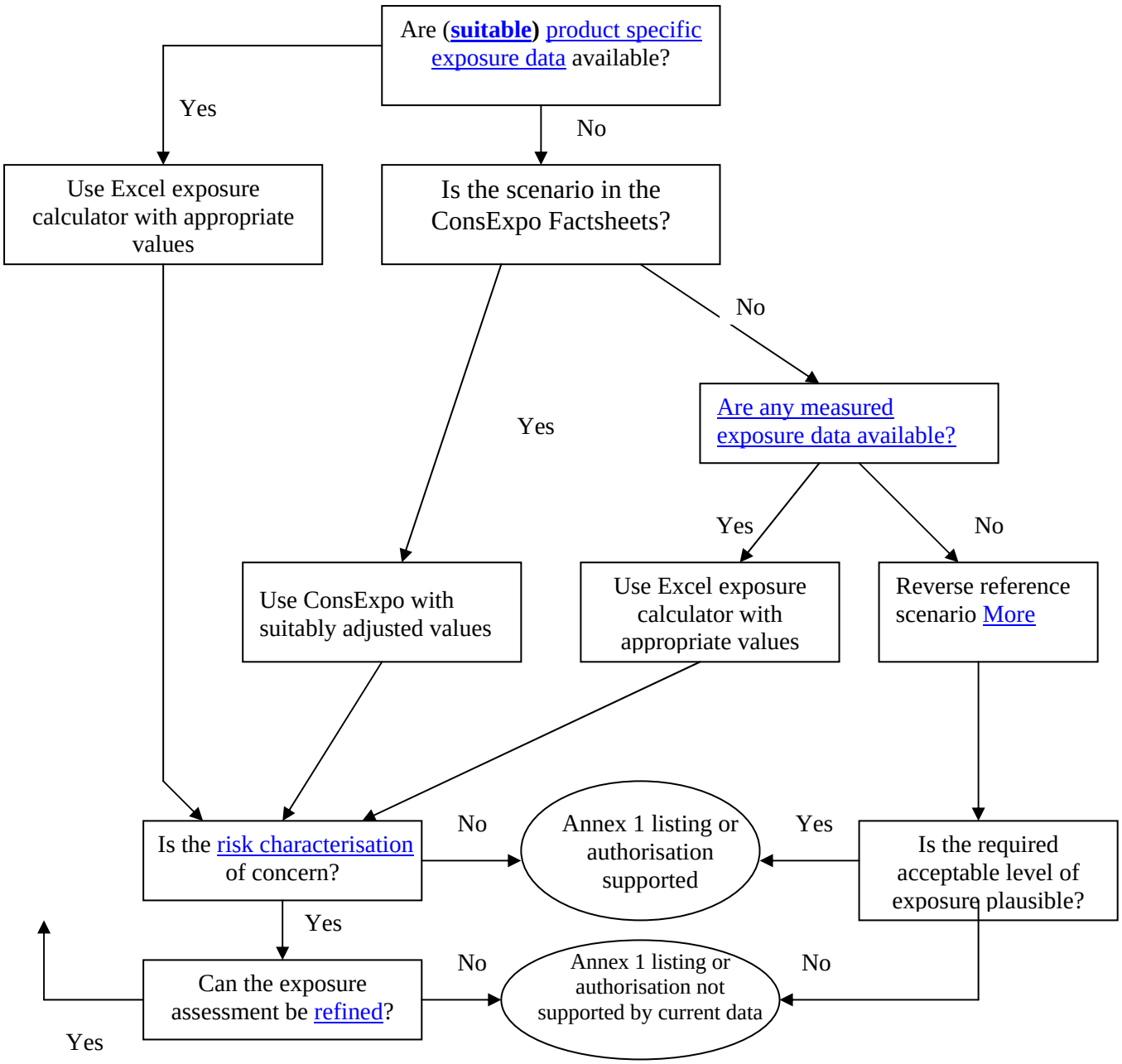


Figure 4: Flow chart for non-professional users

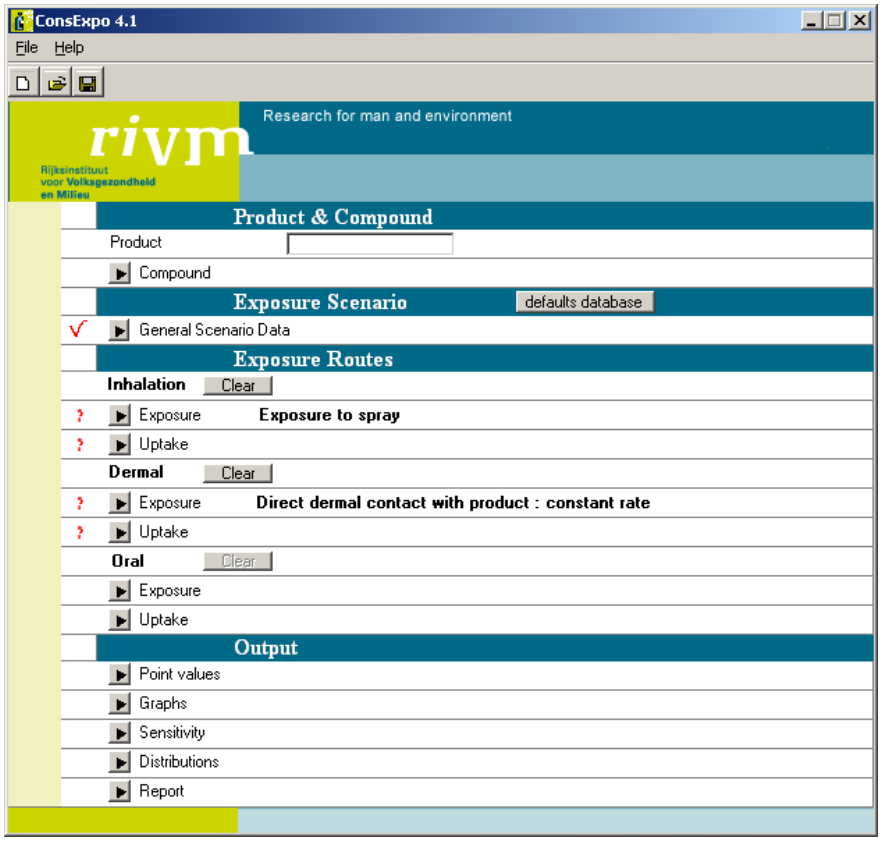


3.3 ConsExpo

ConsExpo 4, successor to ConsExpo 3.0, is a computer program that was developed to assist in the exposure assessment of compounds in non-food consumer products. The wide range of available consumer products is associated with an even wider variation in consumers and product use. Measured data on exposure to compounds in products is not always available. In the absence of these data, ConsExpo 4 can be used to estimate the exposure for different exposure scenarios. The program offers a number of generally applicable exposure models and a database with data on exposure factors for a broad set of consumer products. Together, database and models provide the tools to assess exposure for a wide range of consumer products, whereby only basic additional information on product composition and the physicochemical properties of the compound of interest are needed.
ConsExpo 4 implements a wide range of generally applicable mathematical models describing the exposure processes via inhalation, dermal contact and oral ingestion. The program contains algorithms which have also been included in the EU revised Technical Guidance Document on Risk Assessments (ECB, 2003). For all routes of exposure, ConsExpo 4 offers models of increasing complexity, from simple, rough estimate models to more detailed mechanistic models. The exposure assessment can be carried out using a tiered approach, starting with simple first order models that can be used to estimate the upper level of exposure, and working down to more detailed and complex models when the exposure estimation needs to be refined. For more guidance please see the ConsExpo manual (ref. Delmaar 2005, www.consexpo.nl).

The justification of data in the database is given in the so-called 'factsheets'.
A number of factsheets have been published, that compile relevant exposure information for a main category of consumer products, such as cosmetics, cleaning products, disinfectants, children's toys and pest control products (available via *www.consexpo.nl*). Factsheets on Do-it-yourself products and paint products are in press (a draft version available upon request). A separate factsheet called the 'General Fact Sheet' gives general information about the factsheets, and deals with subjects that are important for several main categories. It gives, for instance, information on anthropometric data and on housing: data that are needed in all product factsheets. In the factsheets, information about exposure to chemical substances from consumer products is collected into certain product categories. These categories are chosen so that products with similar exposures are grouped. For each of the product categories relevant ConsExpo models are described, for a given scenario default parameters are provided and the derivation of the parameters is justified.
The default parameters are available via a database, which is an integral part of ConsExpo 4. When selecting a sample product, the database provides default scenarios and parameter values for the models. When using the database, the user should always consult the corresponding fact sheet, in order to be aware of the limitations and the basis for the selected parameter values. The defaults can serve as a starting point for exposure estimation and should be used in the absence of accurate scenario data only. Whenever more detailed information for the product is available, these data should be used instead.

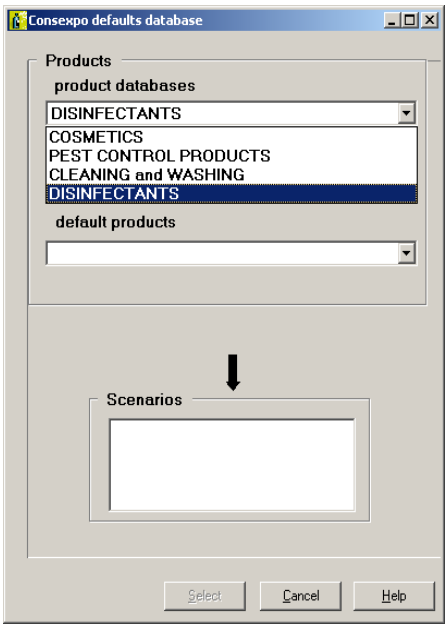
The ConsExpo model can be retrieved via www.consexpo.nl, including the associated database.

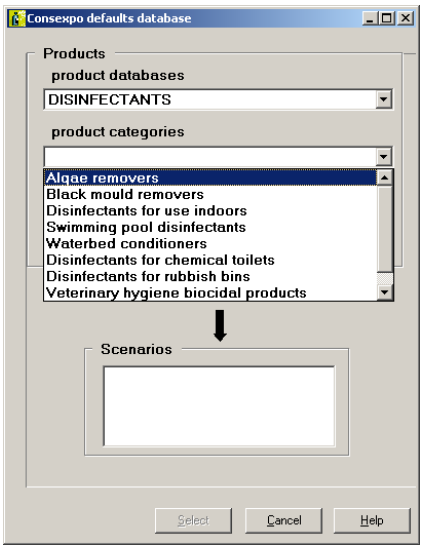


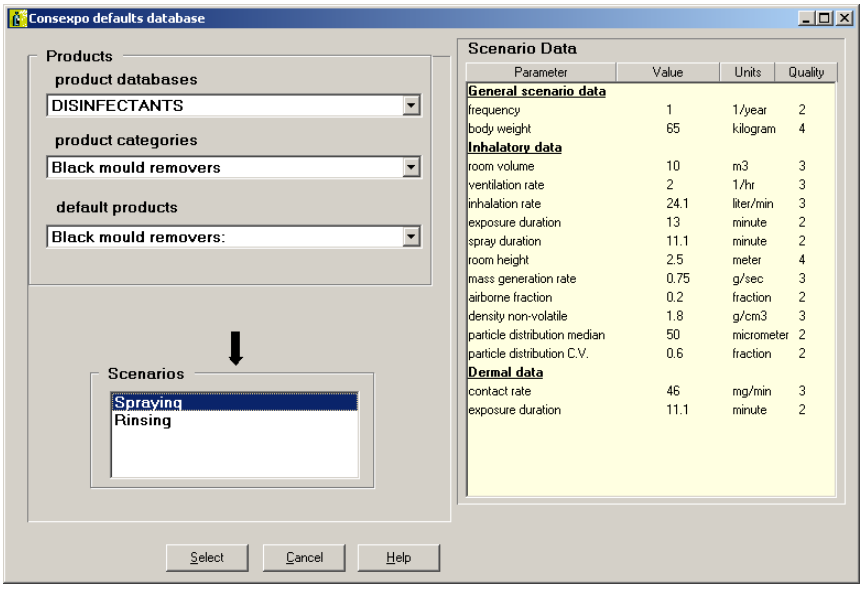
Worked example:
In fact the database provides worked examples. Below, all steps that have to be taken to assess the exposure to (as an example) black mould remover are described.

