TECHNICAL NOTES FOR GUIDANCE

HUMAN EXPOSURE TO BIOCIDAL PRODUCTS

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GUIDANCE ON EXPOSURE ESTIMATION

In four parts:

Foreword and summary

Part 1

Part 2

Part 3

Foreword / Summary

June 2002

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The Technical notes for Guidance is in three parts, as indicated below.

EXECUTIVE SUMMARY

PART 1

Part 1 contains the principles used in human exposure assessment. It links in many ways to the guidance on exposure assessment being developed for New and Existing Substances (NESS).

Part 1 comprises the following chapters:

PART 2

Part 2 contains specific guidance on human exposure assessment. It has links with the Technical Guidance Document (TGD) for Risk Assessment for New and Existing Substances, section exposure assessment.

Part 2 comprises the following chapters:

PART 3

Part 3 contains a set of worked examples that may help the exposure assessor to understand the approaches taken in human exposure assessment for biocidal products.

Part 3 comprises the following chapters:

Executive Summary

This report was funded under contract B4-3040/2000/291079/MAR/E2 of the European Commission, DG-Environment. It builds upon the concepts developed in the 1998 report, reference 97/505/3040/DEB/E2, of the Biocides Steering Group on human exposure assessment.

The report is in three parts:

Part 1 Introduction, sets out the basic concepts and models for estimating exposure

Part 2 Specific guidance on estimating exposure

Part 3 Worked examples

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). Other than the report of the Biocides Steering Group 97/505/3040/DEB/E2, there is no central source of guidance on human exposure assessment to biocidal products.

Specific guidance on particular matters is referenced in the appropriate portion of the text, for example the conduct of surveys to monitor exposure.

How to use this guidance

Part 1 of these Technical Notes for Guidance sets out the background for the estimation of human exposure. It explains the concepts and proposes a glossary of terms. It is recommended that this Part would be read first to introduce exposure assessors to some basic elements. It is not meant to give an overview in full.

Part 2 explains the stages that lead from a proposed biocidal application through to the range of estimates of human exposure expected for such an application. These are estimates of the exposure of the user and of other people exposed as a consequence of the application. The tiered approach means progressive refinement of the estimate, from worst case modelling through to an estimate incorporating risk management measures (such as process control, permits to work and exclusion times, product applicator design, and the use of personal

protective equipment) under field conditions. A summary of the estimation process appears as a flow chart, on page 10.

In part 2, the use scenarios are described and the various typical individuals (professionals and specialised professionals, as well as consumers) are described for which (primary during actual application and secondary after application) exposure is assessed. The essential importance of the use patterns for assessing exposure to biocidal products is expressed by describing the various possible scenarios to the extent known to the authors.

A full list is given of possible database models and mathematical models that can be used in the exposure assessment on the basis of scenario comparison. In addition to this, a new development (BEAT (Bayesian Exposure Assessment Toolkit) model) is described in which worker exposure databases have been computerised in terms of exposure distributions. These models are combined with subjective assessments by the user answering simple questions which make it possible for the BEAT model to ascertain the (non)similarity between the use scenario under consideration and all the data distributions already available. The output is a new exposure distribution and/or a surrogate value as a point estimate for the the new scenario. The BEAT model is still under development, but is operative for assessing body exposure.

PLEASE NOTE that Exposure is expressed as a distribution, and values from that distribution are used in risk assessment. The selection of indicative values for exposure assessment is a matter for policy, informed by scientific judgement. Typical indicative values currently used by regulators include the median (50th), the 75th, 90th and 95th percentile values in the relevant exposure distribution; the arithmetic mean, and the highest data point (if not considered to be an outlier). A WORKING GROUP UNDER THE BIOCIDES TM ARE VERIFYING THE WHICH PERCENTILES TO RECOMMEND IN DIFFERENT SITUATIONS.

Part 3 of this guidance presents a series of illustrative worked examples, for reference only. The fully worked out examples are described in order to facilitate the use by exposure assessors of the various database models, mathematical models, as well as the BEAT model in relation to the pattern of use under consideration.

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.

- Further development of BEAT model

The BEAT model is a new development, which is at present not completed. The current version covers body exposure, but not yet hand exposure and inhalation exposure. Exposure data are available in several cases and in principle these exposures can be incorporated in the model. In the present project time it is, however, impossible to finalise this approach. HSE (UK) has initiated the BEAT development and has assured the authors of the report that BEAT will be further developed for use in the European settings. The results can then be added to the next version of the Technical Notes for Guidance.

- Reference exposure scenarios

A set of relevant reference scenarios should be prepared for assessing secondary exposures. As a possible example for a starting point the US-EPA Residential Standard Operating Procedures (1997) should be considered.

- Technical expert group

It is proposed to install a technical expert group that follows the developments in human exposure assessment, as indicated above. The group should propose updates for the Technical Notes for Guidance on a regular basis.

- User guidance group

It is proposed to install an ad hoc user guidance group as soon as the report is accepted by the Competent Authorities to prepare a user's guide for model selection with respect to the various types and use scenarios. This group should be selected from the project team (HSE, RIVM, TNO, Cefic) and prepare the guidance within six months against marginal costs (2 meetings, travel and lodging).

Flow chart for estimation of human exposure

Biocidal product

composition

intended use

⇓

What is the pattern of use?

Who is the user (professional, non-professional, consumer)

how much

how often

what equipment

⇓

What tasks and what time budget?

mixing and loading

application

post-application

⇒

Who else may be exposed?

during use

after use

duration

⇓ ⇓

Mode of exposure

On / through skin

Inhaled

Ingested

⇓

Quantity of exposure?

Route and uptake

⇒

Tiered approach estimates

three Tiers

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PART 1

SUMMARY OF CONTENTS

This guidance includes the concepts developed in the report of the Biocides Steering Group (97/505/3040/DEB/E2) and refers to guidance on exposure assessment being developed for New and Existing Substances. The guidance is in three parts:

Part 1	Background information; concepts; models used for exposure estimation
Part 2	Specific guidance on estimating exposure, with flow diagrams
Part 3	Worked examples

Part 1 contains the principles used in human exposure assessment and links in many ways to the guidance on exposure assessment being developed for New and Existing Substances. Part 1 comprises the following chapters:

PART 1

CHAPTER 1 INTRODUCTION

1.1 Scope of guidance

This guidance covers the estimation of human exposure to biocides for specific use activities, during professional and non-professional applications, post-application, and certain disposal processes. The current state of knowledge does not permit the formulation of guidance on integrated (aggregated) exposure to a specific substance from different sources (e.g. indirect exposure via the environment). This report therefore concerns the estimation of daily exposure to a biocidal active substance through use of a product as the user or as someone exposed following use.

Industrial processes in which biocides are manufactured and formulated are no different from manufacture and formulation of substances that are regulated under various Directives and through national legislation on worker protection. Similarly, most disposal and waste treatment is otherwise regulated. Guidance on exposure assessment for manufacture, formulation and regulated disposal is given in the guidance being developed in the TGD. This report therefore concentrates on guidance on exposure during use of biocidal products.

The estimation of human exposure is not straightforward, nor will it be fully developed for many years. While the current approaches are felt to be good enough at present, there is fundamental research underway which has the capacity to change these approaches. Consequently, these Technical Notes for Guidance should be regarded as “state-of-the-art” rather than definitive.

This part of the guidance contains fundamental concepts and information derived in large part from the Biocides Steering Group report (97/505/3040/DEB/E2). It underpins the specific guidance in Part 2. Those new to exposure estimation need to comprehend the concepts set out in Part 1 before considering in detail the more specific guidance.

1.2 Requirement to estimate human exposure

Directive 98/8/EC (The Biocidal Products Directive) requires risk assessment of biocidal active substances and biocidal products, before these are placed on the European market. The estimation of human exposure is a fundamental element of the risk assessment process. Risk assessment for humans compares the toxic adverse effects of substances with a predicted dose. When a product can be shown to be capable of use with an acceptably low level of risk, the active substance in that product may gain access to Annex I, IA or IB of the Directive. When a substance cannot be shown capable of use with an acceptably low risk, given all reasonable exposure abatement measures, that active substance would not gain access to Annex I, IA or IB of the Directive.

1.3 Methodology for human exposure estimation

Historically, human exposure in the workplace has been regarded in terms of specific substances, and mostly in terms of the inhalation route of exposure. There has been little or no information on the time spent in the range of tasks during specific exposures or to the other routes of exposure. In contrast, the fundamental concepts underlying the approach in this guidance require consideration of exposure by all routes of exposure and the range of exposure scenarios that could occur during use of the biocidal product.

Human exposure assessments for biocidal products should therefore take into account exposure by inhalation, via the skin, and ingestion for professionals and non-professionals, in all the phases of use of a biocidal product. This should include estimates for primary exposure (that of the biocidal product user) and for secondary exposure (other people's exposure).

Exposure scenario

The exposure assessment is carried out through an evaluation of different exposure scenarios. An exposure scenario is the set of information and/or assumptions that describes how the contact between the worker and the substance takes place. It is based on the most important characteristics of the substance in view of occupational exposure e.g. the physico-chemical properties, pattern of use, processes, tasks and controls. An exposure scenario will therefore describe a specific use of the biocidal product with a set of specific parameters.

Pattern of use

The "pattern of use" is a fundamental aspect of “exposure” which must not be overlooked, but adequate data are sparse. The pattern of use contains information about the time budget, the task, the frequency and duration of elements of tasks comprising the scenario, the ancillary operations, and information on those who may be exposed as a result of a product having been used.

Many of the elements in the pattern of use will result in distributions, for example the in-use concentration and the application time. The pattern of use is not universal is likely to show considerable variability between user sectors and between Nations or Regions.

Task

Human exposure may be time-weighted or averaged according to some other dimension (e.g. one process cycle), but the critical determinant is the task. The task is a universal attribute, applying to both professionals and non-professionals alike. The overall scenario (e.g. using preserved paint) is composed of a series of tasks, which can often be allocated clearly to mixing and loading, application, and post-application phases of use. Subsidiary determinants of exposure include aspects such as the method of application, direction and distance of the point of application from the user, and physico-chemical attributes of the biocidal product such as volatility, viscosity and dustiness.

Exposure data

There is a vast range of potential exposure scenarios within each biocide product type. By expressing task-related exposure in terms of in-use biocidal product, exposure data may be used generically across the full range of products and active substances used for the specified scenario. For example, skin exposure in changing a dip-tube for dispensing concentrated biocide into a process is dependent on the task, and inhalation exposure is dependent on the substance volatility and the task.

Using the generic "in-use product" approach requires that the assessor knows the amount of active substance in the biocidal product being assessed but it does allows a reasonable way of managing both exposure information and risk assessment. It also enables some simplification of the various processes and optimises the use of the modest amount of available exposure data, but the approach introduces uncertainty.

Users

Biocidal products are used by professionals and by non-professionals. Professionals differ from non-professional users in a number of aspects and a distinction between the two is necessary in risk assessment.

Professionals

Professional users will handle and be exposed to biocidal products at work and the workplace risk will be controlled through observance of statutory requirements such as formal control measures. They have access to Material Safety Data Sheets (MSDS) and may have some basic knowledge about classification and labeling. The workers are trained and skilled in the main objectives of their occupation and may have some experience and skill in the use of personal protective equipment (PPE) if that is necessary for their normal work.

If the use of biocidal products is not routinely required in the workplace or no consistent part of the business (e.g. incidental use of slimicides, insecticides, irregular disinfections) the qualification to apply biocidal products may be no better within the group of professional users than within the general public. This holds especially true for the sub-group of Small and Medium-sized Enterprises who will not necessarily have the knowledge and skills to handle hazardous biocidal products.

In some occupations the use and application of biocidal products is a frequent or significant element of work (e.g. pest control operators or water service company workers). Within this subgroup of *Specialised Professional users* it is probable, that they 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) are supposed to be carefully 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.

For a broad range of hazardous chemicals (biocidal products included) there will be no concern if specialised professional users use them under the framework of worker protection legislation. However, for the use of potentially more hazardous substances (e.g. very toxic, carcinogenic, mutagenic, explosive), expert judgment and formal approval systems for the professional users may apply or additional product specific measures by those who place the

substance on the market may be, depending on the Member State's legislative requirements, a precondition to reduce concern for professional users to a tolerable level.

Non-professionals

Non-professional users are usually consumers - who may or may not read a product label. 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, though they may use household protective equipment (e.g. gardening or kitchen gloves).

The patterns of use differ for the professional and non-professional sectors. It is anticipated that professionals are likely to be exposed to greater quantities of a given product or biocide than are non-professionals. Conversely, the post application exposure phase is much more important for non-professional users than professionals, however, the magnitude of exposure may be lower.

Phases of use

Primary human exposure

There are up to four phases of biocide use that are relevant to human primary exposure:

- Mixing & loading includes the tasks in delivery and handling biocide product concentrate, dilution to the in-use product, and its introduction to the application apparatus or system.
- Application this includes 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 though cleaning and maintaining process equipment and tools. This can also lead to the exposure of people who are present following the use of a biocidal product (secondary exposure), recycling, etc.
- Removal includes the deliberate removal of biocides for disposal, for example, exhausted surface coatings.

The contribution to each route of uptake may vary considerably between these phases with any given active substance. Each phase of use requires separate assessment, 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).

Secondary human exposure

This includes exposure of people who are present during or following the use of a biocidal product. The post application phase is particularly important for non-professional exposure assessment because:

- residues of applications in the residential environment will stay in that environment;

- there can be prolonged contact in the residential environment because people live there;

- children, old people and sensitive subgroups are present in the residential environment.

The task based approach does not apply to post application phase, because there are no well defined tasks in post application exposure. Instead, a scenario approach is proposed, containing the following two post-application scenarios for the residential environment:

1. Children playing on the floor where biocides have been applied. In this scenario, they transfer the biocide to their skin by contact with contaminated surfaces such as floors and walls. Oral contact may take place via hand-mouth transfer and toy-mouth transfer.

2. People present in the house after application, exposed to the residues in air and on surfaces.

Experience indicates that post application exposure of children may be the most important exposure to a biocidal substance. This is because children are a sensitive group (higher ventilation in relation to body weight, play at ground level where the concentration of residues may be higher) and they may have a prolonged duration of contact, in the order of days to weeks. During application, concentrations are higher, but duration of contact is significantly shorter (minutes to ten of minutes typically).

In the above sense, post-application is subtly different from secondary exposure. The post application exposure is a consequence of the application of a biocide. It is secondary in the sense that the children are not aware of their exposure. The use of copper chrome arsenic (CCA)-treated wood, for instance, would constitute a secondary exposure, but does not fit post-application exposure.

Routes of exposure

Human exposure follows use, through any or all of three potential exposure routes - inhalation, dermal contact, and ingestion.

Inhalation exposure

Inhalation exposure is sometimes a small component of total exposure to biocides but can, in some cases, become the predominant route of exposure. Conditions where exposure by the inhalation route becomes important usually involve the use of volatile biocides or of dusts, fumigants and sprays, especially in enclosed spaces. It should also be borne in mind that a higher proportion (up to 100%) of the inhaled dose may be bioavailable, compared with a lower proportion absorbed by dermal exposure.

The assessment of inhalation exposure is well characterised and understood, with standard metrics and sampling methods. There is a large body of national guidance and scientific literature on the conduct of surveys to determine exposure to vapours and aerosols by inhalation and this matter is not developed further in this document. It is important to have some knowledge of the likely distribution of particle sizes of an aerosol generated from a

solid product. Also, some biocides have a low, but nonetheless significant, vapour pressure and deposits on air sampling filters can evaporate into the sampled air stream, and special sampling techniques are required.

The user's exposure should be measured using personal monitoring. It is the airborne concentration in the breathing zone (by convention, within 30 cm of the nose and mouth). It is expressed as mg/m^3 as a time-weighted average (TWA) concentration over a stipulated period, for example 8-hours or 15 minutes. It should be measured during the task or over a representative sampling period. The airborne concentration may refer to a single substance, or to a product in-use.

Exposure of others as a consequence of use - secondary exposure – is often evaluated either using static (background) monitoring, or more usually determined through mathematical models (see Part 2.3). Secondary exposure by inhalation is generally expressed as mg/m^3 (TWA over a defined period) of a stated substance.

Dermal exposure

Exposure of and via the skin is usually a significant aspect of human exposure to biocides. While this has been commonly considered for risk assessments for plant protection products, it is not so for biocides. Exposure data for deposition of biocides on work clothing and exposed skin have only recently been established. The pattern of distribution over the body differs with the task - for example, sometimes, only the hands will be exposed. Dermal exposure can be subdivided in potential dermal exposure and actual dermal exposure.

Potential dermal exposure is the amount that deposits on the clothes and on exposed skin over some defined period of time. Common metrics include mg active substance deposit per kg active substance handled (mg/kg a.s.). However, in numerous biocide exposure scenarios, the amount of biocide handled simply cannot be estimated (e.g. drilling mud). Another common metric is the amount of in-use biocide that deposits per unit time, or per task (mg/min; mg/cycle). Practical evidence from field studies indicate that metrics for potential dermal exposure such as "mg/min; mg/cycle" are useful. Potential dermal exposure normally has to be measured or estimates may be obtained using database models (see Part 2.3).

Actual dermal exposure arises through:

- direct deposition on exposed skin such as the face;
- permeation through clothing, penetration of clothing around fastenings, openings and along seams; and
- incidentally through contact with surfaces, and when putting on and taking off contaminated clothing (including protective gloves).

It is often impossible to know the actual dermal exposure, i.e. the sum of the total direct and indirect exposure of the skin. Studies using fluorescent dyes can provide a useful indicator of actual dermal exposure, but there are few data available. The quantity of a substance deposited on the skin can be expressed in terms of mg/cm^2, with the amount of skin exposed expressed in cm^2. However, it is more likely to find the quantity on the skin simply expressed as a weight (mg on skin). Such metrics take no account of the rate of accumulation on the skin.

Ingestion exposure

This is the mass entering the mouth other than that which is inhaled. At present, it can only be inferred from biomonitoring or (worst case) modeling using "Standard Operating Procedures (US EPA). It is expressed as mg per event or mg/day.

Biomonitoring for biocides, which is currently the only practicable way of attempting to measure the contribution of ingestion exposure, requires individual expert advice and appraisal of the results. As a route of exposure, ingestion is currently poorly defined, though it may be the most important route in some circumstances. This is particularly true where inhalation and dermal uptake are low or where children have secondary exposure.

Systemic exposure

Systemic exposure to a specific substance through a use should be integrated over the various phases of use on a "per day" basis.

Human systemic exposure is expressed as mg of substance per kg bodyweight per day, mg/kg/d. It is based on default values or data ranges for inhalation rate, clothing penetration and particularly on the intake/uptake into the body via the three routes of exposure i.e. inhalation, ingestion and dermal.

Intake

Intake and uptake are fundamentally different processes. Intake is the process that material is taken into the body i.e. ingestion and inhalation. It stays outside of the body boundary and so limits the amount of material or active substance that is available for uptake.

Uptake

Uptake is passage of the body boundary, at the lungs, at the gastrointestinal tract or at the skin. The amount taken up contributes to the total systemic dose. Where an active substance has a systemic mode of action, contributions from all routes of exposure have to be summed to calculate total dose. The rate of uptake is the key factor in summing the different routes. It is a function of the contact time and default values are quoted in Part 2.3.

Uptake via the skin depends on a number of factors such as:

- the active substance physico-chemical properties, the other components of the preparation and the in-use biocide's concentration;
- the conditions (temperature, relative humidity, work rate, exposed surface area, concentration per surface area, occlusion of contamination on the skin, etc.);
- the duration of exposure; and
- the condition of skin (location on body, physical damage, disease, etc.).

The uptake rate depends linearly on the concentration difference between the product on the skin and the concentration in skin/blood, however, this linear relationship breaks down at very high concentrations.

Uptake may be estimated by two methods:

1. Estimate the fraction taken up from:

- Default considerations - simple default estimates can be used where there are no better data. Based on the deposit and the nature of the substance and its vehicle, default skin uptake values of 1%, 10% and 100% can be used in exposure assessment. Unless there are better data, it should be assumed that retention by inhalation approximates 100% of the airborne concentration in the breathing zone. For ingestion the default is 100% of the material ingested.

- Experimental results - in this case, care must be taken to match experimental conditions with realistic exposure, especially concerning duration of contact, concentration of active substance and specific conditions of exposure. If the concentration, duration and specific conditions in the experiment are different from the expected exposure, expert judgment is needed to compare the impact of different exposure regimens.

2. Estimate uptake directly by diffusion through the body boundary. A critical parameter is the permeability of the body boundary. For the skin, skinperm provides a Quantitative Structure Activity Relationship (QSAR). The diffusional process also includes the concentration of the active substance and the duration of exposure.

Mathematical models such as CONSEXPO have well-documented routines to calculate uptake by all routes over a range of tasks. Database models such as REx complete estimates through a procedure based closely upon US-EPA data and standard operating procedures (SOP). These issues are explained in more detail in Part 2.3.

Bioavailability

There is a subtle difference between uptake and bioavailability. Both can be expressed as percentage of an amount applied to the body or amount taken in. Bioavailability is measured using plasma or target organ concentrations. In case of the oral route, it includes first pass metabolism by the liver. If a substance is subject to an extensive first pass metabolism resulting in detoxification, its bioavailability may be low while the uptake may be large. To a lesser extent, this may happen in the lungs and skin too, but the metabolic capacity of these organs is much lower than that of the liver.

Biomonitoring

Biomonitoring involves the analysis of markers of exposure, effect or susceptibility. Common markers of exposure are the active substance or it's known metabolites contained in blood or excreta. These markers reflect the total body burden irrespective of the route of uptake of the active substance. A drawback of biomonitoring is that the kinetics of the substance needs to be adequately characterised and several time points are required to estimate past exposures with confidence. It may serve as a means to compare the plausibility of results estimated for total body burden. In addition, biomonitoring appears to be a suitable tool to test the effectiveness of exposure mitigation measures.

Analysis of exposure data

There is no easy concept of "exposure". It cannot be simply ascribed attributes such as "low" or "high". Exposure can only be described adequately in terms of "*distributions*" - expected ranges into which exposures for tasks will fall. Studies to measure exposure through inhalation and potential dermal exposure (that which deposits on work clothing and exposed skin) generally produce distributions of results that are skewed. These are often approximated by a log-normal distribution - that is, many results at the lower end of the range with a long tail of results much higher in the range. Occupational exposures generally follow this pattern and very many data are needed to establish a distribution for application of statistical methods.

It is important to be aware of the breadth of exposure data distributions. In this process exposure variability and uncertainty should be clearly disentangled to facilitate greater transparency in risk assessment and decision-making. Exposure variability refers to the true distribution of exposure even after applying perfect measurement techniques and sampling designs, whereas uncertainty is a description of the imperfection of the information (or 'lack of knowledge') about exposure. Both are important issues, which should be considered carefully before selecting a particular indicative exposure value from the data distribution.

Indicative values from exposure distributions are used in risk assessment. The selection of values from an exposure distribution depends on a number of factors such as:

- the size and reliability of the data set;
- the user sector / population exposed;
- the use patterns;
- the precedents (for example, related to highly toxic products);
- the level of the assessment (screening or detailed), and
- the availability and validation of predictive models.

Typical indicative values currently used by regulators include the median (50^{th}), the 75^{th}, 90^{th} and 95^{th} percentile values in the relevant exposure distribution; the arithmetic mean, and the highest relevant data (excluding clear outliers in the distribution). Detailed guidance on the selection of indicative values appears in Part 2.1

Models

General predictive models are available for generic substances and for specific scenarios. These can take account of the physical properties of active substances such as the particle size of aerosols and volatility of liquids. Mathematical and empirical (database) models exist for a number of scenarios and tasks (Part 2.3).

Mathematical models relating to physical evaporation processes normally relate to a specific substance, and require data on physical properties such as saturated vapour pressure. Models relating to dispersive processes such as spraying, typically relate to the in-use product emerging from the spray nozzle.

Database models may be highly specific (e.g. relating to an active substance discharged from a hand-held aerosol can), or generic (relating to the in-use product, including propellant, held within the can).

Tiered approaches to exposure estimation

The tiered approach is a logical stepwise approach to risk assessment that uses the available information to the optimum extent, while reducing unnecessary requirements for human exposure surveys or studies. Alternatively, the need for an exposure study can be justified through elimination of all other possibilities.

Tiered Approaches use increasingly sophisticated approaches, exposure controls and parameter sets. Initial tiers should provide conservative assessments of exposure that are refined in subsequent tiers.

When predicted exposures give "adequate" margins of safety when compared with appropriate toxicological endpoints, assessment can stop. Where margins remain inadequate, safe use cannot be demonstrated.

This guidance does not comment on margins of safety or risk assessment. However, exposure estimation is inextricably linked with the other parts of the risk assessment process. Exposure reduction options must be evaluated for their effects on exposure - for example, reducing the likelihood of exposure, or reducing the quantity of exposure. Such exposure reduction measures must then be reflected in the conditions for use, and may restrict a product to a stipulated user sector. Applications of the tiered approach and exposure abatement measures are set out in Part 2.2.

Pattern of use information is essential for any exposure estimation.

The tiered approaches to risk assessment should be applied in respect of biocidal products as follows:

Tier 1

The screening tier in the risk assessment process should be quite simple. The assessor would select an indicative exposure value from an empirical (database) or mathematical model, or a reasoned worst case, or by reading across validated data from tasks likely to produce similar exposure distributions. A "reasonable worst case" exposure estimate should include reasonable worst case pattern of use information. Tier 1 estimates must not take account of personal protective equipment (PPE). Tier 1 estimates also represent foreseeable misuse.

When the result of a Tier 1 exposure assessment produces an unacceptable outcome in risk assessment, a Tier 2 estimate is required.

Tier 2

The second Tier in the exposure estimation process is more complex.

The exposure estimate needs to state the default values selected and all assumptions. Exposure estimates are required for all relevant populations, for all tasks (except where exposure is obviously trivial) and for all relevant exposure routes.

Tier 2 estimates are appropriate for a detailed exposure assessment of specialised professional users because within this subgroup it is probable that these users have specialised knowledge

and skill in handling hazardous chemicals. Protective measures (instruction, training, exposure control, PPE) are supposed to be carefully observed.

In Tier 2, any misunderstanding about the way a product is used will lead to an incorrect risk assessment. The assessment must also take account of the likely existing control or exposure reduction measures.

If the resulting exposure estimate produces an unacceptable outcome in the risk assessment, the exposure abatement measures may be successively refined and the exposure estimate revised, until the options for exposure reduction are exhausted.

Where control measures or exposure reduction measures are necessary to reduce exposures to an adequate level, these must be stated clearly as they may lead to non-inclusion or influence the conditions of the Annex 1 entry.

Tier 3

The final Tier of the assessment recognises that valid estimates of human exposure are produced through surveys or studies with the actual product or with a surrogate.

Exposure surveys need to be large enough, well enough reported, and representative, to be convincing. Studies may need to cover an entire scenario or provide detailed information on patterns of use and the key tasks within the scenario.

The surveys or studies may include biomonitoring to show systemic uptake - biomonitoring is a useful and persuasive tool. The information is particularly useful where a workforce has been studied over a period of time, and at a known (fairly continuous) level of exposure. Validated information is needed on the dynamics and kinetics of exposure, skin absorption, and / or metabolism of the substance or substances under assessment. But biomonitoring may be intrusive and logistically difficult to conduct, particularly in respect of secondary exposure.

It should be noted that biomonitoring studies should be carried out in accordance with the Helsinki Declaration.

Convincing distributions of workplace exposure would normally require 20 to 30 measurements of personal monitoring data for inhalation and potential dermal exposure, possibly more, depending on the biocide application tasks. These should normally be taken from a number of different exposure studies.

Where task-specific information is needed, then smaller scale studies or laboratory or workshop simulations using surrogate substances may be adequate. Real information on worst case task-related exposures may be easier to obtain, and will be important in the context of fulfillment of the requirements of product approval.

The restrictions and controls in Tier 3 field exposure studies will lead to the same default controls being specified in the conditions for biocide use, in order for the risk assessment to be acceptable.

<u>Estimating total exposure</u>

The estimated combined exposure for a job is summed from the exposures arising from individual tasks (inhalation and dermal) through the different phases of use. For instance, the

tasks may include handling concentrated material (mixing and loading), spraying a formulation and handling a wet object post-application. Appropriate selection from available data distributions should allow a reasonable estimate of daily exposure to be produced which takes into account the time budget.

It is important to recognise that simple summation of precautionary estimates can lead to gross errors. Unless there are good reasons to do so, exposure estimates should not be summed for primary and secondary exposure.

Aggregate exposure to a specific substance includes both primary and secondary exposure and exposure to the same chemical in different products and matrices (e.g. indirect exposure via food/water). It is not currently feasible to aggregate the personal daily exposure to a substance through all such sources.

1.4 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 and is available for uptake through the skin.

aggregate exposure *

application refers to using the in-use biocide.

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.

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, etc.

exposure data - 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. Data are expensive to acquire and surveys can interfere with normal work patterns.

exposure information includes the frequency and duration of exposure, the selection of product 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.

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.

household 'protective' equipment such as washing-up or gardening gloves may be advised in the method for consumer use of a biocidal product, (but their presence cannot be assumed, and account should not be taken of this advice in terms of exposure estimates).

in-use biocide is the product as it is being used, 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.

indicative distribution model is a log-normal distribution pattern that which is generally considered to be representative of the pattern of exposure that would result from a biocide application task, but the data do not exist. This is used in Tier 1 assessments.

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 consumer, amateur and recreational 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 - who may or may not read a product label. 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 task 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 from exposure.

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

post-application covers the scenarios of sampling, maintaining, cleaning etc. and may also 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, stabilisers, etc.

primary exposure is that which occurs to a biocide user.

probabilistic (stochastic) modelling is used to combine data in order to derive fair "central tendency" and "reasonable worst case" values. See deterministic estimates.

professional user 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. Professional users will however not necessarily have the knowledge and skills to handle hazardous biocidal product (e.g. incidental use of slimicides, insecticides, irregular disinfections, use of products containing preservatives, etc.).

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

reasonable worst case in a distribution is a value that reflects the exposure around one time in 10 or 20. Unless the data set is sparse, the reasonable worst case value should not normally be the highest point in the data set.

reasoned case is an argued case in lieu of exposure data and is used in Tier 1 and Tier 2 assessments.

removal and disposal phase includes removing exhausted antifoulant coatings, disposing of used preservative fluids, 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 user 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) are supposed to be carefully 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 are used in surveys and studies as tracers to enable analysts to trace the exposure pattern - e.g. strontium salts, dyes, fluorescent agents.

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.

combined exposure is the total exposure arising from individual tasks (inhalation and dermal) through different phases of use.

cumulative exposure covers concurrent exposure to the same active substance from different biocidal products.

Citations:
The TGD on Risk Assessment has the following :

"Consumer exposure to a substance can occur from multiple sources, because products contain many substances and a substance will be contained in multiple products. Hence when the individual scenarios are assessed separately account should be taken of the fact that these exposures to a single substance need to be aggregated over all scenarios, the so-called aggregated consumer exposure. This aggregation is not a simple summation of the individual estimates but includes an assessment of priority scenarios. The question how to calculate aggregated consumer exposure breaks initially down in the following two:

1. What is the co-occurrence of products with the same chemical in households ?
2. What is the co-use of products with the same chemical ?..."

From the guidance document on Annex I inclusion :

"As set out in the TNsG on Practicalities Section 1.5 of Document IIC, a risk assessment for "combined exposure" is required. In order to conduct this risk assessment, one first has to calculate the possible combined exposure.
A person can have multiple exposures to an active substance within one product type on a single day. Whereas each of the individual exposures might prove acceptable during risk assessment, it can occur that risks from possible, realistic multiple exposures combine to reach an unacceptable level. In order to assess the risk, the exposure assessment must first be conducted and this can be known as the "combined exposure".
Combined exposure occurs when someone is a member of different exposure populations during a period. For example, a person could use product(s) containing the active substance as an operator (for example applying a fly spray, rodenticide or wood preservative) and then be exposed to the same active substance for the same use as a bystander or user at home.
In addition, there could be an exposure from food and drink via environmental exposure.
Therefore it can involve both primary and secondary exposures.
Where multiple exposures are considered possible, the relevant exposure scenarios should be presented and explained in the exposure assessment.
The individual exposure values, as derived in the three previous sections, should be totalled and carried forward to the risk characterisation."

Therefore, as far as can be understood from this, the terms used for biocides aggregate and combined exposure cover the same concept.

PART 1

Chapter 2 EXPOSURE INFORMATION

"Exposure" covers two types of information:

- the pattern of use;
- the potential for exposure that is anticipated through use.

2.1 Pattern of use

"Pattern of use" contains information about the scenario that enables the assessor to tell how a product will be used. Information on the pattern of use information can only be gathered through surveys or generic data from similar products. Such information is only rarely available in scientific or published literature. Those placing biocidal products on the market will need to conduct research into the pattern of use, directly with the users if actual or surrogate data are not available.

While there may be common tasks (for example, coupling a reservoir of biocide to a dilution system), and the ranges of duration for these tasks known, the number of times a day such tasks could be undertaken would depend on the product type, the user group and climatical zone.