Black mould remover:
In the defaults database (see button on ConsExpo screen), first a product type has to be chosen. In this example disinfectants, choose the product category black mould remover, then default products: black mould removers. One has then to choose a scenario, in this case spraying or rinsing. By selecting spraying and press ‘select’, the relevant default parameters are automatically fed into the model. Compound specific data are not part of the default set and have to be filled in manually, using information from the product under study. Also product specific data like weight fraction should be filled in manually.
The default parameters that are proposed for the black mould remover (and disinfectants in general) are described in the factsheet ‘Disinfectants’ (see www.consexpo.nl). It is strongly recommended to carefully compare the data in the database (and their derivation as reported in the factsheet) and the assumptions in the exposure scenario (also reported in the factsheet) with the actual situation that has to be assessed.

Deviations should be reported, and the choice for alternative input parameters has to be motivated.







3.4 Standard format for exposure assessments

When undertaking a deterministic calculation, there is always the possibility of introducing arithmetical errors. One way around this, is to use a simple routine in the format of a spreadsheet. The spreadsheet is embedded within the computerized BEAT database and can be accessed directly from BEAT. In addition to minimising arithmetical errors, the spreadsheet is designed such that after performing the calculation a standard format for presenting the results, in the form of an appendix, is produced. The spreadsheet is also designed such that it can be saved and the data later manipulated, outside of BEAT. An output format is presented in the example in Table 5 (Chapter 5).

3.5 Use pattern database for professionals

Introduction
This section of the guidance introduces the patterns of use database. The purpose of the database is to establish generic use patterns for all different biocide product types. The pattern of use database provides defaults for duration and frequency of the different tasks for each biocidal product type for different formulation types. These defaults are set up based on currently readily available information and generic assessments. The defaults are limited for professional use only. For consumers the ConsExpo factsheets should be used.

Information sources for the pattern of use database
The pattern of use database was developed by using all relevant information gathered from the contact points for biocides of the Commission Services, members of EBPF (European Biocidal Product Forum) and Competent Authorities of the USA (EPA), California (Cal-Department of Pesticide Regulation) and Canada (Health Canada Pesticide Management Regulation Agency), as well as the Biocides Taskforce of the American Chemistry Council (ACC). In addition to this, available information from branch/sector organisations and single firms was used. Also databases of the competent authorities (CTB in NL, the Biocide/Pesticide Approval Systems in UK, BVL in Germany) were searched for relevant information. The University of Ulster (TEIC Innovation Centre) in Northern Ireland, UK, which also provides the so-called Biocide Information Services (BIS) provided requested information through structured telephone interviews with a large series of companies that are leading and relevant for all product types. Also the literature was searched with relevant descriptors and gathered information was used to set up the pattern of use database. After setting up the database based on all the information gathered, the industry (mainly through the EBPF) was allowed to check the information on accuracy and completeness before the final version was developed.

When to use the pattern of use database
The defaults presented are based on reasonable worst case values and are meant to be used for the exposure estimation. Whenever more detailed information for the product is available, these data should be used instead. However the use of other data should be fully justified, with underlying documents and/or information.

The database is not comprehensive but covers about 90% of all possible patterns of use. If a use pattern is, however, not contained in the database, the registrant should provide their own defaults with underlying documentation and/or information.

Defaults for duration and frequency
For frequency and duration standardised values are presented. Presenting standardised values prevents a large number of different durations being used in practice. The values are based on reasonable worst case assumptions. For the duration the minimum value is 10 minutes and the maximum is >8 hours. This means that if a specific task lasts for about 2 minutes the nearest default (in this case 10 minutes) is presented in the database. If the duration of a task is about 20 minutes the nearest default is 30 minutes and therefore presented.

Framework pattern of use database and used terminology
The database consists of a number of tables for each product type and for each formulation type. The tables consist of the following columns (see also Figure 5):

1. **Formulation:** In this column the type of formulation is presented.

2. **"Other" formulation:** In this column the specific description of the "other" formulation is filled in (if you find no good choice).

3. **Mixing and loading phase:** In this column the mixing and loading phase, i.e. the task(s) a professional user has to do before application is presented (e.g. preparing the biocidal solution or filling spray equipment with the biocidal product). The following types of different mixing/ loading scenarios are listed:

    - closed transfer: refers to the biocidal product that is transferred through a closed system (e.g. wood preservatives that are added automatically to a vacuum treatment vessel);
    - pour and dilute: refers to the biocidal product that has to be poured into a receiving vessel/ container/ equipment device and than diluted;
    - fill undiluted: refers to the biocidal product being poured into a receiving vessel/ container/ equipment device without dilution;
    - other and dilute: refers to other formulations e.g. tablets that are put into a receiving vessel/ container/ equipment device and than diluted; and
    - no mixing and loading required: refers to the biocidal product that can be directly used without any mixing and loading required (e.g. most ready for use products but for example also products used for application on the skin directly from a pump device onto the hands).

4. **Total duration mixing and loading per day (default):** This column refers to the duration a specific phase will take during any particular day. This means that the total duration can consist of repeated tasks. The total duration refers to the duration of the mixing and loading and not to the contact duration of the professional user with the biocidal product.

5. **Exposure frequency (default):** this column refers to how often an exposure will take place (daily, weekly, monthly) Daily means every day during a workweek (e.g. 5 times a week). The frequency may indicate whether the exposure is acute, semi-chronic or chronic.

6. **Application phase (category):** in this column a specific application group (task) can be chosen. The task "handling" is unspecified meaning that the professional is handling the biocide and performs different subtasks with it (e.g. sprayed on hands and rubbing it in or adding a biocidal product to a system volume) The others tasks mopping, wiping, scrubbing etc. are self-explanatory and are taken from the RISKOFDERM[6] project.

7. **Description of phase:** In this column a short description of the application phase (task performed) is presented.

8. **Total duration application per day (default):** this column refers to the duration a specific phase will take during an exposure day. This means that the total

[6] Ann Occup Hyg, 47: 595-652 (2003); Ann Occup Hyg, 48: 183-297 (2004)

duration can consist of repeated tasks. The total duration refers to the duration of the application and not to the contact duration of the professional user with the biocidal product.

9. **Exposure frequency (default):** this column refers to how often an exposure day will take place (daily, weekly, monthly, etc.) Daily means every day during a workweek (e.g. 5 times a week). The frequency indicates if the exposure is acute, semi-chronic or chronic.

10. **Comments:** In this column specific comments on the use pattern are presented if applicable.

Figure 5: Example patterns of use database table (first rows only)

Formulation *(column 1)*	**If formulation is "other" then define** *(column 2)*	**Mixing and loading phase** *(column 3)*	**Total duration mixing and loading per day (default)** *(column 4)*	**Exposure frequency (default)** *(column 5)*	**Application phase (category)** *(column 6)*	**Description of phase** *(column 7)*	**Total duration application per day (default)** *(column 8)*	**Exposure frequency (default)** *(column 9)*	**Comments** *(column 10)*
Liquids									
Liquid		No mixing and loading required			Handling	Sprayed on hands and rubbed in	30 minutes	Daily	about 20 times a day for about 1 minute
Liquid		No mixing and loading required			Handling	Wash hands	30 minutes	Daily	about 20 times a day for about 1 minute

Specific boundary conditions for each product type
In this section the boundary conditions (if applicable and/or not self-evident) are listed for each product type

Type 1 Human hygiene products
- disinfectants applied to the (human) skin
- excluding biocide in cosmetic products which are covered by the Cosmetics Directive (76/768/EEC) and products intended for medical purposes (e.g. antiseptics) which are covered by the Medical products Directive

Type 2 Private area and public health area disinfectant, etc.
- excluding disinfectants specifically intended for use with medical devices which are covered by the Medical Devices Directive (93/42/EEC)

Type 3 Veterinary hygiene products

- excluding substances used for disease control or prevention which are covered by the Veterinary Medicinal Products Directive (81/851/EEC as last amended by Directive 93/40/EEC)
- disinfectants for milking equipment may be covered by Directive 92/46/EEC (production and placing on the market of milk) but are also included here

Type 4 Food and feed area disinfectants

- excluding disinfectants intended for use in the food-processing industry which are mainly defined or within the scope of other directives e.g. 89/109/EEC (materials and articles intended to come into contact with foodstuffs), 92/46/EEC (production and placing on the market of milk), 89/437/EEC (production and placing on the market of egg products), 89/1107/EEC, 88/388/EEC and 95/2EC (food additives and flavourings), 91/493/EEC (production and placing on the market of fishery products), 95/5/EC (production and marketing of certain products of animal origin)

Type 5 Drinking water disinfectants

Type 6 In-can preservatives

- excluding in-can preservatives for medicine, toys, cosmetics and human hygiene products since these products are covered by other directives

Type 7 Film preservatives

- excluding biocides used in priming wood-care products, for which the main function is a protection of the wood against microbial deterioration. These are included in product type 8

Type 8 Wood preservatives

- excluding biocides for preservation of paints, where the effect of the biocide is to preserve the paint itself since these are covered in product type 6 and 7

Type 9 Fibre, leather, rubber and polymerised materials preservatives

Type 10 Masonry preservatives

- excluding biocides for preservation of insulation materials, which are included in product type 9

Type 11 Preservatives for liquid-cooling and processing systems

- including district heating systems since these are neither liquid-cooling systems nor processing systems
- including biocides used for preservation of the liquid cooling system or air-conditioning systems are included here although the biocides in semi-open systems may serve as both preservatives and disinfectants
- excluding slimicides (product type 12) and products used for the disinfection of drinking water (product type 5), drinking water drain work (product type 4), preservation of metalworking-fluids (product type 13) and moisteners used in the printing process (product type 6)

Type 12 Slimicides

Type 13 Metal working fluids

Type 14 Rodenticides

Type 15 Avicides

Type 16 Molluscicides
- excluding agents for prevention of mollusc fouling on the surface of vessels and equipment for aquaculture which are included in product type 21

Type 17 Piscicides

Type 18 Insecticides, acaricides, etc.
- including products used against vermin on cats and dogs
- including both products used to kill the target organism and products that in some way obstruct the normal development of the target organism

Type 19 Repellents and attractants

Type 20 Preservatives for food or feedstocks

Type 21 Antifouling products

Type 22 Embalming and taxidermist fluids

Type 23 Control of other vertebrates
- excluding products that control the animals by an attractive or repellent action are which are included in product type 19

The Excel database is embedded below and has included explanatory text and indicates the various formulations that may occur. For each PT there is a list of durations and frequencies for the most relevant formulation types.

Use Pattern Database

3.6 Other models

In the sections 3.6-3.9 several models are presented which may be of help in specific cases. Several of these models have also been described on the Global CEM Net Website of JRC/IHCP/PCE in Ispra (Italy). It should be noted that most US models rely on large databases, which contain US specific data. These data should be used carefully in European situations.

3.6.1 SprayExpo model

Theoretical background and model features
The Fraunhofer Institute for Toxicology and Aerosol Research has developed a deterministic model for predicting aerosol exposure during spraying [Koch, et al., 2004]. "SprayExpo" is suitable for all different types of applications that involve large-area indoor spraying or nebulizing of biocidal products, including surface disinfection in hospitals, canteen kitchens and animal husbandry.
The model calculates the time-dependent airborne concentration of the respirable, thoracic and inhalable size fraction of aerosols generated from the spraying of liquid products in indoor environments. In addition the dermal exposure of the sprayer is modelled explicitly.
The model is suitable to calculate short-term exposure originating from the release process during spraying scenarios. Long-term exposure due to the emissions of vapours from walls and other surfaces are not included in the model. One prerequisite for the model is that the biocidal product is composed of a non-volatile active substance dissolved in a solvent with known volatility. This prerequisite is true for most of the biocidal products.
SprayExpo is available as a software package which can be executed under WINDOWS.
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.
To support the user a detailed guidance with one example of indoor spraying of liquid insecticides has been developed. The software package with user guidance, a detailed description of the theoretical background and the worked example are available on the BAuA homepage (http://www.baua.de/nn_7554/en/Publications/Expert-Papers/Gd35.html__nnn=true).