A matrix to inform the collection of pattern of use information appears in Part 2.1.

2.2 Exposure potential

Potential exposures may be measured or modelled, and each approach has advantages and disadvantages. Exposure measurements represent precise observations for a limited number of cases: they can be carried out in the workplace, in the residential environment or through laboratory or workshop studies. Modelled exposures can be estimated from underlying physical processes, the physico-chemical properties of the chemical, characteristics of the formulation and an understanding of the nature of the contact with the chemical.

The way a substance is used will dictate the type of measurement that is most appropriate to obtain the most useful information. When estimating exposure for risk assessment, assessors must be satisfied that the estimate is reliable and relevant. In the residential setting, exposure can be constant rather than transient, and thus the relevance of prolonged contact with the substance may need to be addressed.

Measuring Exposure

Measured data are often available for occupational exposures, sometimes for indirect exposure via the environment (e.g. measurements of substances in drinking water), but are seldom available for consumer exposures. Measured data may reflect investigations of certain sub-populations or in specific geographical regions; hence they may not be sufficiently representative of a broader population.

Inhalation

There are few validated methods that relate exclusively to air monitoring and the determination of biocidal agents. Less than 10% of the substances listed by the EC in its provisional list of existing biocidal substances, have been found to have specific workplace measurement methods (as vapour or aerosol). It is beyond the scope of this paper to address any specific sampling strategy. However, it is essential that the sampling strategy chosen collects the substance of concern with a high collection efficiency and without giving preference of one phase over the other (e.g. substances which are present both as vapour and as aerosol). The important criteria and appropriate selection of sampling devices are outlined in a review by Findlay, 1995. Other relevant texts include the CEN Standard on workplace atmospheres (EN 689:1995), Deutsche Forschungsgemeinschaft publication (DFG, 1993) and HSE Methods for the Determination of Hazardous Substances (MDHS Series)

Potential and actual dermal exposure

Dermal exposure data are difficult to acquire and interpret. However, documented methods are available for the sampling process. The determination of potential dermal exposure is well described in an OECD guidance document (OECD GD (97) 148). An HSE review (EH74/3) sets out how surveys have been conducted in Britain, using a modified WHO protocol (WHO 1982), which was validated by the Institute of Occupational Medicine, Edinburgh. Popendorf and Ness (1994) gave a comprehensive review of the use of patches.

A new and simple method to determine whole body potential dermal exposure has been developed by the UK Health and Safety Laboratory (HSL) involving quasi-random cut out samples from used work-wear. Initial indications are that the technique very closely represents full suit analysis, with reduced quantities of reagents and analysis time.

Further research is in progress, which will indicate the likely proportions and spatial distributions of typical work clothing penetration, using surrogate biocide products.

Exposure to the hands is often highly significant. Sampling gloves provide a measure of potential dermal exposure when coming directly into contact with solids, fluids and aerosols - these may over-sample but can reflect actual dermal exposure. Thin cotton sampling gloves worn beneath protective gloves demonstrate actual hand exposure but again may over estimate exposure.

Poor procedures in putting on and taking off gloves can lead to significant hand exposure, regardless of the barrier properties of the protective glove material. Sampling protocols need to recognise that sampling gloves will collect pre-existing contamination inside protective gloves.

Fluorescence can be used as a means of tracing contamination. Qualitative methods involve scanning surfaces with UV light and observing any fluorescence. Quantitative methods have been developed which allow estimation of potential dermal exposure and actual dermal exposure. Advanced systems have been developed at TNO in the Netherlands and at HSL. Other systems have been developed in the USA. The fluorescent tracer technique for the quantitative assessment of dermal exposure to biocides is a powerful tool that can yield results not obtainable in any other way. Formulations need to be compatible with tracer compounds used in such experiments.

Ingestion

Oral exposures are caused by ingestion of biocidal products. Ingestion may occur by hand-mouth contact, by object-mouth contact, by accidentally treating and eating contaminated food, or by aerosol ingestion during inhalation. Hand-mouth contact and object-mouth contact may be most prominent in young children, as they show extensive mouthing behaviour around 1 years of age when teeth cut through.

Quantification of the intake rate is very difficult. Figures have only been established for soil uptake for soil contamination assessments using chemical markers although data specific for biocides have not been reported. The aerosols that deposit in the upper thoracic region during inhalation will be swallowed. Dosimetric models (e.g. ICRP-models, CIIT-models) provide estimates for the fraction involved.

<u>Laboratory methods and expression of results in reports</u>

Details on assay methods will be included in active substance dossiers. These include methods to evaluate environmental exposure. As a general rule, samples taken for occupational hygiene purposes will be less difficult to determine than environmental samples.

"None detected" results should refer to the limits of detection and quantitation (LoD, LoQ). There are alternative treatments of such values, and the issue requires scientific resolution.

For example:

- results <LoD and LoQ are assumed to be zero and treated as a likelihood of exposure to the distribution of non-zero values
- Results <LoD = 0.5 x LoD and <LoQ = LoD

Other options are feasible, however, other than commenting on data quality (Part 2.1), this guidance does not cover laboratory measurement of biocides in products or hygiene samples.

Modelling Exposure

In the absence of measured exposure data or representative data on analogous substances, exposure must be estimated using recommended modelling approaches. To ensure that the predictions are realistic, all relevant exposure-related information on the substance should be used in an iterative manner.

Generally, exposure models fall into one of three types, mathematical mechanistic models, empirical/knowledge-based models and statistical mathematical models. These models predict exposure levels from a mechanistic description of a process, an empirical database or statistical relations.

The use of exposure models requires the selection of various input parameters. Insufficiently detailed information on exposure scenarios or lack of sufficient data may require the use of default values. Input data or default values used for the calculations must be clearly documented. Computer programs have been developed to implement mathematical predictive models and empirical models. Statistical models have been developed using available data and appropriate statistical methods. Model choice should be justified by showing that the model uses the appropriate exposure scenario (e.g. as judged from the underlying assumptions of the model). Expert judgement may be required to check the realism of the exposure value derived from a model, particularly if default or "reasonable worst case" values have been used. Modelling of exposure can be performed either by taking discrete values (point estimate) or distributions for the model variables (probabilistic modelling).

Mathematical mechanistic models

Commonly, mathematical models are based on mass balance equations. These can incorporate the physical and chemical properties of the substance, together with patterns of use. They are used to characterise the rate of release of the product into a space, and its subsequent behaviour. Mathematical models should cover all relevant processes or tasks contributing to exposure in a scenario. For many tasks, a number of models could be appropriate. The underlying assumptions for each model, and the processes it represents, help the assessor in model selection. More than one model can be run, to assure consistency. The advantages of mechanistic models are:

- the mechanisms and main processes are clearly stated;
- their inputs and outputs are clearly stated;
- they are well documented and can be validated and
- they can be improved using real life data.

However, if the underlying assumptions do not apply to the task, they can be poor approximations of the real world. Importantly:

- they make a number of simplifying assumptions, for example, instantaneous complete mixing of the substance in air.
- they account only for the main variables that affect exposure.
- care must be taken not to rely completely on point prediction.

Empirical models

Empirical models are probably best described as models based on exposure measurements obtained from real situations. This type of model can be used to predict the likely exposures in other comparable situations, i.e. the informed use of generic data. If sufficient and high quality data are used in empirical models they are likely to account for the many variables that influence exposure. An example of an empirical model is the EASE model, which is used to predict to occupational exposures. Currently, no empirical models exist for predicting consumer exposures since the available databases on exposure measurements are not sufficiently large.

The main advantage of empirical models is their amalgamation of multiple studies into a large data set, which reflects the distribution of results better than a small exposure study. The disadvantages include:

- uncertainties about the quality of the information fed into the model;
- uncertainties about input default settings;
- important factors that influenced the recorded exposure level may become hidden;
- the output from the model may be misapplied or misinterpreted; and
- outputs may be imprecise, which can lead to skepticism over the answer.

Statistical mathematical models

Statistical models have not yet been used for EU exposure estimations. Such models use empirical relationships to predict exposures from statistical indicative distributions together with historical data. In principle, they reflect a combination of empirical and mechanistic models together with consideration of the distribution of the input parameters. One of the most important steps in the procedure is represented by the implementation of the probabilistic approach, which allows the use of distributions in the calculation.

Probabilistic techniques use distributions instead of point values for variables in model estimations. Distributions reflect the variability and the uncertainty of a variable. From this point of view it enables the assessor to introduce an additional approach to describe data quality. Probabilistic analysis may reveal the factors that really drive the exposure. It may also help to differentiate subpopulations with respect to exposure, and thus to identify groups of people at risk. Knowledge of the range and distribution of exposures allows the assessor to select from appropriate points in the distribution to inform the decision making process and to perform an appropriate sensitivity analysis.

Many exposure data are needed to establish a distribution and allow application of statistical methods. Probabilistic analysis therefore requires input data of sufficient number and quality.

Otherwise, misinterpretations of the probability distribution that represents the variables, e.g. underestimating the variance, can seriously hamper the interpretation of the outcome. In cases where the assessor has little data of low quality, a reasonable worst case point estimate of exposure in combination with expert judgment is preferable. There are a number of computer software-packages available that can perform probabilistic calculations, e.g. CRYSTAL BALL, @RISK, ANALYTICA. Predefined models for consumer assessment, e.g. CONSEXPO, CEM are also able to perform probabilistic estimations. When the probabilistic approach is applied, the outcome will be a probability distribution of exposure. The uncertainty and variability included in the exposure assessment should be used to support decision-making processes to protect human health. Effectively, higher percentiles of the exposure distributions can be used to characterise exposure. In addition, assessing the relative importance of the different input variables should be performed to identify potentially effective risk reduction strategies.

In summary, probabilistic assessments integrate distributions of exposure factors to produce an estimate of exposure. They increase insight in the uncertainty of the assessment (via uncertainty analysis) and the contribution of each exposure factor in the end result (via sensitivity analysis). If data quality is adequate, a probabilistic analysis is advocated, at least to underpin a deterministic presentation of the results.
Currently, not enough experience is available for general use of probabilistic analysis in the regulatory process.

2.3 Data quality

To conduct exposure assessments, different types of data are required. These data may be actual measurements of human exposures or they may be data that can be used for exposure factors in modeling approaches. Data may be derived from experimental studies, industry monitoring programmes, or from other monitoring studies. Such data may often vary within wide ranges and so they have to be evaluated carefully and their representativeness and quality should be characterised. Measured data from surrogate substances or analogues may also be useful when estimating exposure levels, especially when generated to have a generic relevance.

The advantages of experimental exposure data are:

- they reflect an actual measurement of exposure;
- quality standards are available to judge adequacy of techniques and data quality;
- the experiment can be well documented.

However,

- they reflect the exposure in a specific, often limited situation, and are not always relevant for the exposure assessment;
- they do not always reflect the full variability in exposure.

The available data have to be assessed for their reliability. The confidence in measured exposure levels is determined by the adequacy of techniques, strategies and quality standards applied for the sampling and analysis protocol. In general, exposure levels established using recognised good quality sampling strategies and techniques should be given preference. However other measured data not meeting these criteria may also be considered adequate for use in the risk assessment on a case-by-case basis.

The representativeness of the data needs to be established. The type, location, duration and the frequency of measurement should be evaluated. When evaluating the representativeness of the data the assessor should consider how much data are needed to understand a realistic profile of exposure; the exposure scenario and if the use is foreseeable. The most important prerequisite for an adequate and realistic estimation of exposure is that data of high quality are used. Whenever possible, high quality and relevant measured exposure data should be used in preference to modelled data. However, it should be recognised that experiments under controlled conditions may produce misleading results if they do not reflect actual exposure situations.

2.4 Recent and current research

A full literature search (HSE Information Services) was commissioned for reports since 1995 concerning human exposure for processes using biocidal products. This produced only 33 potentially useful reports, a quarter of which were written by the co-authors of this guidance. In addition, many of these reports relate to a specific active substance, defeating the potential to use the data in creating a model.

Contacts in CEFIC, in Portugal, the USA and California, Canada, and Australia were approached for information. Articles requesting information - particularly on patterns of use - were placed in the BOHS / BIOH Occupational Hygiene Newsletter, Pesticides News, and Biocides Today. The HEROX database of ongoing human exposure research (www.herox.org) database provided few leads not already known to the authors. The results of these researches were as anticipated, sparse.

Research of direct relevance to biocides appears to be concentrated in a few Institutes only. The "RISKOFDERM" project is more widely distributed, with exposure to substances in general as its focus.

Current research that should be of value to human exposure estimation includes:

- smoke dispersal of aerosols through passive ventilation - CFD methods
- dermal absorption - method standardisation
- development of analytical methods for biocides (e.g. chemical electrophoresis, liquid chromatography - MS/MS; in drilling muds, metal-working fluids, etc.)
- exposure database model development (Bayesian approach)
- clothing contamination mapping by Direchlet tessellation
- penetration of work clothing (standard method)
- portable applicators (potential for contamination in cleaning and maintenance)
- exposure in cleaning mobile spray equipment
- biomonitoring (urinary arsenic and chromium in CCA workers)
- concentrate transfer (mixing and loading)

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 in the United States. They aggregate exposure from multiple sources, at the cost of needing good input data for each source. LIFELINE is an effort by the Hampshire Research Institute, funded by US-EPA, to develop a dietary and nondietary residential exposure model that will estimate aggregate exposure over a lifetime. CALENDEX is a model under development by Novigen that can estimate daily to annual nondietary residential exposure and works in a probabilistic environment. CALENDEX does link with Novigen's DEEM dietary model to produce an aggregate model. CARES is an industry effort to create an aggregate and cumulative risk assessment model. CARES stands for Cumulative and Aggregate Risk Evaluation System. It intended to contain the dietary components from DEEM (it will not contain DEEM itself) and the REx model. The REx model itself is another model for aggregated exposure assessment and it is structured according to the US-EPA SOPs for pesticidal residential exposure assessment (for the latter, see REAW, 1996). All these models are under development and first results are expected in the near future.

The American consortium has a Residential Exposure Joint Venture (US-EPA, CAL-EPA, PMRA-CAN, Industry) to develop calendar or diary based surveys to determine demographic and spatial (geographic) characteristic of households using registered pesticide products, and temporal use information beyond that stipulated on labels. The research will identify residential characteristics - areas treated, quantities used over time and per treatment, pests treated and substances used. It will extend over 12 months.

The same consortium of regulators announced a non-dietary exposure task force to address residential residues of pyrethroids and synergist.

PART 1

Chapter 3 DATA REVIEW AND PROCEDURES

3.1 Essential data for exposure estimation

The essential data are:

- the pattern of use, as set out in Part 2.1 and Part 2.3
- good exposure data, as set out in Part 2.1 or a stated exposure model (Part 2.3)
- a clear tabulation of the default values used (referenced), or exposure model inputs
- a clear tabulation of the assumptions made (justified where necessary).

An exposure estimate is only as good as the input data. Unless these are clearly reported, the audit trail for the decision on exposure cannot be followed. If new data (for example, the pattern of use) are discovered, or a more relevant mathematical model is developed, there is a ready means to amend the exposure estimate.

Examples of exposure estimates appear in Part 3 of this document.

3.2 Variations in the patterns of use

It is expected that there will be geographical variations in the patterns of use for some of the biocide products. However, no structured sources of information were available to enable any informed guidance on the similarities or differences between the patterns of use in member states.

3.3 Low exposure and reasoned cases

The Commission required development of guidance scenarios to illustrate when waiving would, and would not, be appropriate.

Reasoned Cases in Exposure Estimation

There are instances where part of an exposure scenario will not apply; and instances where "low exposure" is asserted for waiving of an exposure data requirement. The applicant may provide a reasoned case that sets out why that data requirement may be waived. That case should be based on scientific arguments or other information that demonstrates that the generation of new data is unnecessary. The case may contain comments on the commercial implications, but commercial concerns alone are insufficient. A reasoned case should not just present a description of data - it should also interpret how these relate to the requirement for which waiving is sought.

Grounds on which to base a case against generating new exposure data include:

- the outcome of a study can be predicted from existing data;
- existing data on one scenario can be read across to fulfill the data for another;
- the data are not scientifically justified (for example, residential exposure assessment is unnecessary if the substance is never going to be used in residential areas);
- the data are not relevant (e.g. long term exposure data are not relevant as chronic or repeated exposure does not occur);
- a study is not technically feasible.

Examples of biocide use where the foreseeable exposure for certain tasks might be sufficiently low include:

- inserting solid borate rods in pre-drilled holes;
- deploying a pre-prepared, robust bait station containing non-volatile bait;
- in-situ generation of disinfectant in a closed process cooling system
- in-can preservative contained within a closed system (e.g. in aircraft fuel, with steps to prevent exposure in maintenance)

However, the risks from secondary exposure would still need to be addressed through the reasoned case. In these and similar cases, the Technical Notes for Guidance on Data Requirements states that it is possible to waive the submission of some toxicological data.

PART 1

Chapter 4 REFERENCES

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PART 2

SUMMARY OF CONTENTS

This guidance includes the concepts developed in the report of the Biocides Steering Group (97/505/3040/DEB/E2) and refers to guidance on exposure assessment being developed for New and Existing Substances. The guidance is in three parts:

Part 1	Background information; concepts; models used for exposure estimation
Part 2	Specific guidance on human exposure assessment
Part 3	Worked examples

Part 2 contains specific guidance on human exposure assessment. It has links with the Technical Guidance Document (TGD) for Risk Assessment for New and Existing Substances, section exposure assessment.

Part 2 comprises the following chapters:

Principles:

- **Human primary exposure is related to the task.**
- **Task analysis leads to the identification of suitable exposure models.**
- **Time budget (pattern of use) information leads to a potential exposure estimate.**
- **Uptake modifiers lead to the prediction of systemic dose.**
- **Human secondary exposure is that which is not primary.**

PLEASE NOTE that Exposure is expressed as a distribution, and values from that distribution are used in risk assessment. The selection of indicative values for exposure assessment is a matter for policy, informed by scientific judgement. Typical indicative values currently used by regulators include the median (50th), the 75th, 90th and 95th percentile values in the relevant exposure distribution; the arithmetic mean, and the highest data point (if not considered to be an outlier). A WORKING GROUP UNDER THE BIOCIDES TM ARE VERIFYING THE WHICH PERCENTILES TO RECOMMEND IN DIFFERENT SITUATIONS.

CHAPTER 1 SPECIFIC GUIDANCE ON EXPOSURE ESTIMATION

1.1 Identifying use scenarios

Information on the tasks involved in using a product, and how it is is intended to be used, is essential to ascertain how exposure will arise (and to whom it will occur - see Part 2.1.2).

For example, a product concentrate may be marketed to preserve a process fluid (such as metalworking fluid). The concentrate can be put into the process fluid in a number of ways:

- bulk delivery into a holding tank and biocide metered into the coolant circuit;
- drum or IBC (intermediate bulk container) delivery, the container fitted with dip tube and biocide metered into the coolant circuit;
- drum on a stillage and dispensed (tap or poured) into a measuring jug, and the biocide poured into the coolant circuit.

In this mixing and loading phase (removal of the product from its container and introduction to the coolant fluid), all scenarios have potential for human skin exposure. Minor spillage would require consideration in all scenarios. Exposure by inhalation would only be anticipated if the product were potentially volatile. Experimental evidence suggests that metalworking fluids may be aerosolised in appreciable amounts when subjected to shear forces or higher temperatures (evaporation and/or formation of condensation aerosols).

The application phase involves the use of the coolant. Exposure by skin contact is through direct contact with fluid, articles contaminated with fluid, and deposition from airborne aerosols. Exposure by inhalation is through airborne aerosols generated at the cutting head. This means that co-workers will also be exposed.

In that application, the worker population can be separated in 3 categories: (a) biocide specialists (Service Company workers) trained to work on concentrates, (b) the workers working on machines who should be trained but are not experts to work with biocidal products and (c) the co-workers and maintenance workers who have no special expertise in that particular field and do not really work with the biocide.

There is a wider range of scenarios that can occur in the post-application phase, such as:

- changing a drum fitted with a dip-tube or changing a dispensing tap;
- recycling or disposing used coolant;
- routine cleaning coolant sumps and filter maintenance;
- cleaning a drum for recycling;
- cleaning of wet articles, etc.

The examples show that a sufficiency of detail is required to well identify a good scenario. Good scenarios for exposure estimation must be well documented, realistic, and work on reasonable worst cases in absence of good data. Exposure as a result of accidents or from abuse shall not be addressed (see Technical Guidance Document in support of Commission Directive 93-67-EEC Part 1- Chapter 2 §2.1).

Consequently, a sufficiency of detail is required. The scenarios subject to exposure estimation must include those that are reasonably foreseeable and include reasonable worst cases.

For the above example:

- gross spillage in mixing and loading can be envisaged, but it is not appropriate to assess risk on such "accident" events;
- the user population should be assumed as carrying out all phases of use, unless good evidence shows that this does not occur.

1.2 Identifying user groups and those at risk through secondary exposure

The primary user group is relatively simple to identify. Primary exposure is that of the user performing the task. The user may be professional (at work) or a non-professional. The differences between these groups include:

- The workplace is subject to worker protection legislation.
  The *professional user* has residual risk controlled through control measures; this may include the use of PPE if that is necessary for the normal work.
  The professional user however will not necessarily have the knowledge and skills to handle hazardous biocidal products. If the use of biocidal products is not routinely required in the workplace or no consistent part of the business (e.g. incidental use of slimicides, insecticides, irregular disinfection, use of products containing preservatives, etc.) the qualification to apply biocidal products is no better within the group of professional users than within the general public.
- The *specialised professional user* will probably have specialised knowledge and skill in handling hazardous biocidal products, the pattern of use will show greater frequency and/or duration of use.
- Some *users* have a profession that does not involve biocides (e.g. office workers) but may be exposed to biocides in their work environment, either by measures of the employer, or by their own initiative. Although these users may be subject to worker protection legislation, their use and exposure compares with non-professional users.
- The *non-professional user* is unlikely to take informed measures to control exposure and to exactly follow the description of use.
- The *non-professional* pattern of use is expected to show lesser frequency and/or duration of use.

Secondary exposure is all that which is not primary. This group at risk through secondary exposure is less easy to delimit.

However, the intended location of use will provide useful indicators. The location of use (indoors, outdoors; industrial, residential, recreational) will help to determine the population at potential risk through secondary exposure, and suggest their exposure routes.

Location and secondary exposure

Primary use location	**Secondary exposures – examples and potential routes**
Industrial	Maintenance workers (inhalation, skin contact), launderers (skin contact), users of treated articles (skin contact, ingestion)
Residential outdoors	Residents and children (skin contact, ingestion)
Residential indoors	Residents and children (inhalation, skin contact, ingestion)
Recreational outdoors	General public and children (skin contact), ingestion
Recreational indoors	General public and children (inhalation, skin contact, ingestion)

For example, as in the previous section 1.1, a product concentrate may be marketed to preserve a process fluid (such as metalworking fluid). Secondary exposure scenarios at industrial stages include:

- recycling scrap concentrate drums
- home laundry of work clothing
- handling vapour degreasing fluids containing coolant residues
- handling of waste fluids, etc.

All of these scenarios involve skin contact and possibly exposure by inhalation.

Secondary exposure in the residential environment may result from professional and non-professional applications. A professional application is, for example, wasp nest eradication, and a non-professional application is, for example, air space spraying against mosquitoes. Secondary exposure results from residuals remaining in the residential environment. These exposures include

- dermal contact of contaminated surfaces or handling contaminated objects;
- oral contact by mouthing contaminated objects or hand-mouth contact;
- inhalation of residues in air.

Toddlers and infants will play on the floor and are identified as a group at risk through secondary exposure because they may contact contaminated surfaces. Especially babies that do not yet walk will have intensive contact with the floor and show much mouthing of toys, other things and fingers. At 6-12 months of age, mouthing behaviour is most extensive (Steenbekkers, Ann. Occup. Hyg., 2001, 45, suppl. 1: S125-S130). They transfer formulation, for example, from the floor to their skin and cloths.

In addition, adults are also expected to experience secondary exposure through the contacts listed above. For this group, residues on the floor are less of a concern, and other contaminated surfaces may be of interest. For example, if dilution occurs on the kitchen top, subsequent use of the top may cause secondary exposure.

1.3 Data quality and data adequacy

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 variability's 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's
- engineering measures in use
- recommended (or in use) personal protective equipment
- matrix-matched recovery data (field and laboratory)
- limits of detection and quantitation
- 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 concentration
- analytical aspects (technique and documentation)
- container size/type
- formulation (type)
- activities involved, differentiated according to the 'job-classification' (see above)
- 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	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

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, vapor, 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. shoveling, intermittent heavy lifting with pushing or pulling), *very heavy* (e.g. shoveling wet sand).
Categorical (yes/no)	Inadvertent exposure of food through treatment/contamination

We realise that most studies of human exposure to biocides that have previously been undertaken will not report detailed data for many of the above. However, we consider that in the future further efforts should be made to collect such data.

1.4 Determining the pattern of use for each scenario

The pattern of use data must be based upon current (local) practice. There is an issue for mutual acceptance of products that the pattern of use should be substantially similar

This may well involve commissioning research. While some authorities hold data for the pattern of use of some products, there needs to be evidence that these are valid outside the country in which they were derived.

For example, use of a domestic hand-held aerosol insecticide space spray is currently assumed as a frequency of 4 times daily and a duration of 6 seconds per use, in Britain. The default patterns of use are set out in Part 2.3.2.

It is acceptable for the data on frequency and duration of use to report ranges (minimum to maximum values). Alternatively, the entire range can be used through probabilistic modelling techniques. Imprecise data can be used (for more details see Part 2.3.3).

For example, an activity such as changing a drum of concentrate and moving the dip tube, may take place once a week and take a few minutes. It is legitimate to assume a value for use in exposure estimation, event-based as follows:

- Mixing and loading concentrate:
  Frequency for exposure assessment: one per day
  Duration for exposure assessment: 2 minutes' exposure per event.

  Frequency on a weekly, monthly or yearly basis.

The essential data are:

- the product and its purpose;
- where, how and by whom the product will be used;
- expected exposure controls (for example, process enclosure);
- tasks, frequencies and duration's for mixing and loading;
- tasks, frequencies and duration's for application or use;
- tasks, frequencies and duration's for post-application activities;
- who else may be exposed (secondary exposure).

Particularly for professional users, it is important to know the time budget. That is, the time spent in using the product (mixing and loading, application, post-application) as a proportion of the work day. The preparation of time budgets requires research, or a reasoned case made.

<u>Pattern of use</u>

Information on the pattern of use can only be gathered through surveys. Such information is only rarely available in scientific or published literature. Those placing biocidal products on the market will need to demonstrate a scientifically sound basis for MOS calculations (Part 2.3.2) or conduct research into the pattern of use, directly with users. The magnitude of MOS may trigger additional analyses, e.g., most critical route, most effective exposure mitigation measures etc.

While there may be common tasks (for example, coupling a reservoir of biocide to a dilution system), and the ranges of duration for this task known, the number of times a day such tasks could be undertaken would depend on the product type and location.

The pattern of use may be a seasonal, regional or local issue, and Competent Authorities will need to assure the relevance of a stated pattern of use in product authorisation. For example, ground injection of insecticide for termite control occurs only in countries where termites thrive.

The data requirements to determine the pattern of use has been derived from those developed in an OECD workshop on human exposure to wood preservatives (OECD, Workshop on 'Human exposure to wood preservatives', Ottawa, June 19-21, 2000).

Pattern of use - data requirements

Data requirement	**Priority**	**Comment**
Product		
- physical state	Essential	liquid / solid / in-situ generation / particle size, aerosol, volatility
- package details	Essential	volume, material, closure, bulk delivery, etc.
- formulation details	Essential	active substance and co-formulants
- site inventory	Desirable	amount, delivery frequency
- storage information	Desirable	
Purpose of product		
- where used	Essential	location / system treated
- description of tasks	Essential	how used, application rates
- equipment used	Essential	pressures, volumes
Use environment		
- containment	Essential	barriers to exposure, ventilation
- pattern of control	Essential	full containment, LEV, segregation, dilution ventilation
- use pattern	Essential	closed system, within a matrix, non-dispersive, wide dispersive
Mixing and loading phase		
- task	Essential	description
- frequency per task	Essential	events per day
- duration of task	Essential	event duration
- quantity used per task	Desirable	
- dilution rate	Essential	
Application phase		
- task	Essential	description, continuous / intermittent / event
- frequency per task	Essential	events per day
- duration of task	Essential	event duration
- quantity used	Essential	not always relevant
- area / volume treated	Essential	not always relevant
- timing	Desirable	seasonality etc.
Post-application phase		
- task	Essential	description, continuous / intermittent / event
- frequency per task	Essential	events per day
- duration of task	Essential	event duration
Disposal		
- task description	Desirable	e.g. strip old coatings, collect dead vermin
Primary exposure		
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.		

Examples of pattern of use studies are shown in:

- RIVM Draft Report 612810-013, Residential Use of Biocide Sprays - Observational Study (Baas and Van Veen, 2001).
- Weegels, M. F., 1997.Exposure to chemicals in consumer product use. Delft, the Netherlands: University of Technology; report nr. ISBN 90-5155-008-1.
- Chorleywood Food Research Association, Chipping Campden, Report Patterns of Disinfectant Use in Food Production (HSE Contract no 4009/R72.052) (Taylor et al., 2001).

The following table sets out a format for information to produce a scenario-based time budget that is compatible with modern exposure modelling software.

Time budget for a stated scenario

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

For example, using metalworking fluids, the tasks identified above, the mixing and loading, application and post-application tasks can be mapped onto a task classification matrix (e.g. as in Part 2.1.5). This should simplify the selection of an exposure model for the task, and the estimate of exposure for the scenario.

1.5 Classifying tasks and modes of exposure for scenarios

Each biocidal product is applied by one or more procedures. These are "scenarios", and each is composed of phases:

- mixing and loading
- application
- post-application and
- disposal or removal.

The exposure of the biocide *user* is "primary" and occurs in all phases. The exposure of *other* people is "secondary", during application and in particular, post-application.

The primary exposure matrix on the next page is based broadly upon the EU-project "RISKOFDERM" task classification. It assists in classifying the tasks leading to primary exposure, listing determinants of exposure, the usual control measures encountered, and a time budget. That process helps in selecting the correct mathematical and/or database models for preparing primary exposure estimates.

That matrix is not intended for secondary exposure estimates. The secondary exposure route matrix follows on the subsequent page.

It is to be noted that for hygienic measures to be taken the order should of priority should be starting at the source and ending with personal protective equipment (see Part 2.2.3).

Task classification matrix

Part 1: Task analysis - biocidal products	
1.1	**Handling objects**
1.1.1	Transfer - filling and emptying solids / dusts and weighing
1.1.2	Transfer - filling and emptying liquids and weighing
1.1.3	Handling wet objects (see also 1.4)
1.1.4	Handling dry / dusty objects
1.2	**Dispersion of product with hand-held tool**
1.2.1	Mixing and diluting
1.2.2	Wiping surface (includes polishing)
1.2.3	Scrubbing, scouring and abrading surface
1.2.4	Spreading onto surface with comb, trowel or float
1.2.5	Pouring onto surface
1.2.6	Coating surfaces with brush or roller
1.2.7	Application using a placement device (e.g. caulk gun, nozzle)
1.2.8	Sweeping using broom
1.2.9	Mopping
1.3	**Dispersion of product with hand-held pressurised equipment**
1.3.1	Spraying liquids for surface treatment
1.3.2	Spraying dusts for surface treatment
1.3.3	Foaming for surface treatment
1.3.4	Spraying for surface coating
1.3.5	Spraying air spaces (e.g. knock-down treatments)
1.3.6	Injection of liquid or dust into soil or surface layers
1.4	**Immersion**
1.4.1	Bathing, showering
1.4.2	Washing articles
1.4.3	Manual dipping articles
1.4.4	Automated dipping articles
1.5	**Interface with machinery and industrial systems**
1.5.1	Systems dispersing liquid aerosols or dusts
1.5.2	Systems with liquid streams or sumps
1.6	**Ancillary activities**
1.6.1	Maintenance, servicing, cleaning, assembly and fitting
1.6.2	Sampling and in-situ testing
1.6.3	Other (define)

Part 2: Exposure determinants	
2.1	Application rate (amount used per unit time)
2.2	Application pressure
2.3	Barrier between user and the application process (see control measures)
2.4	Distance from source of emission (e.g. paint brush = 0, spray lance = 1 meter)
2.5	Orientation of application (overhead - level - down - all)
2.6	Frequency and extent of contact with contaminated surfaces
2.7	Wetness or dustiness of objects
2.8	Product properties (solid - dustiness, liquid - viscosity, volatility)
Part 3: Anticipated control measures	
3.1	*Personal protective equipment*
3.1.1	Work clothing - long-sleeved shirt and long trousers, shoes
3.1.2	Disposable gloves
3.1.3	Protective gloves
3.1.4	Coverall and head protection
3.1.5	Apron
3.1.6	Face protection e.g. visor and eye protection
3.1.7	Foot protection
3.1.8	Respiratory protective equipment
3.1.9	Chemical suit
3.2	*Engineering controls*
3.2.1	General ventilation
3.2.1a	Outdoor use only
3.2.2	Local exhaust ventilation or extraction system
3.2.3	Contained use
3.2.4	Closed system
3.3	*Administrative procedures*
3.3.1	Training and familiarisation
3.3.2	Exclusion and permit to work
Part 4: Time budget	
4.1	Time for the scenario
4.2	Frequency of the scenario, per day
4.3	Task list for the phases within the scenario
4.4	Estimate of % of time per task, within the scenario

Secondary exposure has the following sources

Secondary exposure routes - biocidal products	
1	**Exposure by inhalation**
1.1	*Application phase*
1.1.1	Vapour during application
1.1.2	Liquid or dust aerosol during application
1.2	*Post-application phase*
1.2.1	Volatilised product
1.2.2	Generated dust aerosols in reworking treated objects
1.2.3	Re-suspended solid aerosols (e.g. through vacuum cleaning) or removal (e.g. paint stripping)
2	**Exposure by skin contact**
2.1	*Application phase*
2.1.1	Deposition on exposed skin
2.2	*Post-application phase*
2.2.1	Contact with treated surfaces or articles
2.2.2	Contact with dusts
2.2.3	Contact with contaminated areas, clothing or tools
3	**Exposure by ingestion**
3.1	*Post-application phase*
3.1.1	Ingestion of dislodged dust and deposits (children)
3.1.2	Mouthing treated articles (children)
3.1.3	Ingestion of food / water contaminated with direct deposits
3.1.4	Ingestion of food contaminated with dislodged deposits

1.6 Task-based exposure prediction and indicative value selection

At this stage, the assessor must be clear on the tasks involved in the scenario and the potentially exposed populations. The options for estimating exposure through the Tiered Approach are as outlined below.