Status of validation
Initial validation with regard to the airborne concentration in a model room under different conditions has been undertaken. The model experiments were carried out with fluorescent tracers representing the biocidal active substance in aqueous solutions. Concentration levels and their temporal pattern were predicted with reasonable accuracy by the model however, there is a tendency towards overestimation.
At present there are no validation data available as for scenarios where dermal exposure and/or the impaction of droplets play a role. Thus the corresponding modelling results are quite uncertain and should therefore be interpreted with some caution. The BAuA has planned a study that aims to diminish the amount of uncertainty and to improve the overall validity of the model. The final report of this study may be available by mid 2009.

References
W. Koch, E.Berger-Preiß, A. Boehncke, G. Könnecker, I. Mangelsdorf, Arbeitsplatzbelastungen bei der Verwendung von Biozid-Produkten, Teil 1: Inhalative und dermale Expositionsdaten für das Versprühen von flüssigen Biozid-Produkten, Forschungsprojekt F1702 der BAuA, Dortmund 2004.
W. Koch, Arbeitsplatzbelastungen bei der Verwendung von Biozid-Produkten – Transformation und Erweiterung eines DV-gestützten Modells zur Abschätzung der inhalativen und dermalen Exposition bei Sprayprozessen -, Forschungsprojekt F2022 der BAuA, Dortmund 2004.

3.6.2 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. The main use of these models is for 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.

1 Screening tier models

E-FAST
Features Provides screening-level estimates of the concentrations of chemicals released to air, surface water, landfills, and from consumer products. Estimates provided are potential inhalation, dermal and ingestion dose rates resulting from these releases. Modelled estimates of concentrations and doses are designed to reasonably overestimate exposures, for use in screening level assessment. E-Fast contains the Consumer Exposure Module (CEM) that includes and updates the former FLUSH, DERMAL, and SCIES tools. This means that instead of running the individual cluster of DOS-Based tools, a user now only needs to run the E-FAST model.

- E-FAST calculates appropriate human potential dose rates for a wide variety of chemical exposure routes and estimates the number of days per year that an aquatic ecotoxicological concern concentration will be exceeded for organisms in the water column.
- To execute the E-FAST model in order to assess general population exposure and aquatic environmental exposure and risk resulting from industrial releases, you will need to enter: amount of chemical releases; media of release; days per year of release; certain chemical properties; where possible, detailed release location data; if no detailed location data is available, generic industry codes can be applied. To execute the consumer exposure assessment modules in E-FAST, the user will need to enter: the type of product; weight fraction; vapour pressure; and molecular weight.

Theoretical The Consumer Exposure Module (CEM) is an interactive model within E-FAST which calculates conservative estimates of potential inhalation exposure and potential and

absorbed dermal exposure to chemicals in certain types of consumer products. The scenarios covered with relevance to consumer biocide use are:

- liquid cleaners (Types 2.01 and 6.02);
- latex paints (Type 6.02);
- laundry detergents (Type 6.01)
- air fresheners (vapour dispersion, Types 18.02 and 19.02);
- bar soap (Type 1)
- custom.

CEM allows for screening-level estimates of acute potential dose rates, and average and lifetime average daily dose rates. Because the model incorporates either a combination of upper percentile and mean input values or all upper percentile input values for various exposure factors in the calculation of potential exposures/doses, the exposure/dose estimates are considered "high end" to "bounding" estimates. Consumer inhalation exposures modelled in CEM use the same approach and calculations as the Multi-Chamber Concentration and Exposure Model (MCCEM) (Versar, 1997b), as well as scenarios depicted in the Screening - Level Consumer Inhalation Exposure Software (SCIES) (Versar, 1994). Dermal exposures are modelled using the same approach and equations as the DERMAL Exposure Model (Versar, 1995).

Availability E-Fast is available from the web site of US-EPA OPPT as a beta version:
http://www.epa.gov/opptintr/exposure/

ChemSTEER
Features The tool provides screening tier exposure estimates for
• occupational inhalation and dermal exposure to a chemical during industrial and commercial manufacturing, processing, and use operations involving the chemical.
• releases of a chemical to air, water, and land that are associated with industrial and commercial manufacturing, processing, and use of the chemical.
The first set of estimation methods are useful to identify exposure to biocides

ChemSTEER allows users to select predefined industry-specific or chemical functional use-specific profiles or user-defined manufacturing, processing and use operations. Using these operations and several chemical-specific and case-specific parameters and general models, the ChemSTEER computer program estimates releases and occupational exposures. The methods in ChemSTEER were developed by the EPA Office of Pollution Prevention and Toxics (OPPT); Economics, Exposure, and Technology Division; Chemical Engineering Branch.

Availability ChemSTEER is available from the web site of US-EPA OPPT as a draft version:
http://www.epa.gov/opptintr/exposure/

2 Higher tier models

US-EPA Multi-Chamber Concentration and Exposure Model (MCCEM), Version 1.2
Features The Multi-Chamber Concentration and Exposure Model (MCCEM) was developed for the U.S. EPA Office of Pollution Prevention and Toxics to estimate indoor concentrations for chemicals released in residences (GEOMET, 1995). The feature of MCCEM is as follows:

- MCCEM need time-varying emission rates for a chemical in each zone of the residence and outdoor concentrations. The emission rates of pollutants can be entered into the model either as numbers or as formulas.
- Inhalation exposure levels are calculated from the estimated concentration if the user specified the zone where an individual is located in a spreadsheet environment.
- MCCEM has data sets containing infiltration and interzonal airflow rates for different types of residences in various geographic areas. The user can select from the data sets, or can input zone descriptions, volumes and airflow rates.
- Concentrations can be modelled in as many as four zones (chambers) of a residence.
- The program is capable of performing Monte Carlo simulation on several input parameters (i.e., infiltration rate, emission rate, decay rate, and outdoor concentration) for developing a range of estimates for zone-specific concentrations or inhalation exposure.
- The program has an option to conduct sensitivity of the model results to a change in one or more of the input parameters.
- The percentage of cases for which modelled contaminant concentrations are at or above a user-specified level of possible concern or interest is determined.

Theoretical This multi-chamber mass-balance model has been developed by using air infiltration rates and corresponding interzonal air flows for a user-selected residence or a user-defined residence. This model provides a spreadsheet environment to the user for entering time-service data for emission rates in one or more zones, the zone of exposure, and concentration values of the contaminant outdoors.

Information assembled by Brookhaven National Laboratory concerning measured infiltration/exfiltration airflow, interzonal airflow, and the volume and description of each zone for different types of structures in various geographic areas has been incorporated in the software for access by users. Two generic houses represent average volume (408 m^3) and flow information in summer or fall/spring that has been complied from a large number of residences. One generic house has a bedroom and the remainder, while the other has a kitchen and the remainder.

Remarks The user's guideline listing good examples enable risk assessors to handle easily the full items within MCCEM. In addition, MCCEM contains a database of various default house data that are needed to complete each calculation such as air-exchange rates, geographically based inter-room air flows, and house/room volumes. However, so many data might confuse risk assessors who aim to evaluate the risk tendency of pesticides for a typical population at the first tier approach. Therefore, it seems reasonable that the user’s guide suggests that a two-storey residence will be chosen by defaults, and that US EPA(1997) recommends a fixed storey using the above generic house in summer to estimate a high-end assessment.

Availability MCCEM is available as version 1.2 from the web site of US-EPA OPPT as a beta version: http://www.epa.gov/opptintr/exposure/

References

GEOMET Technologies, Inc., *USER’S GUIDE; Multi-Chamber Concentration and Exposure Model*, Maryland, 1995.

Residential Exposure Assessment Work Group, (1997) *Standard Operating Procedures (SOPs) for Residential Exposure Assessments*, Contract No. 68-W6-0030, Work Assignment No. 3385. 102.
U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, *Series 875 - Occupational and Residential Exposure Test Guidelines, Group B - Post application exposure monitoring test guidelines,* Version 5.3, 1997.

US-EPA Wall Paint Exposure Assessment Model (WPEM)
Features The Wall Paints Exposure Assessment Model (WPEM) estimates the potential exposure of consumers and workers to the chemicals emitted from wall paint which is applied using a roller or a brush. WPEM is a user-friendly, flexible software product that uses mathematical models developed from small chamber data to estimate the emissions of chemicals from oil-based (alkyd) and latex wall paint. This is then combined with detailed use, workload and occupancy data (e.g., amount of time spent in the painted room, etc,) to estimate exposure. The output of WPEM was evaluated in a home used by EPA for testing purposes and, in general, the results were within a factor of 2. The WPEM provides exposure estimates such as Lifetime and Average Daily Doses, Lifetime and Average Daily Concentrations, and peak concentrations.

Remarks WPEM uses US units (feet and gallons) instead of SI-units. User input and interpretation of results is hampered for those not used to these units. It should also be noted that some US units are not the same as the UK's imperial weights and measures, e.g. gallons.

Availability WPEM Version 3.2 was developed under a contract by Geomet Technologies, a subsidiary of Versar, Inc. for the EPA's Office of Pollution Prevention and Toxics, Economics, Exposure, and Technology Division, Exposure Assessment Branch. This project was accomplished in co-ordination and co-operation with the National Paint and Coatings Association (NPCA), in addition to paint manufacturers and chemical suppliers. WPEM is available as version 3.2 from the web site of US-EPA OPPT: http://www.epa.gov/opptintr/exposure/

3.6.3 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.

Features 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.

Theory 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 build 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.

Availability Internet provides two versions of the document. The last full version is of December 1997 version and is available as pdf-document under:

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

The 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

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.

3.6.4 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.
For information, and as sources of information, the FQPA-initiated models are described below.

SHEDS
Features The Stochastic Human Exposure and Dose Simulation model for pesticides (SHEDS-pesticides) is developed by the US-EPA, Office of Research and Development,

National Exposure Research Laboratory in Cupertino with ManTech Environmental Technology Inc. Overall goals of SHEDS are

- to characterise variability and uncertainty in population estimates;
- to quantify infants and children's aggregate and cumulative exposure and dose to pesticides;
- to identify significant media, routes, pathways and exposure factors;
- to provide a framework for prioritising measurement needs under FQPA.

Exposure estimates are based on the inhalation, dermal and oral route of exposure, application and post-application exposures, for users and the entire population. SHEDS calculates a longitudinal 1-year exposure profile with averaging time periods of 1 day, 7 days, and 30 days and a seasonal and annual average.

Theory The basic unit of the SHEDS model is the exposure profile of an individual during a 1-year time period. Total exposure is a summation from residential and dietary exposures. From a simulated personal activity pattern and the application times of pesticides over the year, route specific exposure profiles are calculated. Activities of a person are based on the simulation of a 1-year diary, differentiating the four seasons and differentiating weekdays from weekends. Population estimates are generated by simulating many persons by Monte Carlo sampling.
Residential exposure estimation is largely based on the Residential Exposure SOPs (US-EPA, 1997). Refinements include

- variability within a day;
- dermal hand and dermal non-hand body parts separately;
- bathing and hand washing adjust dermal profiles;
- non-dietary ingestion via both hand-mouth and object-mouth;
- hand-mouth ingestion linked to dermal hand exposure.

Calculation includes uptake of the active ingredient, distribution in the body and elimination by urine of the substance and its metabolites.

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

References
US EPA. 1997. Standard Operating Procedures (SOPs) for Residential Exposure Assessments. US-EPA, Draft.

Lifeline
Features. The LifeLine™ model is developed by the Lifeline group (Price et al., 2001). It defines the exposures to pesticides from dietary residues, residential uses, and contamination of tap water that occur on each day of an individual's life. These exposures determine the doses that result from the exposures, which are in turn summed to give an estimate of the total or aggregate dose.
The model determines the individual's exposures by modelling where people are born, how individuals grow and age, how they move from home to home and region to region of the US, how they use or do not use pesticides, and their daily activity and dietary patterns. Using chemical-specific information on the fraction of the dermal, oral, and inhalation exposures that are absorbed, the LifeLine™ model calculates the total absorbed dose received from the oral, dermal, and inhalation routes for each day of the individual's life. These estimates of absorbed dose can be summed to give the total systemic (aggregate) dose that can provide the basis for assessing aggregate risk.

Residential exposures Estimates of exposure from residential uses of a pesticide are based on data on pest pressure collected in the National Home and Garden Survey (US EPA, 1992b). This survey determined the frequency with which specific pests required treatment in different residential microenvironments. These data are used to determine the probability and frequency of using each pesticide in the residence. User-supplied data on pesticide product's characteristics are then used to predict the residues on surfaces and in the air of the residences that result from the use of the pesticide.
LifeLine™ contains information on the US housing stock, including information on room sizes, air exchange rates and other factors. Using these data and the exposure equations described in US EPA SOPs for residential exposure assessments (US EPA, 1997) the model estimates the exposures that occur by the oral, dermal, and inhalation routes. These data are used to estimate the absorbed doses for each route and the aggregate dose. These exposures include both the application-related exposure and the post-application exposures. The post application exposures considered by LifeLine™ include exposures that happen on the day of application and on subsequent days.

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

References
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US Environmental Protection Agency, 1992b. *National Home and Garden Pesticide Use Survey*. Prepared by the Research Triangle Institute for the Office of Pesticides and Toxic Substances, Biological and Economic Analysis Branch.
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Calendex
Features Calendex™ has been developed to provide a flexible, but powerful, tool to use in estimating consumer and occupational exposure to chemicals. FQPA specifically requires estimation of aggregate exposure due to residues in the diet and drinking water as well as those encountered due to residential uses of pesticides. The Calendex™ software provides a vehicle for managing the various scenarios and data sources in complex analyses of aggregate and cumulative exposure and providing full documentation that is suitable for regulatory situations. Detailed objectives and uses of Calendex™ currently include the following:

- Calendex™ provides estimates of exposure that are statistically representative of the US population as well as a wide range of user-specified subpopulations.
- Calendex™ permits the estimation of exposure to single or multiple compounds for a wide variety of time periods (daily/acute, short-term, intermediate-term, and chronic (up to one year) time periods).
- Exposure to chemicals can result from residues in food, residues in or around the residence, and/or residues from occupational uses of the chemical. The route of exposure can result from oral, dermal, or inhalation, or a combination of these routes.
- Calendex™ is designed to permit the inclusion of the temporal aspects of exposure in each assessment.

- Calendex™ is designed to permit the inclusion of the spatial aspects of exposure in each assessment. For example, the types of pests encountered in a home in Florida may be very different than those found in a home in northern Maine.
- Calendex™ is designed to permit the user to conduct simple exposure estimates based on point estimates or probabilistic estimates based on distributions and Monte Carlo analysis techniques.

Theory The goal of non-dietary exposure assessments is to characterise the exposure of the population of concern (e.g., adults, toddlers, etc.) and to identify the variability associated with that exposure. Typically, the primary objectives are to estimate the level of exposure via ingestion, inhalation, or dermal absorption of the substance and to identify the sources of both variability and uncertainty in the estimate. In addition, the exposure assessment can also be useful in identifying the potential importance of a specific route relative to other pathways of exposure.
The general exposure model is of the form *Contact x Residue = Exposure.* To assess the total aggregate or cumulative exposure, three types of data for each product or use are required:
- use pattern information of products of interest, frequency of application and amount of product applied;
- environmental concentration data on days before, during and after treatment (residue factors); and
- exposure factors such as body weight, breathing rate, and activity patterns (contact factors).

Calendex™ currently uses the calendar day as the basic unit of time for calculating human exposure to one or more chemicals. All reporting periods longer than a day are built up from sequential daily exposures to an individual, summed, and averaged over the number of days included in the reporting period to provide an average daily exposure for that individual over the time duration specified in the analysis. The calendar model:
- Uses the probability that individual exposures occurs around specific dates
- Calculates exposure for individual chemical uses and exposure routes
- Combines the exposure-probability distributions for individual uses using Monte Carlo sampling techniques

Availability 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.

CARES/REx
Features. CARES stands for Cumulative and Aggregate Risk Evaluation System. It contains a part that models dietary exposure to pesticides and a part that models residential exposures to pesticides, the REx model. REx is a **R**esidential **Ex**posure Model which automates the calculations required to estimate exposure and associated risk from residential use(s) of pesticides. REx provides a multi-pathway, multi-route modelling approach and includes multiple assessment methods (e.g., post application whole-body dermal transfer coefficients and/or unitless bodypart- specific transfer factors). It allows the risk assessor to examine exposure values for selected applicator or post-application scenarios and considers inhalation, dermal, and incidental ingestion routes. Multiple subpopulations are addressed simultaneously. Exposure factors associated with these subpopulations can be customised by the user. Further, the default scenarios and algorithms currently specified in the EPA

Standard Operating Procedures for Residential Exposure Assessment are included as optional selections in REx.

Theory The product use scenarios in REx are those based on EPA's Residential SOPs draft document (US-EPA, 1997). One or more (up to six) scenarios can be aggregated to estimate exposure and dose to receptors of interest.

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

References
US EPA. 1997. Standard Operating Procedures (SOPs) for Residential Exposure Assessments. US-EPA, Draft.

3.6.5 EUROPOEM

The European Predictive Operator Exposure Model Database Project (EUROPOEM)
EUROPOEM I constructed a generic database of monitored operator exposure studies on plant protection products in Europe. EUROPOEM II now expands that objective, also covering bystanders and re-entry workers, and examines mitigation measures.

- **Exposure data on a range of techniques including:**
  - boom sprayers
  - knapsack sprayers
  - airblast sprayers
- **Dermal and inhalation exposures included**
  - Measured by
    - patch techniques
    - whole body dosimetry
    - personal air pumps
    - fixed site air collectors
  - Allows
    - scenario subsetting
    - statistical analysis
    - exposure summaries
  - Useful for
    - designing exposure studies
    - predicting exposures

- model validation
- risk analysis
- comparing application techniques
- product authorisation
- defining need for protective clothing

Availability EUROPOEM is available though http://europoem.csl.gov.uk

4 Glossary of Terms

It is important that there is a clear understanding of the terms used in exposure assessment. This glossary was developed in conjunction with that in Annex III of the OECD guidance on the conduct of studies. Where no definition appears, that in the TGD applies. In addition, the definitions in the Biocidal Products Directive apply and in doubtful cases override other definitions.

abuse is intentional misuse, for example inhaling aerosol propellant - as such, it is not included in exposure estimation.

active substance (a.s.) is the chemical agent with biocidal activity as defined in the Directive.

actual dermal exposure is the amount of active substance or in-use biocide formulation that reaches the skin through e.g. (work) clothing or gloves and is available for uptake through the skin.

aggregate exposure *

application refers to using the in-use biocide.

biocidal product is a formulation that contains a biocidal active substance.

biological monitoring is the sampling of blood, urine, saliva or exhaled air at suitable times before, during and after the task, and analysing for the substance or a metabolite to determine the body dose. The sampling regime needs expert advice and ethical clearance.

bulk samples are samples of the biocide in use (and where necessary, the concentrate).

central tendency in a distribution is a value that describes best the central value. The central tendency may be used in exposure estimates where well trained operators show practically continuous use.

clothing can range from minimal (e.g. T-shirt and shorts) through leisure wear, work clothing and coveralls, to impermeable suits. It includes personal protective equipment (PPE).

combined exposure *

cumulative exposure*

deterministic estimates are single-value, including worst-case estimates.

dislodgeable residues are post-application residues that are available for uptake through human contact with substances on surfaces.

empirical (database) model is a data distribution of exposures derived from site surveys or laboratory simulations, strongly associated with the biocide application task or tasks. The only inputs are new exposure data to reinforce the model. The outputs are "indicative exposure values" which when modified by pattern of use data, are compared with toxicological endpoint data. This is used in Tier 1 and Tier 2 assessments.

exposure reduction measures are techniques to reduce risk through substitution of products, controlling the product, its sectors for use, specifying in-use control measures.

exposure data (experimental) - each personal sample (for inhalation and dermal exposure) is a data-point. It is unlikely that a sufficiently powerful data set would exist for meaningful statistics to apply to most scenarios.

exposure information includes the frequency and duration of exposure, the selection of products in preference to others on the market, and the patterns of use.

exposure models are used to predict exposure from databases, from statistical relationships and through mechanistic calculations. They provide information which, in conjunction with other data, leads to a quantitative estimate of exposure.

exposure via the environment is an element of secondary exposure. It includes bystanders and consumers, including children, who are inadvertently exposed to biocides by inhalation of plumes drifting off-site and ingesting contaminated food or water.

field blank samples are sampling media that are treated in the same way as monitoring media, without being exposed to the biocide in use.

foreseeable non-proper (incorrect) use is the use of biocidal products not in line with the instructions for use or without the consideration of some or all common and specific technical, operational and personal protective measures (e.g. the over-application or inadequate dilution of a biocide, common spillage scenarios, use without or with non-proper RPE and PPE). Accidents, malfunctions or deliberate misuse are not addressed.

likelihood of exposure is the expression of probability that exposure will occur at all. It can be quoted to reflect "none detected" values in exposure surveys and studies. See also LoD, LoQ.

in-use biocide is the product as it is being applied, whether or not diluted by the user, as a paint, a dust, a spray, a solid, a solution, or as a component of a fluid.

ingestion arises from the swallowing of biocides. Ingestion can also occur through poor hygiene practice (e.g. through dislodging from contaminated skin to food or cigarettes, by hand-mouth contact, or through applying cosmetics).

inhalation exposure reflects the airborne concentration that is available in the breathing zone. The substance is then available for uptake via the lungs or following mucociliary elevator action, the gastrointestinal tract.

LoD, LoQ - limits of detection and quantitation are levels, below which the biocide cannot be detected, and cannot be measured accurately, respectively.

mathematical model is a tool whereby inputs by the user result in a prediction of exposure through calculation. This is used in Tier 1 and Tier 2 assessments.

mixing & loading - handling biocide concentrates, diluting them and where necessary, putting the in-use formulation into the application apparatus.