Exposure is expressed as a distribution, and values from that distribution are used in risk assessment. It is important to be aware of the width of data distributions. The selection of a value depends on a number of factors such as:

- the size and reliability of the data set;
- the user sector / population exposed;
- the use patterns;
- the precedents (for example related to highly toxic products);
- the level of the assessment (screening or detailed);
- the availability and validation of predictive models;
- biological mechanism (chronic vs. acute effects).

It is possible to formulate some science-based, generic guidance on the selection of values. For example:

- Selection of indicative exposure values for chemicals with chronic and acute effects should be based on relevant time frames (i.e., long-term and short-term exposure averaging, respectively); in a given data set this generally implies that values for acute toxins should be represented by higher cut points of the exposure distribution compared to chemicals with chronic effects.
- Indicative values may reflect so-called 'typical' and 'reasonable worst case' (RWC) situations, aiming at identification of workers toward central tendency values and high-end values of the exposure distribution, respectively.
- where exposure data are sparse or the quality of the data set is relatively low, higher values from the range should be selected, to provide a degree of reassurance;
- for screening (Tier 1) assessment, higher values should be selected.

Exposure is expressed as a distribution, and values from that distribution are used in risk assessment. The selection of indicative values for exposure assessment is a matter for policy, informed by scientific judgement. Typical indicative values currently used by regulators include the median (50^{th}), the 75^{th}, 90^{th} and 95^{th} percentile values in the relevant exposure distribution; the arithmetic mean, and the highest data point (if not considered to be an outlier).

Percentiles can be calculated without making assumptions as to the nature of the distribution (though empirical estimates of higher percentiles are only obtainable with extensive data sets). The following descriptions lead to policy on selecting typical or reasonable worst case values from exposure distributions, for risk assessment:

Since (occupational) exposures are generally log-normally distributed, the geometric mean (GM) is the median or central tendency value for exposure. The GM value alone may not be relevant to risk assessment as a central tendency value because exposure itself has, in general,

a direct relationship to health effects and averaging the real exposure data is therefore more appropriate than averaging the log-transformed exposure data.

In the process of determining typical and RWC exposure estimates two aspects should be considered appropriately. The time frame of the exposure assessment and hazard evaluation of the chemical should be comparable in the risk assessment process: i.e., one should distinguish between RWC exposure estimates for chemicals with chronic and acute effects. Moreover, the quality of the measurement series or level of uncertainty has to be taken into account. The uncertainty is a description of the 'lack of knowledge'.
Both are important issues, which should be considered carefully before selecting a particular indicative value from the data distribution. The various steps, which should be considered when selecting individual exposure values for risk assessment can be summarised as follows.

A selection of an indicative exposure is based on 1) biological relevant timeframe and 2) uncertainty. The timeframe concerns chronic and acute as the most relevant ones, and uncertainty contains elements of validity and precision.

Biological relevant time frame
The multiplicative interactions of underlying determinants generally result in skewed exposure distributions, with a large amount of relatively small values and a few large observations. This exposure distribution is not one-dimensional and two important components can be distinguished: heterogeneity between workers ('between-worker' variability) and variability from day to day ('within-worker' variability). Unfortunately, in most exposure assessments for risk assessment only one measurement per person is available, precluding a proper evaluation of these components of variability. For measurement series with one observation per subject a cut point of the exposure distribution, say the 95th percentile, reflects that 5% of the measurement days will exceed this value. This phenomenon is referred to in the literature as the 'exceedance'. The probability that the long-term average exposure of an individual exceeds a particular threshold, which is referred to in the literature as 'overexposure', cannot be directly distracted from such a distribution. The determination of the probability of 'overexposure' requires insight into the exposure heterogeneity between workers. This is only possible when repeated measurements on at least a random sample of the workers is available. If a series of measurements are available for individuals, then their long term average exposure should be estimated by the arithmetic mean of the repeated measurements (regardless of the shape of the distribution). As few exposure studies are of this format, in general there is no scientific justification for using the arithmetic mean.

The 75th percentile of a log normally distributed exposure data set –without high GSD- often approximates the calculated arithmetic mean and is the most commonly adopted estimate of the typical exposure value for chronic health effects.

Reasonable worst case value for chronic exposure
Despite the fact that the 'overexposure' concept appears to be logically correct for chemicals with chronic effects, only the 'exceedance' can be calculated in most measurement series. The interrelation between 'exceedance' and 'overexposure' has been extensively discussed by Tornero-Velez *et al.* (Risk Anal 17:279-292, 1997). There appears to be no universal level of exceedance, which provides an acceptable or conservative proxy for overexposure. As a general rule, however, it can be considered that with increasing total variability and an increasing proportion of within-worker variability smaller and smaller values of exceedance

are necessary to provide a conservative estimate of overexposure. It is proposed that the 95 percentile of the distribution may be considered a sound indicative value for chronic exposure. The rationale behind this choice is that there exists substantial potential for 'overexposure' if a more lenient cut off point is chosen. For a detailed description on issues related to 'exceedance' and 'overexposure' we refer to Tornero-Velez *et al.* (Risk Anal 17:279-292, 1997). Based on this paper some recommendations have been made for exposure assessment for risk assessment by Tielemans *et al.* (Determining exposure levels for risk assessment using various information sources. 2001, TNO report).

Reasonable worst case value for acute exposure
Ideally, the estimation of RWC exposure estimates for fast-acting chemicals with acute toxicity or irritation should be based on empirical data with relevant short averaging times. However, most measurement series are task- or shift-based. Therefore, it seems obvious in most existing data sets to focus on the extreme right tail of the exposure distribution. Yet, it is in general very difficult to define a specific cut point for acute exposures, since the log-normal distribution is, in theory, an unbounded distribution. Hence, according to the log-normal distribution even extreme exposure levels may occasionally occur. It is obviously not likely that such extreme exposure values are captured by small measurement series. Hence, selecting the highest values among limited measurement series is not a valid strategy.

One may therefore follow a procedure according to which a (log-normal) distribution is fitted on the basis of available empirical measurements. Subsequently, an extreme cut point such as the 95^{th} percentile of that fitted distribution may be arbitrary considered as an indicative value relevant for the risk assessment of acute effects. One should realise, however, that especially extreme cut points are sensitive to the choice of the fitted distribution. For this reason it is necessary to check the fit of data graphically or by goodness-of-fit tests. When substantial deviations from the fitted distribution are observed the results of parametric analyses should be interpreted cautiously.

Accounting for uncertainty

In order to effectively select indicative exposure values for risk assessment, one should also be aware of the quality and related level of uncertainty of the exposure data. Yet, current lack of guidelines for estimating exposure levels in the face of data uncertainty hinders efforts to make reasoned decisions. The uncertainty of exposure data can be disentangled into two issues: i.e., validity and precision of the data. A prerequisite for the interpretation of precision and validity issues is the availability of a comprehensive set of contextual information.

Validity
Basically, to safeguard health of workers, a safety factor (=uncertainty factor) should be applied when the exposure data at hand have a limited degree of validity. Several aspects of validity have been discussed earlier and are related to issues as representativeness, systematic error, and lack of basic core information. The risk assessor is forced to be conservative and use overestimates or a very broad range of estimated exposure to protect against underestimation in the face of (unsuspected) uncertainty. It can be concluded that there is no obvious and transparent way according to which adjustments can be made. Obviously, such adjustments should only be applied if the potential for unsuspected errors is present and relevant for the RA process. The evaluation of data quality and validity should be conducted by experienced exposure assessors with a sufficient level of experience in this research field .

Precision
The level of precision of exposure estimates is a function of both variability of the observations and the sample size. Moreover, the level of precision is also dependent on the particular cut point chosen; estimates of extreme percentiles of the exposure distribution can be quite unstable as compared to measures of central tendency. Hewett and Ganser (Appl. Occup. Environ. Hyg. 12:132-138, 1997) have introduced some simplified procedures for calculating confidence intervals for percentiles of log-normally distributed exposure data. These confidence intervals indicate the degree of uncertainty in the point estimate of the percentile.

The 95th percentile value can be taken to represent the "reasonable worst case" for chronic exposure and also to reflect the anticipated exposure through foreseeable misuse.

The 95th percentile value can be taken for acute exposures.

It should be noted that these considerations refer to exposure issues. In the hazard evaluation, at least some of these issues are also of concern, and a warning should be given that uncertainty should not be counted twice in the risk assessment

The recommendations for use of data in a Tiered Approach (see Part 2.2.1) appear below.

Tier 1

- there exists a directly relevant model or a precedent that can be adapted
- there is no such model or precedent and a new deterministic estimate is to be made.

The assessor will select a model and use the 75th percentile value, if the dataset is representative and appropriate. If not, the 90th percentile is a better choice. Where the task duration is relevant, the 75th percentile value will be used to produce the exposure estimate. Exposure through the phases of use (mixing and loading, application, post-application, removal) shall be simply summed based on their time-weighted average time budgets.

There shall be no exposure reduction through exposure reduction measures.

Tier 2

- there exists a directly relevant model or adequate exposure data
- there exists an indirectly relevant model or a meta-model

The assessor will select a model and use the 75th percentile value, if the dataset is representative and appropriate. If not, the 90th percentile is a better choice. Where the task duration is relevant, the 75th percentile value will be used to produce the exposure estimate. Exposure through the phases of use (mixing and loading, application, post-application, removal) shall be simply summed based on their time-weighted average time budgets.

There shall be iterative consideration of exposure reduction through increasing levels of exposure reduction measures.

Where probabilistic estimation is conducted using the full data sets, and combining exposures through the phases of exposure, the 75^{th} or 95^{th} percentile outputs may be used as the exposure estimate. The current knowledge on dealing with appropriate probabilistic assessments, however, is at the moment insufficient for use in the general case for exposure assessment in regulatory processes.

There could be a lower predicted risk where professionals use an active substance that is managed by a sole manufacturer under product stewardship rules. Product stewardship implies some supervision of user companies, and some influence over their control of risks and worker behaviour. However, the current state of product stewardship is such that no formal generic way of lower predicted exposures can be proposed.

Tier 3

- a project protocol shall be required, to fill a stipulated data requirement.

Such a protocol should be prepared by the registrant and proposed to the knowledgeable competent authorities for consideration. Important elements here are the representativity of the scenarios to be studied and the appropriate size of the study for that goal. Competent authorities should take care of issues of ‘mutual recognition’ between member states that can come into play.

The selection of models is explained elsewhere in this document (Part 2.3). The choice of surrogate values from these models should be based on the above choices and the database itself.

1.7 Multiple and repetitive tasks and exposure summation

Human exposures are distributions, not single values. But single values need to be extracted from 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 fairly reflected 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 outlined as an example in Part 3.

(for more details see Ann. Occup. Hyg. 45 Suppl. 1, 2001)

1.8 'Validation' of exposure estimates and critical commentary on outputs

The Tiered Approach to risk assessment requires that decisions be made on reasonable exposure estimates.

Considerable expert judgement is required in order to take a view on whether or not a given exposure estimate is reasonable. That expertise will only develop over time. It is useful to state that there is no right or wrong answer for an exposure estimate. Very much depends on the percentile extracted from data distributions for use in risk assessment.

It is therefore important to have means for deciding whether an estimate is acceptable or unacceptable. (It is inappropriate to describe an estimate as right or wrong, as expert judgement is involved).

An estimate may be acceptable so long as it is corresponds with an anticipated value.

As a rule-of-thumb:

- for inhalation data, within a factor of 3;
- for potential or actual dermal exposure data, within a factor of 5.

Is this a point estimated or time-accumulated estimate?

Tier 3 surveys and studies would be required to confirm the validity of exposure estimates. But some validation is necessary within Tiers 1 and 2. Three techniques are proposed for enabling a degree of validation, and the assessor should record the output of such validation.

Estimate using more than one method

This is deriving estimates by more than one route, and comparing the outputs for consistency. For example, a computer model output value can be compared with a simple worst-case default value deterministic calculation.

Comparing sparse study data with expected distributions for inhalation and dermal exposure

A data range (inhaled, dermal) for a type of task is readily estimated using a model or through personal expertise on the part of the expert assessor. This can be compared with study data. The comparison indicates that the study data are acceptable if the distribution of study data falls within the expected distribution, and the median value matches *within one third (inhaled) or one half (dermal) an order of magnitude*.

An expected distribution for potential dermal exposure can be generated using the "indicative exposures" meta-model (see Part 2.3), or from data distributions for broadly analogous scenarios.

If the study data do not fall within the expected distribution, the reasons for mismatch need to be established and recorded.

Comparing new deterministic outputs with Examples (Part 3)

Ultimately, the Commission may decide to compile a compendium of exposure assessments, to augment the Examples in Part 3 of this guidance. This offers the potential guidance based on precedent and it is recommended that such "knowledge management" be instituted at an early stage.

CHAPTER 2 PROCEDURE AND FORMAT FOR EXPOSURE ESTIMATION

2.1 Role of Tiered exposure estimation in risk assessment

Tier 1 Screening

The screening Tier in the exposure assessment process should be quite simple. The assessor would select the top end value in a study, a worst case mathematical or deterministic estimate, or a high-end indicative value from an empirical (database) model.

The "reasonable worst case" exposure estimate includes reasonable worst case pattern of use information. Tier 1 estimates do not take account of personal protective equipment (PPE).

The format should be shown in the following form:

- scenario description and task descriptions for phases of use by the relevant populations;
- default values used;
- assumptions made;
- models used;
- output values for summed reasonable worst case uptake (mg/kg/day).

If the Tier 1 exposure estimate is sufficiently safe, as concluded from the risk assessment, there is no need to continue with next Tiers.

Tier 2 Realistic exposure estimation

The second Tier in the exposure estimation process is more complex that Tier 1.

The exposure estimate needs to state the default values selected and all assumptions. Estimates are required for all relevant populations, for all tasks (except where exposure is obviously trivial) and for all relevant exposure routes. In Tier 2 the estimate must take account of the likely existing control or exposure reduction measures.

If the resulting exposure estimate produces an unacceptable outcome in risk assessment, an iterative procedure begins. The exposure reduction measures (exposure controls) are successively refined and the exposure estimate redone, until the options for mitigation of exposure have been exhausted.

The format should be shown in the following form:

- scenario description, user population and task descriptions for phases of use;
- default values used;
- assumptions made;
- exposure reduction option dependent on user group, and protective effect;
- models used;
- method used to add exposures in the phases of use;
- output values for reasonable worst case uptake (mg/kg bw/day).

Where control measures or exposure reduction measures are necessary to reduce exposures to an adequate level, these must be stated clearly as they may lead to non-inclusion or influence the conditions of inclusion of the Annex I entry. But where the final outcome remains unacceptable, a Tier 3 assessment is required.

Tier 2 estimates are appropriate for a detailed exposure assessment of Specialised professional users. Because within this subgroup it is probable, that these users have specialised knowledge and skill in handling hazardous chemicals. Protective measures (instruction, training, exposure control, PPE) are supposed to be carefully observed (see Part 1.1.3).