NOAEL - the no observed adverse effect level.

none-detected values from exposure studies - see likelihood of exposure, limits of detection.

non-professional applications where products are for amateur/consumer application, and include examples where people in a workplace are not employed to use biocides (e.g. fly sprays in an office).

non-professional users are the general public - consumers - .There is an expectation – but little guarantee – that non-professionals will comply with instructions for use of a product. They have no access to controls or formal PPE.

penetration of PPE - that proportion of biocide that by-passes PPE, e.g. by soaking through seams and zips, being drawn in at neck, cuffs and ankles by the "bellows effect", that gets inside protective gloves by them being donned with contaminated hands.

permeation of PPE - the migration of biocide through the PPE barrier, e.g. solvent-based product through latex-based gloves.

personal monitoring is the sampling of a biocide during its application or mixing and loading, using samplers deployed on the person. See also static monitoring.

personal protective equipment (PPE) includes head, eye, respiratory (RPE), body, hand and foot protection that is designed to protect the wearer.

phases of activity are mixing & loading, application, post-application and removal of the biocide.

post-application covers the scenarios of sampling, maintaining and cleaning and may give rise to secondary exposure.

potential dermal exposure is the deposition of active substance or in-use biocide product on the outer surface of clothing and on any bare skin.

preparation or formulation is the biocidal product as placed on the market; the active substance with its coformulants, diluents, carrier materials and stabilisers.

primary exposure is that which occurs to the user (i.e. the person who applies the biocide).

probabilistic (stochastic) modeling is used to combine data in order to derive fair 'central tendency' and 'reasonable worst case' values. It is based on distributions of parameters. See deterministic estimates.

professional users (e.g. employees and the self-employed) will handle biocidal products within the framework of statutory requirements. They are trained and skilled in the main objectives of their occupation and may have some experience and skill in the use of the personal protective equipment (PPE) if that is necessary for their normal work. Not all professional users will have the knowledge and skills to handle hazardous biocidal products (e.g. incidental use of slimicides, insecticides, irregular disinfections and use of products containing preservatives).

protocols are detailed descriptions of the work to be undertaken in surveys or studies and the objectives to be achieved.

removal and disposal phase includes removing exhausted antifoulant coatings, disposing of used preservative fluids and burning treated timber.

risk assessment is the comparison of a predicted human dose from undertaking a task or tasks with appropriate toxicological endpoint values or NOAELs.

scenario is one or a number of well defined tasks for which exposure can be characterised.

secondary exposure is that which is not primary. It is characterised through the exposed person having little or no control over their exposure, which may be acute or prolonged. It includes re-entry to treated zones (contact with treated surfaces, inhalation of residual vapours, ingestion of residues).

specialised professional users probably have specialised knowledge and skill in handling hazardous chemicals. Protective measures as foreseen in the European Communities regulations on safety and health at work (instruction, training, exposure control, PPE) should be observed. Qualification might be documented by the endorsement of management systems for occupational safety and health, by certification to branch-specific standards or by approval through competent authorities.

static monitoring is sampling of background atmospheric concentrations or deposition.

studies are short laboratory simulations of limited tasks, or workplace based small surveys to indicate a likely exposure pattern.

surrogates or tracers - e.g. strontium salts, dyes, fluorescent agents - are used in surveys and studies to enable analysts to trace the exposure pattern.

surveys are extensive measurement of exposure resulting from real biocide application tasks.

task covers the phases of use of a biocide. It is a unit of operation within one or several scenarios.

Tier 1 is a screening level risk assessment.

Tier 2 is a detailed risk assessment, taking into account patterns of work and risk management measures.

Tier 3 is the output of an individual exposure study, possibly generated as a result of a data requirement for product registration.

TWA - time weighted average exposure by inhalation.

user sectors: industrial, professional, non-professional and secondary.

ventilation has several meanings. It may be a control measure in the workplace; it may refer to passive air changes within a building; and it may refer to the human breathing rate. The context should be clear from the text.

visualisation involves the introduction of a coloured or fluorescent tracer to the biocide in-use formulation for post-exposure quantitation.

work clothing - work uniform or work wear is a set of clothes worn at work. They are not designed to protect the health and safety of the worker and do not constitute personal protective equipment. However, they do protect the wearer to some extent from dermal exposure.

* The group preparing this document would have liked to use the following definitions for aggregate, combined and cumulative exposure. These do, however, not fit with other guidance, as can be seen from the citations below:

aggregate exposure covers exposure to a single chemical from multiple sources i.e. through primary exposure, secondary exposure and exposure to the same chemical in different products and matrices through various routes of uptake.

combined exposure is the total exposure arising from individual tasks (inhalation, dermal and oral) through different phases of use with a single product.

cumulative exposure covers concurrent exposure to different active substance with similar toxicological effects.

5 Worked Examples Database

The professional users worked examples database consists of a number of integrated databases, search algorithms and statistical routines designed to assist exposure assessments for professional use scenarios. Components of the system include the following elements.

- A database of fully worked examples of exposure assessments for professional use scenarios for all 23 product types. Each example contains a full description of the scenario, details of tasks performed, pattern of use, PPE, suitable indicative exposure values for relevant routes of exposure and all other quantitative data required to calculate total internal dose. Users can add their own new scenarios to this database.

- An export facility to an Excel exposure calculator that presents a calculation of internal dose in an approved standard format for each worked example.

- A database of measured exposure data (inhalation and dermal) for a wide range of occupational exposure scenarios relevant to biocides. Data are presented generically in terms of in-use formulation as rates of dermal exposure per minute and as air concentrations (low volatility formulations only). This database contains full contextual information on every measurement.

- Task-based search algorithms that search the measurement database on the basis of information provided in a worked example (e.g. formulation properties, tasks performed, method of application, environment and control measures) and return the most appropriate generic data sets. The search algorithm ranks these data sets according to their strength of analogy with the user provided information. It should be cautioned that these algorithms have only been designed to assess analogy between dermal exposure scenarios.

- Automated statistical analysis providing summary statistics and recommended indicative exposure values for each dataset. A second version of this system incorporates a Bayesian pooled analysis of all selected generic exposure data sets, weighting each data set by its strength of analogy to the assessment scenario.

A user of this system can thus create new worked examples for their own exposure scenarios, search for appropriate generic data and suitable indicative exposure values, calculate internal doses to the active substance and present these calculations in a preferred format suitable for inclusion in a product dossier. Users are not restricted to using exposure values extracted from the measurement database and can instead insert other suitable values taken from elsewhere (including product specific exposure data or predictions from mathematical models). It is envisaged that this system will develop further with time via the incorporation of additional measured exposure data and expansion of the catalogue of worked examples of exposure assessments.

In the computerised database a series of worked examples for workers has been collected, as indicated by title in Table 4.

Table 4: Overview of Worked Examples of Primary Professional Use Scenarios

Product type	Use scenario	Formulation type
PT 1: Human hygiene products	Sprayed on the hands and rubbed in for disinfection purposes	Liquid
PT 2: Private area and public health area disinfectant, etc.	Disinfection of floors, walls, furniture by using a cloth or a mop	Tablet
PT 3: Veterinary hygiene products	Disinfection of feet and hoofs of animals	Liquid
PT 4: Food and feed area disinfectants	Disinfect equipment, materials, walls and floors by spraying	Liquid
PT 5: Drinking water disinfectants	Disinfection of water (drinking-, pipes, wells) by adding product type to the water	Liquid
PT 6: In-can preservatives	Cleaning of cars using a car shampoo and hand held cloth	Liquid
PT 7: Film preservatives	Indoor decorative painting use a brush	Liquid
PT 8: Wood preservatives	Water-based vacuum timber pre-treatment	Liquid
	Solvent-based double vacuum timber pre-treatment	Liquid
	Application of curative paste using a trowel (reverse-reference approach)	Paste
	Brush application of curative paste	Liquid
PT 9: Fibre, leather, rubber and polymerised materials preservatives	Mixing and loading of biocide for an automated dipping process	Liquid
PT 10: Masonry preservatives	Spray application of masonry preservative	Liquid
PT 11: Preservatives for liquid-cooling and processing systems	Loading of biocide into a closed system	Liquid
PT 12: Slimicides	Loading of biocide into a closed system	Liquid
PT 13: Metal working fluids	Machining of metal parts	Liquid
PT 14: Rodenticides	Filling and placing boxes with bait	Granular bait
PT 15: Avicides	Spreading/ scattering pellets by hand	Pellets
PT 16: Molluscicides	Spreading/scattering bait by hand	Pellets
PT 17: Piscicides	Pour directly from the container (package) into the water	Ready for use liquid
PT 18: Insecticides, acaricides, etc.	Low pressure spraying	Liquid
PT 19: Repellents and attractants	Filling and placing boxes with bait	Granular Bait
PT 20: Preservatives for food or feedstocks	Fogging of empty food storage rooms with portable fogging machine (ULV technology)	Liquid
PT 21: Antifouling products	Use of antifouling paints in all phases: Task of a pot-man (mixing & loading), ancillary worker (lineman) and sprayer.	Liquid
PT 22: Embalming and taxidermist fluids	Use of formaldehyde in human pathologies during filling of sample vessels, cutting of tissue and disposal work	Liquid
PT 23: Control of other vertebrates	Professional ground-man placing bait	Solid

In section 3.3 an example is presented for ConsExpo (consumer exposure).

Example of an exposure assessment using a reverse reference scenario approach

This example reflects primary exposure of professional and non-professional remedial treatment of timber using wood preservative containing 0.5% active substance pastes by brush, trowel, caulking gun and gloved hand. This task is performed for approximately 30 minutes per day.

There are no generic exposure data for application of pastes. In the absence of generic data or a suitable mathematical model, an option is to assess the maximum exposure to the active substance, which would allow for an acceptable Assessment Factor (AF) based on an appropriate NOAEL and then assess the likelihood that exposures will exceed this level.

The maximum amount of active substance allowable can be calculated by dividing the NOAEL by the appropriate AF. Assuming a NOAEL of 25 mg kg^{-1} d^{-1} and an AF of 100, the maximum amount of active substance is given by:

$$NOAEL/AF = 25/100 = 0.25 \text{ mg kg}^{-1} \text{ d}^{-1}$$

For a non-volatile paste it is assumed that inhalation exposure is negligible and so assuming dermal absorption of 10%[7], to exceed an AF of 100, active substance contamination to the skin would need to exceed:

$$0.25 \text{ mg kg}^{-1} \text{ d}^{-1} \text{ x } 10 = 2.5 \text{ mg kg}^{-1} \text{ d}^{-1}$$

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

If the operator weighs 60 kg then active substance contamination would need to exceed:

$$2.5 \text{ mg kg}^{-1} \text{ d}^{-1} \text{ x } 60 \text{ kg} = 150 \text{ mg d}^{-1}$$

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 150 mg active substance will be

$$150/0.5 \text{ x}100 = 30{,}000 \text{ mg}$$

Assuming that dermal exposure will be predominantly to the hands and that gloves are worn, then rate of actual dermal exposure to the hands inside gloves is required to exceed:

$$30{,}000 \text{ mg } /30 \text{ min} = 1{,}000 \text{ mg min}^{-1}$$

The worked examples database for professional users contains approximately 400 measurements of actual hand exposure inside gloves across a wide range of tasks. The maximum exposure to an in-use formulation is 360 mg min^{-1} with a 95^{th} percentile of 23 mg min^{-1}. On this basis, for chronic exposure, it is concluded that a margin of safety of a least 100 will be achieved. This calculation is presented in the standard format in Table 5.

[7] The correction for dermal absorption is only necessary if in the study the NOAEL is derived from absorption through the used route of uptake is 100% (e.g. an oral study). If the study were a dermal study, then there should not be a correction for dermal absorption.

Table 5: Presentation of reverse reference scenario exposure assessment in standard format

Application of curative pastes **Product**	
active substance % w/w	0.50 %
Potential body exposure	
Indicative value mg/min	0
Duration min	30
Potential dermal deposit mg	0
Clothing type	Cotton coveralls, 20 % penetration
Clothing penetration %	20 %
Actual dermal deposit [*product*] mg	0
Hand exposure	
Indicative value mg/min (actual)	1,000
Duration min	30
Potential hand deposit mg	30,000
Mitigation by gloves	None
Actual hand deposit [*product*] mg	30,000
Total dermal exposure	
Total dermal deposit [*product]* mg	30,000
Active substance mg	150
Dermal absorption %	10 %
Systemic exposure via dermal route mg	15
Exposure by inhalation	
Indicative value m^3/min	0
Duration	30
Inhalation rate m^3/h	1.25
Mitigation by RPE	None
Inhaled [*product*] mg	0
Systemic exposure via inhalation route mg	0
Systemic exposure	
Total systemic exposure a.i. mg	15
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**0.25**

Annex 1: Exposure Data Sources

Data sets presented in this annex are not included within the worked examples database and fall into three main categories: mixing & loading of agricultural pesticides; non-professionals measured using florescence techniques and inhalation only measurement datasets (especially for volatile substances).

Consumer exposure data (all actual skin measurement data)

Description of Exposure Model	Application Method	Indicative Exposures	Uncertainty
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). *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products* 2. Brushing sheds and fences, outdoor (direct from can). *Ann. Occup. Hyg. 44: 421-426 (2000); ACP – SC 11000 – Consumer exposure to non-agricultural pesticide products*	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. *Ann. Occup. Hyg. 44: 421-426 (2000); ACP – SC 11000 – Consumer exposure to non-agricultural pesticide products*	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).

Description of Exposure Model	Application Method	Indicative Exposures	Uncertainty
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. *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products*	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. *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products*	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. *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products*	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.

Description of Exposure Model	Application Method	Indicative Exposures	Uncertainty
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. *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products*	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).

Worker exposure data

Models for Mixing and Loading

Description of Exposure Model	Application Method	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]*Lundehn et al., Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Heft 277, Berlin, Germany*	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]*Lundehn et al., Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Heft 277, Berlin, Germany*	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. *UK POEM, Guidance 1992, PSD, York, UK*	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.

Description of Exposure Model	Application Method	Indicative Exposures	Uncertainty
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. *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products*	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.

Models for Direct Handling

Description of Exposure Model	Application Method	Indicative Exposures	Uncertainty
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. *TNO report V96.064 (Lansink et al., 1996)* *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]*Schipper et al., 1996. TNO report V96.314* [2] *Fenske & Elkner, Tox. Indust. Health 6 :349-371 (1990)*	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. *Popendorf & Selim, Am Ind Hyg Assoc J 56: 1111-1120 (1995)*	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-can 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. *Cattani et al., Ann. Occ. Hyg. 45(4):299-308, 2001. Full data set at www.pesticide-research.curtin.edu.au*	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).

Generic (formulation) inhalation data models

Description of Exposure Model	Application Method	Indicative Exposures	Uncertainty
Professionals at companies ranging from multinationals to small independent engineering workshops handling mineral oils, semi-synthetic oils and synthetic fluids. *HSE report EH 74/4*	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}.
Professional applying insecticide at waist level, indoors, using cold (ULV) foggers. The models are based on simulation studies using professional operators in realistic building settings. *HSE survey 2000*	Cold (ULV) fogging	Inhalation 70.2 mg/m^3	Uncertainty is *moderate.* 90 % C.I. for 75^{th} % 49-102

Exposure Data from MEGA. These data are not generic, because they cover inhalation to a volatile compound.

Description of Exposure Model	Application Method	Indicative Exposures	Uncertainty
Indicative data to assess inhalation exposure to formaldehyde in human pathologies (e.g. product type 22). The dataset is determined by technical measurement services of the Institution for Statutory Accident Insurance and Prevention in Health and Welfare (BGW) in Germany. *The detailed report can be downloaded (www.bgw-online.de)!* The following activities in pathology are covered by the data: 1. Filling of sample vessels with water based formaldehyde solution (4 % w/w). 50-460 vessels up are filled in pathology labs using up to 2 L formaldehyde solution (4 % w/w). Workplace: separate room without LEV. Duration per shift: 7-57 minutes. 2. Cutting of tissue samples onto a cutting board. Formaldehyde (4 % w/w) is present as fixing agent in the vessel, on tissue sample and cutting board. Workplace: Cutting room with under-table extraction. Duration per shift: 11-178 minutes. 3. Disposal of preservatives (tissue samples). The preservatives is formaldehyde saturated (max. 4 % w/w). Workplace: separate room without LEV. Duration per shift: 7-120 minutes.	1. Filling of sample vessels	Inhalation exposure to formaldehyde 0.76 mg/m^3	Uncertainty is *moderate.* 90 % C.I. for 75^{th}: 1.19 – 1.53 . (inhalation, number of data: 42)
	2. Cutting of tissue samples	Inhalation exposure to formaldehyde 0.72 mg/m^3	Uncertainty is *moderate.* 90 % C.I. for 75^{th}: 1.01 – 1.14. (inhalation, number of data: 191).
	3. Disposal of preservatives	Inhalation exposure to formaldehyde 1.43 mg/m^3	Uncertainty is *moderate.* 90 % C.I. for 75^{th}:2.07 – 2.58. (inhalation, number of data: 89).

Exposure Data from PHED (Pesticide Handler Exposure Database)

Description of Exposure Model	Application Method	Indicative Exposures	Uncertainty
Scenario 17 of the PHED (Pesticide Handler Exposure Database) "Granular bait dispersed by hand" presents indicative exposure data for inhalation and dermal exposure. The data presented are summaries of the worker exposure outputs generated by PHED. These estimates are derived from actual field studies and are based on the physical factors of a handler scenario (e.g. the type of protective clothing worn, method of application, formulation type, etc.) Reference: EPA, PHED Surrogate Exposure Guide; Estimates of Worker Exposure from The Pesticide Handler exposure Database Version 1.1., August 1998.	Granular bait dispersed by hand: No clothing scenario	Inhalation exposure: 1034 µg/kg a.i. handled Head and neck exposure: 12.47 mg/kg a.i. handled Upper and lower arm, chest, back, thigh and lower leg exposure: 157.96 mg/kg a.i. handled Hand exposure: no data	Uncertainty for dermal exposure is high due to lack of no glove replicates for this scenario. Uncertainty for inhalation exposure is medium (number of data: 16)
	Granular bait dispersed by hand: Single layer, No gloves scenario	Inhalation exposure: 1034 µg/kg a.i. handled Head and neck exposure: 12.47 mg/kg a.i. handled Upper and lower arm, chest, back, thigh and lower leg exposure: 136.4 mg/lb a.i. handled Hand exposure: no data	Uncertainty is high due to lack of no glove replicates for this scenario. Uncertainty for inhalation exposure is medium (number of data: 16)

Description of Exposure Model	Application Method	Indicative Exposures	Uncertainty
	Granular bait dispersed by hand: Single layer, Gloves scenario	Inhalation exposure: 1034 µg/kg a.i. handled Head and neck exposure: 12.47 mg/kg a.i. handled Upper and lower arm, chest, back, thigh and lower leg exposure: 136.4 mg/kg a.i. handled Hand exposure: 7.94 mg/kg a.i. handled	Uncertainty is medium Uncertainty for inhalation exposure is medium (number of data: 16 and 15 replicates for hand exposure (all non detect (LOQ = 41 µg))

Annex 2: Principles of Good Control Practice

The following text details the principles of good practice for the control of exposure to substances hazardous to health. As such the principles should be followed when considering preventing / controlling exposure to biocides. The focus is on inhalation exposure.

Adequate control
Considerable emphasis should be placed on using good control practice and that it would be considered adequate if:

- the principles of good control practice are applied; and
- a workplace exposure limit is not exceeded.

The primary emphasis for achieving adequate control relies on the application of eight principles of good control practice.

Principles of good control practice
'To be effective in the long-term, control measures must be practical, workable and sustainable'.

There are eight principles (a to h) that have to be followed to develop effective control measures. The principles should be regarded as a 'package', which must all be properly applied in order to achieve effective, reliable and sustainable control of exposure. Applicants and evaluators cannot pick and choose which principles to apply – they are all important in achieving adequate control. Principle (a) is not more important than principle (h), although there is a logical progression in how they are presented and should be considered.

Principle a
Design and operate processes to minimise emission, release and spread of contaminants.

It is more effective to reduce the emission of a contaminant at source, rather than to develop ways of removing the contaminant from the workplace, once it has been released and dispersed. Clearly, with the way that many biocides are applied this approach is often not possible. However, it is possible to consider reducing in number the size, emission or release rate, as much as possible. Indeed it is often not possible to obtain adequate and reliable control unless this is done. Consequently, to identify how people are exposed during the application of biocides, it is essential to recognise the principal sources and how the contaminant is transferred within the workplace. It is easy to miss significant sources and causes of exposure. Application of biocides will lead to the emission and release of contaminants. The way this occurs and the scale of release needs to be understood because only then can alterations be developed to minimise emission, release and spread of the biocide. This is best done at the design stage. Other people, workers or bystanders, may be significantly exposed even though those applying are protected; for example, by wearing PPE. In such circumstances, the most practical option to protect those people not directly involved in application may be to segregate the process.

Once the number and size of sources has been minimised, consideration should be given to whether further reduction can be made by enclosing the process. If enclosure is possible **(**e.g. by sealing a building prior to fumigation), the enclosure should be big enough and robust enough to cope with the application process. For airborne contaminants, properly designed exhaust ventilation applied to the enclosure may be needed to minimise leakage into the

workplace. Work methods should be designed and organised to minimise the number of people exposed, the duration, frequency and level of exposure. For example, when treating a large article with a wood preservative, containment may not be feasible; natural ventilation may, however, with the right precautions, be relied on to disperse vapour. Clearly this would be best done at the end of a shift, in controlled circumstances and when fewer people will be present.

In addition to identifying significant sources, it is essential to identify and consider all work groups and bystanders that may be exposed. It is easy to miss or underestimate the exposure of those engaged in non-routine activities such as work done by maintenance personnel and contractors. Control measures at the outset should be designed for ease of use and maintenance. If they include working methods that are difficult to follow or involve hardware that is difficult to repair, the control measures will probably not be maintained or sustained. Inevitably their effectiveness will fall and exposure will rise.

Principle b
Take into account all relevant routes of exposure – inhalation, skin absorption and ingestion – when developing control measures

The physical and chemical properties of a biocide, in the circumstances of use, have a great bearing on which route (inhalation, dermal or ingestion) of exposure, or combination of routes, is most important. If there is no exposure, there is no risk to health, but for many biocides the usage pattern nearly always leads to some exposure. There is therefore a need to consider:

- the health effects that the biocide can cause;
- the way the biocide is used;
- the degree of exposure; and
- how exposure occurs.

An adequate risk assessment considers all routes by which the biocide might enter the body and, in the case of direct contact, how a biocide might affect the skin and eyes. In some cases, it might be immediately obvious that not all routes apply. Therefore, for the exposure assessment there is a need to:

- identify all sources and routes of exposure; and
- rank these routes in order of importance.

Where inhalation is the most relevant route, the main focus for control will be sources of emission to air. Where the main concern is ingestion or effects on, or as a result of penetration through the skin, the main focus for control will be sources of contamination of surfaces or clothing and direct contamination of the skin. The exposure assessment should identify and, if possible, grade or rank the contribution of all routes of exposure to total exposure. In this way control effort can be directed at the main sources and causes of exposure. Skin contact should be prevented, if possible, where contamination may lead to skin absorption, ingestion or direct health effects on the skin. Regular cleaning of surfaces that can become contaminated, e.g. the outside of a knapsack sprayer, should be undertaken. The frequency of cleaning should be based on the rate at which the surfaces become contaminated and how often skin is likely to come into contact with them. Gloves are often used to provide protection against skin contact with biocides. However, transfer of contamination from the outside of protective gloves to the inside is common. The risk assessment should identify the fact that if gloves are to be worn then users have to be trained

in the correct technique for putting on and taking off their gloves. If biocides are applied in a room, which may become contaminated, and this contamination may contribute significantly to exposure, people should not increase their exposure by activities such as:

- eating;
- drinking;
- smoking; or
- using cosmetics in the workplace.

If the workroom is liable to be contaminated, people should have clean areas to rest, eat or drink. Where skin contact is relevant it will be necessary to provide:

- adequate and accessible welfare facilities for washing and changing;
- laundered or disposable workwear. The frequency of laundering will depend on the degree of contamination and the hazardous nature of the biocide;
- separate storage for day-wear and work-wear;
- clean facilities; and
- segregation of clean and dirty areas if the risk of contamination is severe.

It is good practice to keep workplaces clean, however cleaning methods should not lead to spread of contamination. If dust exposure from contaminated work clothing could be significant, clothing should be used that is made from low dust-retention and low dust-release fabric.

Principle c

Control exposure by measures proportionate to the health risk

The more severe the potential health effect and the greater the likelihood of it occurring, the stricter the measures to control exposure will be required. Control measures that are adequate will take into account the nature and severity of the hazard and the magnitude, frequency and duration of exposure. They will therefore be proportionate to the risk. The consequences of failing to control exposure adequately should be considered. If the health effects arising from exposure are less serious, such as simple, reversible irritation, and are not likely to cause long-term harm, it may be sufficient to reduce exposure by simple low-cost measures, such as replacing lids on vessels. In such cases, it may be unnecessary to go to greater trouble and expense to reduce the risks even further. Where the health effects arising from exposure are more serious then exposure will need to be reduced to low levels. How low these levels need to be will depend on the nature of the hazard, the likelihood of harm occurring and the degree of confidence in the information on potential health effects. The control measures necessary in this case might be extensive, take time to develop and implement, and be relatively costly. The measures should control the risk of both long-term (chronic) and short-term (acute) health effects.