Tier 3 Experimental field exposure estimation

The final Tier 3 of the assessment recognises that valid estimates of human exposure are produced through surveys or studies with the actual product or with a surrogate.

Exposure surveys need to be large enough, well enough reported, and representative, to be convincing (Part 2.1.3). Studies may need to cover an entire scenario; or to provide detailed information on key tasks within the scenario.

The surveys or studies may include biomonitoring to show the extent of the systemic uptake - biomonitoring is a useful and persuasive tool for risk assessment. The information is particularly useful where a workforce has been studied over a period of time, and at a known (fairly continuous) level of exposure. For interpretation, information is needed on the kinetics of the indicator label used for evaluation. But biomonitoring may be intrusive and logistically difficult to conduct, particularly in respect of secondary exposure.

When biomonitoring is carried out, the validated method of data acquisition and data interpretation with respect to human metabolism must be included within the Tier 3 study protocol. The data require expert interpretation. References include British guidance EH56, HS/G/167 and MS/17.

It is further stressed here that the biomonitoring studies should be carried out in compliance with the Helsinki Declaration and only for exposure assessment purposes.

Exposure studies need to cover the relevant entire scenario(s).

Convincing distributions of workplace exposure would normally require 20 to 30 personal data for inhalation and potential dermal exposure, possibly more, depending on the biocide application tasks. These should normally be taken from several independent surveys.

Where task-specific information is needed, then smaller scale studies or laboratory or workshop simulations may be adequate, using the appropriate substance (e.g. 10 data).

The restrictions and controls applied in Tier 3 field exposure studies will lead to the same default controls being specified in the conditions for biocide use.

The Tiered approach is detailed in Ann. Occup. Hyg. 37:499-507 (1993) and endorsed in the OECD Guidance Document (97)148 (1997).

2.2 Secondary exposure estimates - Reference Scenarios

The following paragraphs set out options for estimating secondary exposure to biocides. They should be subject of discussion on Member State level.

Scope and definitions

"Secondary exposure" is the term proposed for use to describe the exposure of people who receive a dose of a substance through being present during an application task, or being present in places where a substance had been used. A key feature is that secondary exposure occurs without the exposed person being aware, or having control over that exposure.

Secondary exposure also includes 'exposure via the environment', e.g. through airborne plumes from treatment sites, through residues in food and in drinking water.

Persons experiencing secondary exposure include the whole population (people at work, bystanders, and residents - children, pregnant women, servants, the infirm; others include the immediate family of a worker, of the contract maintenance engineer, or the launderer of work clothing).

Secondary exposure of any individual is a continuum, through the phase of product application, into the long-term post-application phase and may also result from private use post-application..

Acute phase secondary exposure is closely related to the event of applying a product, and the short period thereafter (e.g. while aerosol particles settle, evaporation from freshly applied paint).

Chronic phase secondary exposure occurs thereafter, in the long term, and may be continuous.

There is an immense range of secondary exposure scenarios within the 23 product types and it is impossible to cover them all. The following list presents a set of examples of secondary exposure:

- indoors, following pest control in a public place (restaurant, swimming pool);
- indoors, during and after use of a household product;
- indoors, long-term, such as the bedridden in hospital;
- indoors, short-term, such as mould eradicator in bathrooms;
- indoors, food in contact with insecticide overspray or with preserved wood;
- indoors, infants mouthing treated articles or articles in contact with treated surfaces;
- outdoors, through contact with treated fences;
- outdoors, children playing on treated timber playground structures;
- industrial, those employed in recycling plant;
- industrial, those wearing work clothing during non-work periods;
- industrial, those washing work clothing at home;
- exposure via the environment (see above).

The US EPA examines a wide range of sub-groups at risk through secondary exposure: infants, children in two age bands, adolescents and adults.

It is considered sufficient to consider adults, children (20 kg) and infants (10 kg) and their behavioural characteristics as appropriate, described in (3.1), and any other groups that the toxicological profile indicates may be at enhanced risk through exposure and that may reasonably be expected to experience exposure.

Adults and children require separate consideration as their routes of exposure can differ significantly:

- inhalation, e.g. volatilised residues;
- via the skin e.g. dislodged residues - crawling infants at enhanced risk of exposure;
- ingestion, e.g. for children, hand to mouth and for infants, foot and toy to mouth;
  e.g. for adults, hand to food or hand to mouth (smoking).

Secondary exposure scenarios need to be reasonably foreseeable and plausible. Examples of reasonably foreseeable (misuse) scenarios include:

- cleaning up a gross spillage
- public bathing in a decorative fountain, the water having been treated with algaecide.

Wilful and intentional misuse is not in scope for secondary exposure evaluation. Examples of such scenarios include:

- sniffing the propellant of a hand-held aerosol product;
- decanting from a container with a childproof closure, into one that leads to ingestion;
- painting a concentrated product intended for use by spraying diluted.

One should always use the probability of occurrence as an argument for the choice of a scenario to be considered.

The Netherlands has developed a computer model that contains elements of probabilistic computation (CONSEXPO - see Part 2.3.4). The model applies to primary and secondary exposure. The NL regulatory authority is in the process of drawing up information sheets (factsheets (see Part 2.3.5), proposing suitable default values for input to scenario calculations.

Another option is the use of US EPA Standard Operating Procedure (SOP) routines (see also Part 2.3.4 under B).

The following page proposes a format for secondary exposure estimation.

Secondary exposure scenario development - options

A fundamental of exposure prediction remains a need for information about the product applications, its pattern of use (frequency and duration, application method and location) and the user and further persons exposed.

Option 1 - the Reference Scenario approach - Tier 1

Knowing the proposed use of a product, it is possible to 'invent' reasonably foreseeable scenarios that will involve reasonable worst case for acute and chronic secondary exposures of adults and children, through inhalation, ingestion and via the skin. These scenarios are termed "Reference Scenarios".

For example, for a residential wood preservation (curative) treatment:

- acute phase, adult: clearing a gross spillage;
- acute phase, child contact with wet surface;
- acute phase, infant mouthing articles contaminated with preservative;
- chronic phase, adult inhalation of volatilised residues;
- chronic phase, child inhalation and playing on the treated wooden floor;
- chronic phase, infant as the child, plus ingestion of contaminated dust..

Option 1A - the refined Reference Scenario approach - Tier 2

This would apply to the acute phase only. Assessment shows acute phase exposure to be unacceptably high, but the likelihood of that event is analysed as very remote (e.g. less than 1 in 10^5). A lesser, more probable Reference Scenario should be selected and the risk through that secondary exposure assessed. This accords with the Tiered Approach.

The probability of the acute Reference Scenario could be estimated through techniques such as fault tree analysis. Fault tree analysis examines a top event - for example a spill of wood preservative - in terms of the probability of individual factors leading to that top event. The individual factors that lead to exposure to a specific active substance include:

- *the likelihood that an average can contained a specific substance*
- *that it was open indoors*
- *that it was upset, and*
- *that contact occurred.*

(ref. Health and Safety Executive, Quantified Risk Assessment: Its Input to Decision-Making, HMSO (1989); International Engineering Consortium (TC 56), Analysis Techniques for system Reliability.)

Option 2 - the reverse Reference Scenario approach - Tier 1

The Reference Scenario is used solely 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 AOEL or the relevant fraction of the most appropriate (taking account of the margin of safety (MOS) or of exposure (MOE)) NOAEL, it is possible to compute the amount of product that would lead to that (systemic) dose by a specific route. That amount

can be related to the amount of exposure that is likely, obtained from experimental or other data.

Addition of chronic phase secondary exposure estimates - Tier 2

Probabilistic estimates are useful where there are significant exposures from multiple routes of intake.

The current situation with probabilistic exposure assessments for regulatory purposes is such that this approach is only acceptable in specific cases.

2.3 Options for exposure reduction and personal protective equipment (PPE)

There are options for exposure controls that assessors can invoke, to abate primary and secondary exposure. Such controls are used in Tier 2 exposure estimates and the options are:

- Structure related
- Engineering
- Administrative
- Personal.

A Structure related control of exposure

This applies to residential environments and workplaces alike. Structure related control means the reduction of exposure by inhalation afforded by general ventilation. For the purposes of biocidal product authorisation:

- general ventilation assumptions will apply in mathematical exposure modelling of primary and secondary exposure by inhalation in residential environments;
- general ventilation assumptions will generally not apply to database exposure estimates or to workplace primary inhalation exposure estimates.

However, in some workplaces there will be provided ventilated refuges to provide segregation between the worker and the biocide. (*For example, in agriculture, appropriately closed tractor cabs act as a refuge and provide at least 20-fold protection*). Such issues may be factored into estimates of primary exposure by inhalation, but good data on the pattern of use and the degree of protection will be required.

B Engineering control of exposure

This applies to workplaces only.

Engineering control in industrial processes means the abatement of exposure by local exhaust ventilation at the point of emission, or by containment in pipework or other systems from which minor emissions only are anticipated. For the purposes of biocidal product authorisation:

- local exhaust ventilation is assumed to reduce inhalation exposure by a factor of 10;
- containment is assumed to reduce inhalation exposure by a factor of 100;
- containment is assumed to eliminate dermal (bare hand) exposure, except for maintenance operations.

C Administrative control of exposure

This applies to residential environments and workplaces 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:

- proper supervision and training of workers should lead to the selection of a percentile from databases other than the reasonable worst case.
- procedural plans, event planning (such as accidental spill procedures) and permits to work for operations such as fumigation and maintenance should lead to less precautionary assumptions being taken in deterministic estimates.

"Safe systems of work", "emergency procedures" and “permits to work” mean that hazardous biocides can 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. Another example would be the use of a toxic fumigant to disinfect a Biological Agent Containment Level 3 facility.

D Personal protective equipment

Personal protective equipment (PPE) means the abatement of primary exposure by the user taking specific steps to limit inhalation and skin exposure. PPE is relevant to primary exposure only. For a recent overview of an appropriate approach, the reader is referred to Brouwer et al., Ann. Occ. Hyg. 45:543-553, 2001.

Residential environment

While residents may wear coveralls, gardening or kitchen gloves, or even a dust mask, such usage cannot be assured and must not be assumed in exposure estimation. For example, amateur users wearing sandals and shorts when applying antifoulants to leisure craft is the rule rather than the exception in warm weather. At the 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.

For dermal exposure, reduction of 50% is assumed for long shirt and trousers. Otherwise, actual dermal exposure is assumed as 100% of potential dermal exposure. The main reason is that potential dermal exposure is identical to the actual exposure when the person is not wearing anything at all, which is most unlikely for the use of biocidal products, apart from possibly swimming with exposure to disinfectants in the water of a swimming pool.

Workplaces

Workers may use PPE at work. PPE includes respirators, gloves, footwear and work clothing. Many of these are subject to EN design and performance criteria, though assessors

need to take great care in interpreting data such as protection factors and permeation / breakthrough data.

Respiratory protective equipment

For respirators, it can be assumed that the equipment fits the wearer and is in reasonable condition. A protection factor for exposure by inhalation should be assumed along lines similar to those quoted in HSE publication HSG 53 (The selection, use and maintenance of respiratory protective equipment, *currently out of print*), as follows:

RPE Assumed factor for protection	EN 149 EN 138 / 269	EN 405 PrEN 12419	PrEN 1827 PrEN 1835	EN 140 EN 141, 143, 371, 372, PrEN 12083	EN 136 EN 141, 143, 371, 372, PrEN 12083	EN 146 EN 12941 EN 147 EN 12942	EN 270/271 EN 139
4	FF P1	FF gas + P1	FM P1	Mask + P1	Mask + P1		
10	FF P2 BA half-mask	FF gas + P2 FF gas + P3 FF gas	FM P2 FM gas + P3 FM gas LDH 1	Mask + P2 Mask + gas Mask + gas + P3	Mask + P2	TH 1 TM 1	
20	FF P3	LDM 1 LDM 2	FM P3 LDH 2	Mask + P3	Mask + gas Mask + gas + P3	TH2 TM2 TM3	Half mask
40	BA full face-mask BA hood		LDH 3		Mask + P3	TH3 hoods, blouses TM3 full face mask	Hood Blasting helmet
100		LDM 3					Full face mask
200							Suit

EN 149	Filtering half-mask, FF series
EN 138/269	Fresh air hose breathing apparatus, BA series
EN 405	Valved filtering half-mask, FF series
PrEN 12419	Light-duty compressed airline BA mask, LDM series
PrEN 1827	Filtering half-masks without inhalation valves, FM series
PrEN 1835	Light duty compressed airline BA hoods and helmets, LDH series
EN 140	Half mask and filters EN 141/143/371/372/PrEN12083
EN 136	Full face mask and filters EN 141/143/371/372/PrEN12083
EN 146, EN 12941	Powered hoods, TH series
EN 147, EN 12942	Power-assisted masks, TM series
EN 270/271, EN 139	Constant flow compressed airline BA hood and filter EN 139.

Other types such as demand flow compressed airline BA and self-contained BA are available with assumed protection factors greater than 40. The factors are, in practice, quoted by the equipment manufacturers and by RPE suppliers.

Protective clothing

There are no such quoted protection factors available for work clothing. It is assumed that chemical suits in good repair afford better protection than simple coveralls. However this may be through administrative controls, such as mandatory washing-off for chemical suits before they are taken off.

The available HSE data set indicates a 73% likelihood of clothing penetration occurring. The relative penetration, inner / outer sampling patch, ranged 1 to 85%, with a 75th percentile at 30%.

Where the challenge is "considerable", that is, potential dermal exposure (whole body less hands) above 200 mg/minute of in-use product, the protection is 95% (that is, 5% penetration).

Where the challenge is "light", that is, potential dermal exposure (whole body less hands) below 200 mg/minute of in-use product, the protection is 80% (that is, 20% penetration).

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)
- human factors (taking gloves off, contaminating the hands, then putting the gloves back on)

The available HSE data set indicates hand exposure inside protective gloves, expressed as in-use product, equivalent to 4.2 mg/minute (75th % value) and 72 mg/minute (95th % value). (Garrod et al., Ann. Occ. Hyg. 44(6):421-426, 2000).
Comparing these values with deposition on the outer surfaces of gloves, a precautionary protection factor of 95% is indicated (that is, 5% penetration).

The HSE data set indicates further that by using disposable gloves and disposing them after use, 30% of hand exposure can be prevented entirely. And when hand exposure occurs when using new gloves, that exposure is reduced by 30%.

The current knowledge, despite the above findings, is incomplete for estimating reduction factors by adequate clothing worn in an appropriate way, let alone the meaning of the terms ‘adequate’ and ‘appropriate’.

Most information on the effectiveness of protective clothing and gloves is obtained in studies with agricultural pesticides. From the available data, analysed in North America and by the EUROPOEM group in Europe, it appears that *an estimate of 90% exposure reduction with proper materials and proper behaviour for registration purposes can be taken as a default value for gloves and for protective clothing*.

Safe systems of work and “Permit to Work” stipulations

The fact of hazard of a biocide active substance can be countered through safe use - Safe Systems of Work, and for potential high-risk situations, Permit to Work procedures. As issues to control risk in Tier 2 assessment, these controls could be stipulated as requirements in the product authorisation.

The Safe System of Work is a procedure laid down for conducting a continuing operation at minimum risk. Where that minimum remains unacceptably high, most often in individual operations such as maintenance, a Permit to Work procedure is needed. This permit sets out the steps to assure that situations are made safe before work starts, remains safe, and includes recommissioning. The Permit specifies the site and process specific actions necessary to achieve the required degree of safety. An example would be the use of a highly toxic fumigant to disinfect a Biological Agent Containment Level 3 facility.

These stipulations are relevant only for professional

CHAPTER 3 EXPOSURE MODELLING

3.1 Default values for use in exposure prediction

RIVM publishes Factsheets with default values to be used for assessing (consumer) exposure with CONSEXPO. These factsheets are in Dutch, but will be translated into English and become part of the present publication. A large volume is now available and is included in Part 2.3.5.

Further reference is given to a recent ECETOC publication (Technical Report 79, ''Exposure Factors Sourcebook for European Populations (with focus on UK data)" (Brussels, June 2001)).

3.2 Patterns of use statements by biocidal product type

The following pages set out statements for the default patterns of use for most biocidal product types and many of the uses that are anticipated to occur. It is important to note the following points:

- The statements are proposals made in the light of best current knowledge. They are neither complete nor exhaustive. They reflect bias from those Member States who have conducted research into patterns of use. The statements are open to revision in the light of better information.
- Information on some product types may be entered under a heading that will prove incorrect. At the time of writing (late 2001), the only clear demarcation is between agricultural pesticides and biocides and scope discussions continue.

A general format for each of the patterns of use statements appears on the following page. A frequent update and further entry of data is essential for appropriate uses.