Sometimes, control measures may be selected that reduce exposure more than is strictly necessary. Usually, this occurs because some controls are more convenient and acceptable. For instance, people may prefer to wear air-fed respiratory protective equipment rather than filtering devices, although the protection offered by the latter would be adequate, if well fitted. Such cases do not undermine the general principle that, overall, control measures should reduce exposure to a level which minimises any risk to health. Control measures should be kept under review to ensure they remain effective enough in the light of new information. Knowledge and understanding of the potential health risks from the biocide

may change. Advances in the application process and control technology and work organisation may enable changes to be made to reduce exposure.

Principle d
Choose most effective and reliable control options, which minimise escape and spread of contaminant from sources

Some control options are inherently more reliable and effective than others. For example, the protection afforded by personal protective equipment (PPE) is dependent upon good fit and attention to detail. In contrast a very reliable form of control is changing the process so that less of the biocide is emitted or released. For example, application by brush may be easier to control than by spraying. The most effective and reliable control option for particular circumstances should be chosen and these should be directed at the main source and cause of exposure. There is a broad hierarchy of control options available, based on inherent reliability and likely effectiveness. These include:

- elimination of the biocide;
- modification of the biocide, application process and/or workplace;
- applying controls to the process, such as enclosure;
- ways of working to minimise exposure; and
- equipment or devices worn by individuals.

Clearly, for many biocidal products, some of the above control options are not feasible. However, raising the profile of the hierarchy of control means that the Applicant should have considered the possibility of elimination and asked the question; can the biocide be eliminated or replaced with something else? Elimination means exposure cannot occur and, as an option, should always be considered first. If it were not possible to eliminate then a reliable form of control would be to change the process so that less biocide is released. Controls applied to the process might be effective, but will require maintenance and are unlikely to be as reliable as elimination. The key message is that there is a hierarchy of reliability of control options and this hierarchy is often linked to their effectiveness. Many of these decisions will be made by the user and not the Applicant.

Providing PPE, such as gloves or respirators, may appear to be a quick and easy option. In practice, it is likely to be the least reliable and effective option. Indeed, it may not actually be the cheapest if a PPE programme is compared like-for-like with the cost of providing other control options. What is required is the development of a set of integrated control measures that are effective and reliable enough to control exposure adequately. The ‘hierarchy’ of control should not be seen as a marker of reliability and effectiveness so rigidly that some control options are viewed automatically as ‘good’ while others are seen as ‘bad’. This ‘good-bad’ view can hinder the development of what is needed, that is, effective, reliable, practicable and workable control measures. There is a large range of control options available. Each will have its own characteristics as to when it can be applied, how much it can reduce exposure, and how reliable it is likely to be. As a matter of principle, the aim should be to select from the most reliable control options. Again, it is important not to be too fixed in one’s thinking as, in many cases, an effective set of control measures will turn out to be a mix of options – some more reliable than others.

Principle e
Where adequate control is not reasonably practicable by other means, provide suitable Personal Protective Equipment (PPE) in combination with other measures

Effective control measures usually consist of a mixture of process and/or workplace modifications; applied controls, such as LEV, and methods of working that minimise exposure and make the best use of controls. Sometimes the mix includes PPE, such as respirators, workwear or gloves. Personal protective equipment tends to be less effective and reliable than other control options, because it:

- has to be selected for the individual;
- has to fit the individual and not interfere with their work or other PPE worn at the same time;
- has to be put on correctly every time it is worn;
- has to remain properly fitted all the time the individual is exposed;
- has to be properly stored, checked and maintained
- tends to be delicate and relatively easily damaged; and
- fails to danger, sometimes without warning.

The possibility of failure at each of the steps needed for successful use of PPE makes it difficult to achieve sustained and effective exposure control across a population of people. Even if a reliable, defined sustained reduction in exposure is achieved using PPE, it offers no protection to others working nearby not wearing PPE. Control options, such as change of process or applied controls, are likely to be more effective and reliable than PPE. They will probably be cheaper long term, but it may take longer to plan and organise them. It is important not to rely solely on PPE as the only control option and believe exposure is adequately, effectively and reliably controlled. Unless, that is, PPE really is the only feasible control option. Normally, PPE should be used to secure adequate control in addition to the application process, operational or engineering measures, and where adequate control of exposure cannot be achieved straight away, or solely by application or use of these other measures.

With respect to biocides PPE may be the essential element for controlling exposure; in which case a programme to organise and manage this element will be required. PPE, including RPE, requires proper:

- selection;
- fitting;
- use;
- storage;
- checking and maintenance; and
- training for use.

A PPE programme involves the careful, routine training of the behaviour of people, including wearers and supervisors. If used, it must be set up carefully, managed properly and checked regularly. Clearly, the type of PPE provided should be both adequate and suitable. Adequate, in this context, means technically capable of providing the required degree of protection; appropriate selection is therefore very important. Suitable, means correctly matched to the needs of the wearer, the job and the work environment. Choice, comfort, user trials and supervision will all be important. Sometimes the PPE chosen may offer protection that is more than adequate, but is chosen for its suitability. For instance, an airline hood may be more comfortable and, therefore, more acceptable than a full-face mask, even though the additional protection is not indicated from the risk assessment. As with gloves, shoes and clothing, one size of respirator will not fit everyone. People must be offered a choice of

device. This is especially the case for half-mask devices, which need a good and complete fit against the face of the wearer to work effectively.

Principle f
Check and review regularly all elements of control measures for continuing effectiveness

Once an effective set of workable control measures have been devised, they need to be put in place and managed. This includes training all relevant people in the use and maintenance of the control measures. The requirement for maintenance covers all elements of the measures to achieve effective and sustained control of exposure. These include any defined methods of working, e.g. supervisory actions and record keeping, (i.e. the 'software' of control) as well as the 'hardware' of control, such as PPE. Certainly, whatever hardware is involved must be checked and must continue to function as intended. In addition a similar approach needs to be taken to check the actions people must take and the methods of working they need to adopt. The effectiveness of control measures should be checked regularly. Which checks, and how often, will depend on the particular control measures. The consequences if the measures fail or degrade significantly, should be considered. Process changes are likely to be more stable and reliable than, say, LEV. In turn, LEV is likely to be more stable and reliable than controls that rely on routine human behaviour. In practice, it is necessary to draw up a simple practical programme for checking essential elements in each set of control measures. For instance, it may be necessary to check every week that operators are still adopting the correct methods of working. Checking on the working of the LEV may only be needed every month. Checking the continuing effectiveness of the process changes may only be needed every six months.
It is however important not to miss the basic checks. It may be very obvious that an important element of a set of control measures has failed and the operator may well be in the best position to check this.

The frequency of checks should be adjusted to what is needed to keep the control measures effective. There is nothing more likely to cause people to ignore or not take checks seriously than routinely measuring and recording 'no change' over long periods of time. Checks have to have some purpose and meaning. Exactly what checks should be done will depend on:

- the control measures in use;
- how reliably they control exposure;
- how well characterised they are; and
- the consequences of control degradation or failure.

When control measures are known to be reliable and effective, the focus of attention should be on checking the critical elements of the measures to ensure continued effectiveness. Where reliability and effectiveness are not known, it may, ultimately be necessary, to measure exposure to the biocide in question.

Principle g
Inform & train all employees on hazard and risks from substances and use of control measures

For control measures to be effective, operators need to know how to use them properly. Most importantly, operators need to know why they should be bothered to work in a certain way and use controls as specified; they need to be motivated. Motivation comes from understanding what the health risks are and, therefore, why the control measures are

important. It also comes from the user having confidence in the control measures and believing that they will protect their health. If the health risk is serious and is chronic or latent in nature, a good appreciation of the risk is especially important. With latent or delayed risks, exposure can often be excessive, with no short-term warning, such as smell or irritation, to indicate that anything is amiss. People exposed during application of a biocide need to be told, clearly and honestly, why they should use the control measures, and the consequences, in terms of ill health, if they do not use them.

Operators need to know how control measures work to use them correctly, and to recognise when they are not working properly. This means training the operators that are directly involved, as well as supervisors and managers. This is so that everyone can identify when controls are being used in ways that reduce their effectiveness. It is important to know whether the individual is working in a way that reduces the effectiveness of control measures because:

- there is no other way of doing the job; or
- because they do not know any better.

If the control measures are difficult to use or get in the way of doing the job, they will need redesigning. If the control measures are well designed and tested but are still misused, then the individual needs retraining and motivating. Most control measures involve methods of working, which means that, at the design stage, it is essential to ask workers and supervisors for their views on how best to do the work so exposure is minimised. They should be asked whether a proposed method of working is practical and how to get the best out of the proposed control measures. Easily followed, convenient and simple procedures, which minimise exposure, and are built-in to the working method, are more likely to be followed.

Principle h
Ensure introduction of control measures does not increase overall risk

Process changes, enclosures, ventilation, new methods of working, PPE and other changes to control exposure can introduce new risks. For instance, process changes may mean that equipment cannot be fully decontaminated before maintenance staff are given repairs to do. New methods of working may create risks of musculoskeletal injury. LEV has to be maintained, introducing possible risks of access and manual handling of heavy parts, while PPE can restrict movement, feel and vision. People designing control measures should look for these ‘new’ risks and minimise them. They must not only focus on the risk from biocides hazardous to health. A good control solution is one which minimises the health risk while reducing maintenance burdens, being relatively foolproof, and not introducing other risk.

Annex 3: Use and Selection of Appropriate PPE

There are two points to acknowledge when consider the implications of using Personal Protective Equipment (PPE) in the field of biocides. These are:

- what default values, for the protection offered by PPE, should be used when undertaking an exposure assessment (this is termed 'proper functioning'); and
- what impact does the recommendation to use PPE have on the operator (this is termed 'proper use')?

Clearly, 'proper functioning' is addressed when undertaking the quantitative exposure assessment, whereas 'proper use' is considered as a means to prevent exposure. It is also important to remember that we are currently primarily concerned with the user of the biocide, however for the use of PPE to be successful both employer and employee need to take an active part in the selection and use of PPE.

Specific requirements to consider when recommending use of PPE

There are eight key issues to consider when considering PPE; this selection will, briefly, address these issues. This Section should also be read in conjunction with the above Section on the principles of good control practice.

- Provision of suitable PPE

It must be remembered that PPE should always be regarded as the `last resort' to protect against exposure to biocides. The provision of appropriate engineering controls and safe systems of work should always be considered first and this should be the basis of the users risk assessment. However, where there are no reasonably practicable other means of adequately controlling the risks, as will often be the case for the application of a biocide, then PPE will still be needed. The PPE which is provided should be appropriate for the risks involved, take into account ergonomic requirements (i.e. the nature of the job and the demands it places on the user) and the state of health of the person who may wear it, be capable of fitting the wearer correctly, and be effective to prevent or adequately control the risk.

- Ensuring that where more than one item of PPE has to be worn to control risks, then it is compatible and is effective against the risks

Where the presence of more than one health and safety risk makes it necessary for a user to wear or simultaneously use more than one item of PPE, then the PPE must be compatible and continue to be effective against the risks, e.g. certain types of respirators will not fit properly and give adequate protection if a safety helmet is worn.

- Assessment of Personal Protective Equipment to determine whether it is suitable

Where PPE has to be provided to adequately control the risks, then an `assessment' has to be made to determine what PPE is suitable before it is chosen. This will ensure that it is correct for the particular risks involved and for the circumstances of its use. The assessment should include assessing the risks to health which have not been avoided by other means and defining the characteristics which the PPE must have to be effective against the assessed

risks. It should then compare the characteristics of PPE available against the defined effective characteristics needed.

- The maintenance and replacement of PPE

Any PPE provided to users has to be maintained in an efficient state, in efficient working order and in good repair. To ensure the equipment continues to provide the degree of protection for which it was designed, an effective system of maintenance is essential and would include, where appropriate, cleaning, disinfection, examination, replacement, repair and testing. The details of the maintenance procedures to be followed and their frequency should normally follow manufacturers' maintenance schedules and should be documented together with who has the responsibilities for carrying them out. Where appropriate, records of tests and examinations should also be kept. This will obviously depend on the type of PPE, e.g. gloves may only require periodic inspection by the user. Generally speaking, PPE should be examined to ensure it is in good working order before it is issued to the wearer and also be examined before it is put on and should not be worn if it is found to be defective or has not been cleaned. A sufficient stock of proper spare parts, where appropriate, should be available to wearers.

- Provision of appropriate accommodation for PPE when it is not being used

Where PPE is required, then appropriate accommodation for it when it is not being used has to be provided. Storage of PPE should be adequate to protect it from contamination, loss, or damage by harmful substances, damp or sunlight. If it is likely that the PPE will become contaminated during use, then the accommodation should be separate from any provided for ordinary clothing. The accommodation required will obviously depend on the equipment and, in some cases, need not be complex or fixed, e.g. pegs would be suitable for weatherproof clothing and safety spectacles could be kept by the user in a suitable carrying case.

- Provision of adequate and appropriate information, instruction and training

Employees have to be provided with adequate and comprehensible information, instruction and training in order that they know the risks which the PPE will avoid or limit, the purpose and manner in which the PPE is to be used and any action the employee has to take to ensure it remains in an efficient state, in efficient working order and in good repair. Everyone who is involved in the use or maintenance of PPE should be appropriately trained. A systematic approach to training, including the elements of theory as well as practice, in accordance with the recommendations and instructions supplied by the manufacturer, is required in order that Users are trained in its proper use, how to correctly fit and wear it, and its limitations; managers and supervisors are aware of why PPE is being used and how it is used properly; and training is given to those people who are involved in its maintenance, repair, testing and selection for use.

The instruction and training provided will obviously depend on the complexity and performance of the PPE but should typically include:

1. An explanation of the risks present and why PPE is needed;
2. The operation, performance and limitations of the equipment;
3. List instructions on the selection, use and storage of PPE related to the intended use. Written operating procedures such as Permits to Work involving PPE should be explained;

4. Factors which can affect the protection provided by the PPE, e.g. other PPE, personal factors, working conditions, inadequate fitting, defects, damage and wear;
5. Recognition of PPE defects and arrangements for reporting loss or defects;
6. Practice in putting on, wearing and removing the equipment;
7. Practice and instruction in inspection and, where appropriate, testing of the PPE before use;
8. Practice and instruction in the maintenance, which can be done by the user, such as cleaning and the replacement of certain components; and
9. Instruction in the safe storage of equipment.

- Ensuring that PPE provided to employees is properly used

Employers have a duty to take all reasonable steps to ensure that any PPE equipment provided to users is properly used and adequate levels of supervision should therefore be provided to ensure that the training and instructions are being followed. Users have a duty to ensure they use the PPE in accordance with any training and instructions they have received, and to take all reasonable steps to ensure that the PPE is returned to the accommodation provided for it after use.

- Duties on employees provided with PPE to report any loss or obvious defects to his employer

All employees who have been provided with PPE have a duty to report immediately any loss or obvious defect to their employer. Arrangements should therefore be made to ensure that employees can report the loss of or defects in PPE and these arrangements should also ensure that defective PPE is replaced or repaired before the employee concerned re-starts work.

Protective gloves
Protective gloves are available in a wide range of natural and synthetic materials; however, there is no single glove material (or combination of glove materials) able to provide unlimited resistance to any individual or combination of chemical agents. There are three ways in which any protective glove will, at some stage, fail to protect the wearer from exposure to any chemical agent and these are:

permeation – the process by which a chemical agent migrates through the protective glove at a molecular level;

penetration – the bulk flow of a chemical agent through closures, porous materials, seams and pinholes or other imperfections in the protective glove;

degradation – a damaging change in one or more physical properties of the protective glove as a result of exposure to a chemical agent.

Selecting suitable protective gloves
The selection of suitable protective gloves is a complicated procedure and the degree of protection they give is not always easy to establish. When choosing gloves, always seek expert help from the manufacturer/distributor of the chemical agent or glove. They are best placed to provide glove performance test data, which can be used to assist in predicting the permeation, penetration and degradation of specific glove materials by specific chemical agents.

There are four requirements which must be met for any protective glove selected to be suitable. The glove must:

- be appropriate for the risk(s) and the conditions where it is used;
- take into account the ergonomic requirements and state of health of the person wearing it;
- fit the wearer correctly, if necessary, after adjustments; and
- either prevent or control the risk involved without increasing the overall risk.

Proper selection should therefore take into consideration the wearer, the workplace conditions and the protective glove. Employees need to be trained in the correct way to put on, wear and then take off protective gloves to ensure maximum protection. If protective gloves are selected or worn incorrectly there is every possibility that this may increase the wearer's overall risk to health because:

- contaminant may get inside the glove to reside permanently against the skin, which could cause greater exposure than if a glove had not been worn at all; or,
- wearing a glove for extended periods can lead to the development of excessive moisture (sweat) on the skin, which in itself will act as a skin irritant; or,
- wearing gloves manufactured in natural rubber (latex) can cause an allergic reaction in susceptible individuals, causing the skin disease contact urticaria to occur.

Selecting protective gloves must be part of an overall health and safety risk assessment for the job to be done. The risk assessment must clearly demonstrate that exposure to the health risk is unavoidable and that other methods of control are not reasonably practicable. Remember that gloves should be used as a control measure only as a last resort and where other methods of control are not reasonably practicable. This is because:

- gloves only protect the wearer – they do not remove the biocide from the workplace environment;
- some types of glove are inconvenient and interfere with the way people work;
- wearing gloves interferes with the wearer's sense of touch;
- the extent of protection depends upon good fit and attention to detail;
- if protective gloves are used incorrectly, or badly maintained, the wearer may receive no protection; and
- for glove design to be effective, the glove needs to be used correctly in the workplace.

Glove selection is a complex issue and the importance of using a material which provides suitable and sufficient protection, depends on the nature of the chemical and extent of exposure. Where there is a choice of glove material, the extent of exposure to the chemical agent will be a significant factor in choosing between, for example, a neoprene glove or a less costly natural rubber glove. If workers' gloves are significantly contaminated for extended periods, the neoprene glove may be required. If, however, there is only occasional splashing of chemical onto the glove, then the less costly natural rubber glove may be adequate. Other factors to consider are the manual dexterity required for the job and required length of the glove (i.e. are gauntlet gloves required?). If workers cannot do their job because the glove material is too thick or stiff, then they may decide not to wear them. Always remember that if the inner surface of a glove becomes contaminated, it will not matter how much care, attention and expertise has gone into the selection process – exposure will occur. If, for example, contaminated gloves are removed temporarily, then the operators' hands may become contaminated from handling the gloves. If the same pair of gloves is then put back

on again, there could be transfer of chemical contaminant to the inside surface of the glove. To prevent this, the gloves should be thoroughly washed before being taking off.

Selecting suitable RPE

The decision to use RPE should only be made after a justification has been made via a risk assessment. Examples of when RPE can be used include:

- where an inhalation exposure risk remains after other reasonable controls have been put in place (i.e. there is a residual risk);
- short term or infrequent exposures (e.g. cleaning of equipment) where it is decided that other controls at source are not reasonably practicable;
- when other control measures are being put in place (e.g. interim measures)
- where there is a need to provide RPE for safe exit from an area where hazardous substances may be released suddenly in the event of a control systems failure (e.g. use of sulphuryfluoride); and
- emergency work or temporary failure of controls where other means of controls are not reasonably practicable.

Ideally, the approval of a biocidal product will not rely on the use of RPE. However, in some cases at the approval stage, e.g. when there is residual risk, it may be necessary to recommend the use of RPE. This should not be because other control measures are inadequate on their own, but to provide additional protection. During the exposure assessment there is an assumption that the user of the product will have put into place all eight principles of good control practice. When RPE is necessary there must be a system to demonstrate that selection of RPE has been made via a transparent and consistent procedure. Detailed information relating to selection of RPE can be found in HSE Guidance '*Respiratory protective equipment at work – A practical guide'* (HSE, 2005).

Annex 4: Human Exposure to Rodenticides (Product Type 14)

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 of 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)
- Gases.

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

These boxes/stations, especially when tamper-proof, are used to prevent contact by humans, and animals larger than the target pest, 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. 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/cycles 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 householders). 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 justified 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 gases (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.
The present TNsG contains few models that are suitable for purpose. 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[8]

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, impregnated 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.

Duration and frequency of the use phase[8]

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, impregnated 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

$ 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).

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, impregnated 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[8]).

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, for example, the 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).

<u>Application phase</u>

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, dispensing

impregnated grain, pellets and other solid formulations, pouring of liquid concentrates and drinking poisons and, finally, handling of dust blowers. 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 for an adult of both forearms including backs and palms of hands is estimated to be 2000 cm^2; combined area of backs and palms of both adult hands being 840 cm^2 (USEPA, 1989).

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 a 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. Using a broom as a means to clean up may give rise to dust containing the active substance.

EXAMPLES FOR TASK-BASED EXPOSURE SCENARIOS

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 $30 \times 0.01 = 0.3$ cm3 of the application substance. The standard wax block is about $12 \times 5 \times 4 = 240$ cm3, 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 a broom for 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:

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

C_{inh} = 50000 × 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 applied directly into rat holes or placed 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.

<u>Use phase</u>
Attending bait boxes normally involves re-filling the boxes with the product which is handled during the application phase scenario (previous scenario).
In the use phase bystanders, e.g. children, may come 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.

<u>Disposal</u>
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 × 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 in restricted 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 sweeping with a broom 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, for example, 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 × 0.005 / 6) × 0.0001 × 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 × 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 while wearing RPE.

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 × log(5)} = 59.2.

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

A 90% confidence interval for the 75th percentile is then given by exp(log(59.2) ± 1.6449 × 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: $\quad p / \exp\left(1.6449 \sqrt{\sigma^2 n^{-1} + z_p{}^2 \sigma^2 (2n)^{-1}} \right)$

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***
	5	1.75	2.45	3.10	3.71	4.31	4.88	5.45	5.99	6.53
Sample	***10***	1.49	1.88	2.22	2.53	2.81	3.07	3.31	3.55	3.77
size	***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***
	5	2.19	3.45	4.78	6.15	7.55	8.99	10.45	11.93	13.44
Sample	***10***	1.74	2.40	3.02	3.61	4.18	4.72	5.25	5.77	6.28
size	***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

Annex 6: Transfer coefficients – Dislodgeable residues

Substrate	Residue	Transfer efficiency	Reference no.
Painted wood (MDF)	Dried fluid	3 %	1
Short pile tufted nylon carpet	Dried fluid	6 %	1
Carpet	Powder	<1 %	4
Nylon carpet	Powder	1 to 3 %	5
Carpet	Dried fluid	9 % averaged	6
Carpet	Powder	9 %, 3 % if trodden-in	8
Rough sawn wood	Dried fluid	2 %	1
White smooth glazed tile	Dried fluid	55 %	1
Brown rough glazed tile	Dried fluid	60 %	1
Non-slip vinyl flooring	Dried fluid	15 %	1
Vinyl	Powder	50 %	8
Various types of surface	Dried fluids	8 to 18 %	2
Smooth surface	Powder	2 to 6 %	3
Cotton, knitwear, plastic, wood	Dried fluid	20 % - dry hand	7
Cotton, knitwear, plastic, wood	Dried fluid	30 % - wet hand	7
Stainless steel	Powder	70 % - dry hand	8

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