General Format

The first part of the statement is in note form, covering:

Background (scope, observations, notes).

Primary exposure

User	(the sector using the product).
Plant & equipment	(the equipment that sets the task and scenario).
Products	(observations on specific categories of product).
Delivery	(how the biocide reaches the user, packages, etc.).
Process & operations	(how the biocide is used)
Frequency, duration & quantity	(core data for estimating primary exposure).
Maintenance, test & clean	(e.g. post-application tasks, with frequency & duration).
Removal & disposal	(where relevant).
Controls	(anticipated for the user)
Market data	(where available).

Secondary exposure

Population, route & time-frame (proposals for identifying those at risk etc.).

The second part of the statement is a table analysing task and exposure, and identifying the task code as set out below, and a time budget estimate (% of time per scenario in relation to the time for the whole task.)

Table

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Application phase			
Post-application phase (includes disposal)			

Part 1: Task analysis - biocidal products	
Task code	
1.1	**Handling objects**
1.1.1	Transfer - filling and emptying solids / dusts and weighing
1.1.2	Transfer - filling and emptying liquids and weighing
1.1.3	Handling wet objects (see also 1.4)
1.1.4	Handling dry / dusty objects
1.2	**Dispersion of product with hand-held tool**
1.2.1	Mixing and diluting
1.2.2	Wiping surface (includes polishing)
1.2.3	Scrubbing, scouring and abrading surface
1.2.4	Spreading onto surface with comb, trowel or float
1.2.5	Pouring onto surface
1.2.6	Coating surfaces with brush or roller
1.2.7	Application using a placement device (e.g. caulk gun, nozzle)
1.2.8	Sweeping using broom
1.2.9	Mopping
1.3	**Dispersion of product with hand-held pressurised equipment**
1.3.1	Spraying liquids for surface treatment
1.3.2	Spraying dusts for surface treatment
1.3.3	Foaming for surface treatment
1.3.4	Spraying for surface coating
1.3.5	Spraying air spaces (e.g. knock-down treatments)
1.3.6	Injection of liquid or dust into soil or surface layers
1.4	**Immersion**
1.4.1	Bathing, showering
1.4.2	Washing articles
1.4.3	Manual dipping articles
1.4.4	Automated dipping articles
1.5	**Interface with machinery and industrial systems**
1.5.1	Systems dispersing liquid aerosols or dusts
1.5.2	Systems with liquid streams or sumps
1.6	**Ancillary activities**
1.6.1	Maintenance, servicing, cleaning, assembly and fitting
1.6.2	Sampling and in-situ testing
1.6.3	Other (define)

General statement concerning product manufacture

Information is taken from:

- Weegels, M. F., 1997.Exposure to chemicals in consumer product use. Delft, the Netherlands: University of Technology; report nr. ISBN 90-5155-008-1
- UBA-INFU Gathering and review of environmental emission scenarios for biocides (June 2000) (research project nr. 360 04 007).
- US EPA Activity Factors Handbook
- TNO BIOEXPO, Development of a concept for environmental risk assessment of biocidal products for authorisation purposes (TNO MEP report R97/443), 1998.

Type 1 Human hygiene products

Background

This product type covers non-cosmetic and non-medical products intended for use in cleaning skin. Examples are hand wipes prior to handling food or healthcare patients, moistened lavatory tissue and baby wipes. It is not certain whether products used for medical scrub-up procedures or anti-bacterial soaps are in scope.

Primary exposure

User

Professionals in food and healthcare. Non-professionals in residential situations, which includes application to infant skin.

Plant & equipment

Not relevant.

Products & delivery

Ready for use in packs or individual sachets. If soaps are in scope, these are marketed as liquid form or as a solid tablet. (Water for bathing at home, as drinking water, contains chlorine). There is no clear information on delivery.

Process & operations

The user removes the wipe from its packing, wipes the hands or skin, and disposes of the wipe as normal or clinical waste. Washing hands and forearms is familiar and simple.

Frequency, duration & quantity

- Tentative values are proposed: wiping - event, 4 per day. The skin dries within 2 minutes. The quantity of liquid deposited on the skin is proposed as 0.5 ml per event.
- Washing - procedure, 4 per day, duration 4 minutes for hands and forearms (Source - UBA-INFU, 2000). The quantity of soap used per procedure is not known.
- Baths and showers - 1 per day, duration 10 and 20 minutes respectively (Source - US EPA Activity Factors Handbook)

Maintenance, test & clean

Not relevant.

Removal & disposal

Disposal is through domestic or non-harmful refuse, or for medical wipes, as clinical waste. Used soap passes to mains drainage.

Controls

None.

Market data

None available.

Secondary exposure

Population, route & time-frame:

Secondary exposure is not foreseeable.

Table: Human Hygiene Products

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Open sachet or dispense soap	-	-	None
Application phase			
Wipe skin	1.5.1	100%	Dermal. No controls. Inhaled for alcohol-based products.
Wash / bathe	1.4.1	100%	Dermal – full skin area
Post-application phase (includes disposal)			
Disposal to refuse or drains	-	-	None

Type 2 Private area and public health area disinfectant

2.01 Disinfectants for medical equipment, biocidal products for accommodation for man or in industrial areas

Background

This product type is used in industry, healthcare, recreational facilities and in the home, to disinfect walls, floors and other surfaces. The type also covers products for disinfecting medical equipment and for fumigating microbiological containment. Medical waste (sharps bins) may contain a disinfectant (Type 2.04). Preservative for medical tissue specimens are addressed under Type 22.

Primary exposure

User

The professional user is either a cleaner, or a professional whose main job is not principally related to disinfection (e.g. nurse, swimming pool attendant). The non-professional user is residential, disinfecting floors, walls and surfaces, principally in kitchens, bathrooms and lavatories.

Plant & equipment

Surface disinfection is done using a ready-for-use (r.f..u.) product, e.g. wipe, trigger spray, or through diluting a concentrate, e.g. for scrubbing, mopping or wiping depending on the degree of soiling. The use of powered sprayers is possible for large areas (e.g. swimming pools).

Medical equipment disinfection is done in a trough or in dedicated cold sterilisation equipment (e.g. for endoscopes).

Space fumigation requires specific equipment to evaporate and disperse the fumigant, and to verify the space free of fumigant before re-entry.

Products

It is anticipated that products for use by professionals are supplied in steel or plastic containers, ready for use in packs or individual sachets. Products for non-professional use are marketed in plastic containers up to 2 litres.

Hypochlorite, used in domestic situations, is normally supplied at 3-5% available chlorine, with typical in-use concentrations at 0.01 to 0.5%. Glutaraldehyde, supplied as a bisulphite addition compound, requires activation before use.

Delivery

There are no data for professional products.. Non-professional products are normally purchased at need and stored at home.

Process & operations

Mixing and loading for surface disinfection requires simple dilution of concentrate in a bowl or bucket. Application depends on the degree of soiling. Post-application, the surfaces are normally wiped or left to dry. Waste disinfectant is disposed to mains drainage. Professional cleaners use products on a prolonged basis, mopping, scrubbing and wiping. A TNO report (V96.314: Schippers

et al., 1996) shows that surface disinfection in healthcare is an intermittent activity. Data for household cleaning activity are quoted by Weegels (TU Delft, 1997), involving mostly wiping and mopping.

Mixing and loading for equipment disinfection may be manual or automatic. Application is by immersion, also manual or automatic. Post-application tasks involve washing and disposal of used disinfectant to mains drainage. A Danish report states that immersion baths for medical equipment should be in well-ventilated areas.

Fumigation involves the evaporation of liquid in a space under "permit to work" procedures. Mixing and loading has an evaporator loaded with concentrate. Post-application, the space fumigated should be certified as free from fumigant residues before reoccupation.

Frequency, duration & quantity

Professional surface cleaning, mopping, scrubbing, wiping:
- frequency - daily, estimated duration up to 8 hours daily
- No data for the quantities of in-use or r.f.u. products for mopping and wiping
  Where glutaraldehyde is used, the in-use concentration is around 0.1%.

Other professionals surface cleaning (Ref. TNO):
- daily, duration 100 minutes (mopping, brushing) or 30 minutes (wiping and scrubbing).
  quantity of dilute product used - 5 litres estimate.

Medical equipment disinfectant baths
- usually one per location, prepared fresh daily.
- mixing and loading - 5 minutes, soaking - 60 minutes, washing - 10 minutes.
- (washing may be part of an automatic cycle)
- quantity of dilute product used - 10 litres estimate, 2% to 3.5% if glutaraldehyde.

There is no information about space fumigation, which would be a periodic task. A default would be one event, and the expected duration of exposure during mixing and loading is transient.

Householders using disinfectant (Weegels)
- up to twice a day, with a probability of use on any day around 20%
- mixing & loading and application take a few minutes per task (sink cleaning, lavatory cleaning, floor mopping) - proposed duration 5 minutes
- quantity used - 55 g of concentrate per application, frequent / heavy users 150 g.

Maintenance, test & clean

No information. It is important to avoid the mixing of hypochlorite with other cleaners, or with formaldehyde, to minimise risks of chlorine gas or bis-chloromethyl ether (BCME) formation.

Removal & disposal

Medical equipment disinfectant baths disposal is to mains drainage. A disposal event would take no more than an estimated 2 minutes, including washing a soaking trough.

Other disposal is to mains drainage, with exposure to dilute disinfectant by splashes only. Used ready-for-use containers are disposed to waste or for pack recycling.

Fumigants disperse to the external environment.

Controls

Cleaners normally wear protective gloves for mixing & loading and application. It is likely that such gloves are contaminated inside. Healthcare professionals would be likely to use disposable latex gloves for cleaning and disinfection of surfaces, and RPE to clear glutaraldehyde spills. Householders may use protective gloves.

Market data

No information.

Secondary exposure

Population, route & time-frame

Adults in healthcare and residential environments: inhalation of volatilised residues (acute)
Children and infants: inhalation and skin contact with wet residues (acute).

There is no foreseeable chronic secondary exposure. The risk of child ingestion of domestic products is minimised through the use of child-resistant package closures.

Table: Disinfectants for medical equipment, etc.

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Surface disinfection - spray	-	-	Ready for use (r.f.u.)
Surface disinfection - concentrate	1.1.2/1.2.1		Hands - gloves, coveralls
Surface disinfection - domestic	1.1.2		Hands - no protection
Medical equipment bath	1.2.1		Hands - gloves. Inhaled - general ventilation
Space fumigant	1.1.2	100	Hands - gloves Inhaled - general ventilation or RPE
Application phase			
Surface spray	1.3.1	100%	Hands - coverall, gloves
Surface wipe (r.f.u.)	1.2.2		
Surface disinfection (mop, scrub, wipe)	1.1.2/1.2.2/ 1.2.3/1.2.9		Hands - disposable gloves (work) lower legs - no protection
Article disinfected	1.1.2/1.2.2/ 1.2.3/1.2.9	-	Hands (home) - no protection
Medical equipment bath	1.4.3/1.4.4		Inhaled - general ventilation
Space fumigant	1.5.1		None
Post-application phase (includes disposal)			
Dispose used disinfectant	1.1.2		Hands

Type 2 Private area and public health area disinfectant

2.02 Biocidal products to be used in swimming pools, etc.

Background

The product type covers the treatment of indoor and outdoor public and private swimming pools, leisure centres (water-slides, wave machines), hydrotherapy pools and spa baths. Spa baths and leisure pools are high challenge environments. Swimming pool filtration equipment contains biocide fixed within the filter medium, to prevent accumulation of biological agents within the filters. As (possibly) Product Type 9.03, this is done during product manufacture and is discussed later. Procedures such as filter backwash are physical procedures and are not covered in this statement.

Primary exposure

User

Professional users are employed at public pools and spa baths. Non-professional users may treat private pools and spa baths, though this can be contracted out to professional maintenance staff.

Plant & equipment

Generating plant (for in-situ generation of chlorine dioxide), or metering plant for liquid and solid dissolution systems. Direct liquid addition is possible for private pools. Systems relying on residual chlorine may require pH monitoring and buffering systems. Outdoor pools may also require dosing with algaecide.

Products

Chlorine gas is held in cylinders. There is no information about liquid or solid products, though some solid products are placed on the market as large, non-friable tablets. Liquids may be delivered by tanker or in an Intermediate Bulk Container (IBC). Indoor facilities containing residual chlorine as disinfectant are likely to have irritant nitrogen chlorides (e.g. NCl_3) present in the air. Other products (quaternary ammonium compounds, biguanides) do not release NCl_3.

Solid, bromine-releasing biocides are used in hydrotherapy pools.

Delivery

No information.

Process & operations

Many public pools have automated dosing systems The mixing & loading phase is of prime importance for professional users. Over-dosing and accident have led to release of chlorine gas inside facilities.

Frequency, duration & quantity

There is no information on the dosing regime.

Changing a cylinder, changing a delivery tube from a drum of liquid, or recharging a solid reservoir would likely to be a single event in a day, with short-term exposure to concentrate.

Poolside workers experience full day exposure to residual chlorine gas and nitrogen halides, principally NCl_3.

A hydrotherapist can experience one 3-hour session in and out of the pool, per day

The US EPA quotes a default value for the general public swimming:
- one per month for 60 minutes, worst case 3 hours
- daily exposure is foreseeable for private facilities and for sports training.
- child or infant ingestion of a small volume of treated water is inevitable volume unknown.

A UBA-INFU document reports 1.4 ppm free chlorine in pool water.

Maintenance, test & clean

Shock dosing may be necessary following the discovery of faecal matter in the pool. Full drain-down, pressure cleaning, refilling and recommissioning is required from time to time. Liquid biocide monitoring equipment and concentrate dosing pump will require periodic maintenance. There are no data for the pattern of use of these activities

Removal & disposal

To mains drainage.

Controls

There is no information on protective equipment that may be used in changing liquid or solid dosing reservoirs.

Market data

None available.

Secondary exposure

Population, route & time-frame

Adults, children and infants in swimming / spa / hydrotherapy pools - skin contact, acute

Table: Biocidal products - swimming pools, etc.

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Professional dosing systems		<5%	Hands - protective gloves
Changing dip tube	1.1.3	<5%	Hands - no protection
Handling solids	1.1.4		
Automated dosing	1.5.1		
Private systems - pour in	1.1.2		
Application phase			
Primary - pool attendant	1.4.1	100%	Inhalation - general ventilation
Primary - hydrotherapist	1.4.1	100%	Inhalation and skin contact
Secondary - pool user	1.4.1		Skin contact and ingestion
Post-application phase (includes disposal)			
Maintenance	1.6.1	-	Skin contact, inhalation

Type 2 Private area and public health area disinfectant

2.03 Biocidal products to be used in air-conditioning systems.

Background

There appears to be considerable overlap between this Type and Type 11, preservatives for liquid cooling and processing systems. The scope appears to be limited to dosing humidifying water sprays with biocide or controlling biological agents in air conditioning condensate sumps. There is no information available on the use of products within this type.

Primary exposure

User

Plant & equipment

Products

Delivery

Process & operations

Frequency, duration & quantity

Exposure to humidified air containing residual biocide would be secondary in nature, by inhalation, during the time spent in the humidified atmosphere.

Maintenance, test & clean

Removal & disposal

Controls

Market data

Secondary exposure

Population, route & time-frame

At work, in shopping centres, cinemas, etc. - inhaled

Table: Products in air-conditioning systems

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Change dip tube	1.1.3		dermal
Application phase			
Dispense liquid	1.5.1		None
Post-application phase (includes disposal)			
Dispose to waste	1.6.3		None

Type 2 Private area and public health area disinfectant

2.04 Biocidal products for chemical toilets, treatment of waste-water or treatment of hospital waste

Background

Chemical toilets are commonly installed on transport (aircraft, buses) and at temporary sites (construction, camping, pop concert). Non-professionals may use chemicals in camper van toilets. Information is sparse and tentative.

So far as is known, biocides are not used in sewage treatment works for waste-water treatment.

Systems for combined heat and biocide treatment of clinical waste exist, but there is no information available. Hospital waste includes pre-dosed sharps bins.

Primary exposure

User

Professionals dosing and emptying chemical toilets. Users of sharps bins.

Plant & equipment

Water loading bowsers and effluent collectors (honey-wagon). Disinfectant supplied in sharps bins is non-volatile and remains contained within the bin.

Products

Toilet additive fluids need to mask colour and odour, as well as rendering pathogenic organisms harmless.

Delivery

Bus toilet fluids are supplied, typically, in a 25 litre plastic container fitted with a tap.

Process & operations

Aircraft toilets are either vacuum or recirculating toilets. Only the latter type uses biocide, recycling the fluid as flush water for the duration of the flight. Bus toilets are once-through and discharge to a holding tank. Concentrate is either automatically dosed into toilet water before loading into the flush water reservoir, or poured manually into the reservoir. Unloading is a process of connecting pipe work from the vehicle to drains, or to a honey-wagon for remote disposal at a treatment works.

Toilets are designed to minimise biocide aerosol generation or splashing during use. It is possible that someone could be using a bus toilet when crossing very bumpy ground.

There is no reliable information on the tasks in waste water or clinical waste treatment.

Frequency, duration & quantity

The following estimates are tentative:

- one dosing episode per bus, aircraft or clinical waste treatment cycle.

Maintenance, test & clean

There is no information available.

Removal & disposal

Removal for disposal is part of the process.

Controls

No information

Market data

No information

Secondary exposure

Population, route & time-frame

Adults and children using toilets - skin contact (acute)

Table: Products for chemical toilets, treatment of waste-water or hospital waste

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Professional, dosing tank	1.1.1/1.1.2	20%	Hands - gloves worn
Application phase			
Secondary - splash	1.6.3		Dermal - wipe off
Post-application phase (includes disposal)			
Connect disposal pipework	1.1.3	80%	Hands - gloves worn Spills on work clothing

Type 2 Private area and public health area disinfectant

2.05 Other products within Biocidal Product Type 2

Background

The scope of this category is unclear. Examples may be the use of disinfectants in laundries. However, there is insufficient information available to complete the statement.

Primary exposure

User

Plant & equipment

Products

Delivery

Process & operations

Frequency, duration & quantity

Maintenance, test & clean

Removal & disposal

Controls

Market data

Secondary exposure

Population, route & time-frame

Table: Other Type 2 products

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Application phase			
Post-application phase (includes disposal)			

Type 3 Veterinary hygiene biocidal products

Background

The demarcation between biocides and veterinary medicines is not clear. Some of the examples quoted may prove to be out of scope. The scope is assumed to include human and animal footbaths for disease control, baths for equipment immersion, cow udder and teat cleaning, egg hatcheries and animal housing and livestock market disinfection. Feed areas are addressed under Type 4. Milking machine cleaning is subject to other legislation. Hand disinfection (to limit the spread of mastitis) is addressed as Type 1.

Primary exposure

User

Professional users comprise farmers and cleaning contractors. Non-professional use is not envisaged.

Plant & equipment

Footbaths and immersion baths are simple equipment. Egg disinfection is by fogging with CDA applicator, by fumigation, or by washing in disinfectant. Animal housing disinfection is through high pressure spraying after gross detritus has been removed by mechanical means (e.g. skid-steer loader).

Products

Chlorine-release products are generally supplied as non-friable tablets. Liquids are in plastic containers of various sizes - peroxyacid containers may be fitted with a fixed-volume dispenser. Other products are supplied in 1 to 25 litre containers, and in tubs of sachets. Products for use in footbaths may be supplied in 200 litre drums.

Delivery

There is no information.

Process & operations

Foot and immersion baths are filled and disinfectant mixed by manual dosing. CDA spraying uses a reservoir of mixed disinfectant, with manual mixing. High pressure sprayers operate from mains water with a concentrate reservoir, loaded before use with concentrate. Fumigant (formaldehyde) is applied by evaporating from a stock solution in an evacuated area.

Typical sizes for animal housing: 4000 m^2 for poultry houses, 390 m^2 for pig units and 201 m^2 for pig breeding, with a usage rate around 0.15 l / m^2 at a concentration around 40 g / litre for poultry houses and 2 g / litre for other animals. Animal transport is disinfected with chlorine-based disinfectants at a concentration around 0.2 g / litre.

Frequency, duration & quantity

The following information is from a UBA-INFU report, coupled with HSE information on high pressure spray operations.

Poultry units:
- cleaned 3 times annually. Suggested duration 400 minutes.
- quantity used - suggested 600 litres of spray fluid.

Pig units:
- cleaned twice annually. Suggested duration around 40 minutes
- quantity used - suggested 60 litres spray fluid.

Poultry unit:
- cleaned several times a year, duration 400 minutes
- quantity used - suggested 60 litres spray fluid.

Transport disinfection would not be expected to last more than 10 minutes.

Livestock market:

- pressure washing - 160 minutes per market day (HSL survey).

Egg disinfection:
- daily - washing is practically continuous, fogging - 10 minutes suggested.
- fumigation relies on exclusion.

Footbaths:

- typically, two footbaths: estimate 20 uses per worker, with hand exposure through scrubbing boots with disinfectant.

- typical footbath volume - 10 litres (boots), 1000 l (animals).

Maintenance, test & clean

There is no information, though pressure sprayers are normally cleaned before storage.

Removal & disposal

Footbaths are normally poured to slurry pits. Livestock market run-off passes to treatment pits before discharge to mains drainage.

Controls

It is expected that coveralls (polyester or waterproof), waterproof boots and gloves, and face protection would be used for high pressure spraying and fogging. Where irritant products are used, and in poultry sheds where there is a zoonotic infection or sensitisation risk, it is likely that respiratory protective equipment would be necessary. However, cleaners do not always use waterproofs when cleaning down livestock markets in hot weather.

Where skin sensitising biocides are used, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

Market data

None available.

Secondary exposure

Population, route & time-frame

Children present on farms as family members - contact with freshly treated surfaces; falling in footbath (acute)

Table: Veterinary hygiene products

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Pressure washer filling - manual	1.1.2		Hand - gloves
Fogger filling - manual	1.1.2		Hand - gloves
Egg washer system filling - auto	1.1.2		Hand - gloves
Foot bath filling - manual	1.2.1		Hand - gloves
Fumigation - manual	1.1.2		Hand and inhalation - ventilation
Udder and teat cleaner - manual	1.2.1		Hand - no protection
Application phase			
Pressure washing	1.3.1		Dermal, inhaled - waterproofs, gloves, RPE
Fogging	1.3.5/1.5.1		Dermal, inhaled - coveralls, gloves, RPE, eye protection
Egg washing	1.4.4		Dermal - coveralls
Foot bath use	1.2.3/1.4.3		Hand - no protection
Fumigation	-		No exposure
Udder and teat cleaning	1.4.2		Hand - no protection
Post-application phase (includes disposal)			
Equipment washing	1.3.1/1.4.2		Gloves

Type 4 Food and feed area disinfectants

Background

The product type covers abattoir, poultry, fruit and vegetable processing, bakery and confectionery, brewery, and food retail. It includes feed area disinfection. The product type does not include preservation through use of salt, vinegar, etc. or through food preservatives. (Food area disinfection means a 5 log reduction in microbes in 1 minute).

Hand disinfection is addressed as Type 1. Domestic food area disinfection is addressed under Type 2.01. Machinery lubricant preservatives are addressed under Type 6.02. Feed water treatment is addressed under Type 11.01.

Primary exposure

User

The users are professionals only. In food factories, the user is part of a cleaning team and has often been trained by the suppliers of disinfectant products. In retail establishments, users disinfect work surfaces, tables, etc. as part of their waiting duties. If the disinfectant is used in containers to wipe/clean shoes, the material may enter the shoes by penetration.

Plant & equipment

There are seven main classes of equipment in use:

- ring-main fed hose or spray lance
- mobile unit for pressure spray or foam application at over 3 Bar
- portable applicator (knapsack, compression and trigger sprayers)
- automatic systems, cleaning in place (CIP), e.g. for cream lines, bottling plant
- manual application (soak tank, bucket and cloth, mop or brush, and pour on - wipe off)
- fogging (manual or automatic)
- ready-for-use disposable wipes for surfaces.

Products

A survey in 2001 (CCFRA for HSE) showed that the most common type of product in use was the class of quaternary ammonium compounds (quats), alone or in combination with other agents. Alcohol and alcohol / quat combinations were usually supplied in r.f.u. trigger sprays or wipes. Hypochlorite was commonly used, most often as foam. Peracetic acid preparations were used mostly in CIP processes and fogging. Iodophors were used for soaking hoses.

Delivery

Products are delivered in r.f.u. packs, in small containers, in drums up to 200 litres and in IBC at 1000 litres. Bulk delivery by tanker occurs for large scale users.

Process & operations

Cleaning gross contamination is always necessary before disinfection. This is done by physical means (scrubbing, pressure spraying, steaming). The disinfectants are supplied as concentrates or ready for use (r.f.u.).

Food disinfection (poultry and salad lines) is automated, with raw food conveyed through disinfectant tanks or past sprays. Food packaging disinfection is similarly automated.

Feed area disinfection is very similar in nature to animal housing disinfection (Type 3) and remedial masonry biocide spraying (Type 10), using high-pressure mobile spray units after removal of detritus. The hygiene standards are unlikely to match those found in food factories.

Total disinfection is needed in breweries when yeast strains become infected. Bottle disinfection (rather than thermal pasteurisation) is becoming more common, mainly on automated treatment lines.

Manual mixing and loading is found in 40% of uses, metered dosing and venturi mixing in 40% of uses, and r.f.u. packs in 20% of uses. Many companies use a combination of techniques, depending on the disinfection task and time of day. Deep cleaning frequently takes place during the night shift.

Where dosed or venturi mixing takes place, there is the need to handle the supply tube in changing the concentrate reservoir.

The application phase is by spraying, foaming, hosing down, fogging, brushing, mopping, wiping, soaking, and pouring into drains. Trigger sprayers hold up to 500 ml of r.f.u. disinfectant. Compression sprayers hold up to 10 litres, and knapsack sprayers between 10 and 30 litres. For ring-main and pressure sprayer operations, the application rate varied between 40 and 1780 mg in-use product per m^2 of area for disinfection, and between 400 and 57200 mg in-use product per m^2 of machinery. Machinery cleaning includes spraying inside restricted spaces.

Using hypochlorite products where there are protein deposits leads to nitrogen trichloride (NCl_3) generation and exposure by inhalation.

The post-application tasks are to rinse deposits from surfaces, or simply to dry off. Microbe swab test samples are taken from disinfected surfaces.

Frequency, duration & quantity

The following values (ranges) are derived from a research project in UK.

ring-main fed hose or spray lance
- mixing & loading - none
- hose application - 1 per day (0.2 to 3), for 120 min (60 - 360 min)
- low pressure spray - 2 per day (1 to 2), for 45 min (30 - 360 min)

mobile unit for high pressure (> 3 Bar) foam or spray application
- mixing & loading - foam - 5 per day (0 to 14), for 2 min
- mixing & loading - spray - 2 per day (0.5 to 0 4), for 2 min (1 to 10 min)
- foam application - 1 per day (0.2 to 1), for 30 min (15 to 720 min)
- spray application - 1 per day (0.2 to 4), for 30 min (10 to 360 min)

portable applicator (knapsack sprayer)

- mixing & loading - 1 per day (1 to 2), for 3 min (2 to 3 min)
- application - 1 per day, (0.01 to 3), for 15 min (5 to 50 min)

portable applicator (compression sprayer)
- mixing & loading - 2 per day (0.2 to 5), for 2 min (1 to 8 min)
- application - 1 per day, (0.2 to 15), for 30 min (2 to 360 min)

portable applicator (r.f.u. trigger sprayer or from dosimeter) with cloth
- mixing & loading - where done, 1 per day (0.1 to 3), for 2 min (1 to 10 min)

- application - 3 per day, or 100 / day in restaurant (1 to 150),
- application for 5 min, or 1 min (restaurant), 60 min (line cleaning) - (1-120 min)

fogging(likely to be fixed in place, but may be portable)
- mixing & loading - 1 per day (0.2 to 1), for 2 min
- application - 1 per day, (0.2 to 1), for 30 min (20 to 40 min)
- 2-3 litres of product used per 100 m^3 space, 10 to 20 micron particle diameter, settling time around 1 hour

automatic systems, cleaning in place (CIP)
- (manual systems) mixing & loading - 1 per day, 2 min (2 to 3 min)
- application - 1 per day (0.5 to 4), 30 min (2 to 180 min)

manual application (soak tank)
- mixing & loading - 1 per day (0.2 to 5), for 2 min (1 to 10)
- application - 1 per day (0.2 to 3), for 30 min (3 to 60 min), exposure on removal from soak.

manual application (bucket and cloth, mop or brush)
- mixing & loading - 2 per day (0.2 to 2), for 2 min (1 to 5)
- application - 4 per day (0.2 to 100), for 40 min (5 to 400 min)

manual application (pour on, wipe off)
- mixing & loading - none
- application - 4 per day, for 5 min.

manual application (disposable wipes)
- mixing & loading - none
- application - 15 per day, (4 to 20), for 1 min (1 to 2 min)

INRS has published data to indicate that formaldehyde products are used for 11 to 65 minutes with airborne concentrations 0.06 to 0.62 mg/m^3, and glutaraldehyde products from 8 to 90 minutes with airborne concentrations 0.01 to 0.25 mg/m^3. Hypochlorite use results in airborne concentrations of NCl_3 which are unlikely to exceed 1 mg/m^3.

Maintenance, test & clean

Portable applicators are generally cleaned after use and left to drain dry. Sprayer maintenance is sometimes done in-house (e.g. maintaining seals); otherwise, maintenance is undertaken by the disinfectant (and equipment) supplier.

Removal & disposal

Wastes pass to on-site treatment plant, or for small users, to mains drainage.

Controls

The sector has strict rules about hygiene to protect food from human contamination. A work uniform is ubiquitous. This includes waterproof boots, coveralls, gloves and head coverings, with disposable gloves. Certain disinfection tasks require the use of protective equipment such as face visors, aprons, full waterproof clothing, and respirators.

Where skin sensitising biocides are used, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

Market data

No EU level data available.

Secondary exposure

Population, route & time-frame

Worker - nitrogen trichloride vapour inhalation - acute
Adult and child - Fast-food restaurant, freshly disinfected table - skin contact, acute

Table: Food and feed area disinfectants

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Supply tube for automatic mixing	1.1.3/1.5.1		Hand - protective gloves. RPE if irritant.
Dispense concentrate to equipment or rfu solution to applicator	1.1.2		Hand - protective gloves
Application phase			
Spray and Foam application Hose application Fogging Soaking Wiping	1.3.1/1.3.3 1.4.2 1.3.5/1.5.1 1.4.3 1.2.2		In all cases, wellingtons, work uniform, gloves, head covering. RPE for fogging.
Post-application phase (includes disposal)			
Swabbing	1.6.2		None

Type 5 Drinking water disinfectants

Background

The shock disinfection and commissioning of domestic and office water systems for the supply of drinking water is covered under Type 11.01. The Type 1 statement covers exposure through bathing.

Primary exposure

User

Professionals treat bulk supplies of water for consumption at industrial waterworks. Professionals (military) and non-professionals treat water batches during wild camping, though water infected with blue-green algae is unlikely to be made fit for consumption.

Plant & equipment

Industrial plant is used for bulk drinking water treatment. Wild camping treatments may use impregnated resin columns or additives.

Products

Bulk chlorine is the most common disinfectant substance. Ozone, chlorine dioxide, chlorine dioxide and iodine have been reported, and permanganate pre-treatment though there is no useful information about these processes.

Control of organic residues in drinking water is necessary to suppress the unwanted generation of trihalomethanes and halogenated phenols.

Delivery

Bulk chlorine by tanker.

Process & operations

The principal process is large scale chlorination, using bulk chlorine. Industrial, often at Major Accident Hazard sites with extensive gas leak monitoring systems and contingency plans in case of disaster. Exposure is via inhalation to low concentrations of chlorine on a short-term basis.

Another system reported used is a silver ion treatment (which relies on residual chlorine).

Users in wild camping situations are exposed by ingestion. Consumers ingest drinking water and are exposed to bathing water.

Frequency, duration & quantity

Plant workers could be exposed by inhalation below 0.5 ppm for several 10-minute periods per day.

Consumers drink tap water at 1.8 litres / day (adult) and 0.8 litres / day (child).

Maintenance, test & clean

Removal & disposal

There is no information.

Controls

Industrial level only

Market data

None available

Secondary exposure

Population, route & time-frame

All consumers including the infirm and infants - dermal contact and inhalation of shower aerosols; (acute); and ingestion (chronic).

Table: Drinking water disinfectants

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Industrial	1.5.1		Inhalation - system of work
Camping	1.2.1		None (tablet, resin column or skin contact (if liquid concentrate)
Application phase			
Consumption of water	1.6.3		Ingestion
Bathing or showering	1.4.1		Inhalation and skin contact
Post-application phase (includes disposal)			
None			

Type 6 In-can preservatives

6.01 Preservatives for detergents

Background

The product type covers industrial and domestic cleaning products, liquid soaps and detergents, and fabric conditioners, to prevent deterioration. The products are mainly placed on the market as fluids. Products such as rinse-aids, scale removers and caustic cleaners are not covered. Household bleach is addressed as Type 2.01. Laundry disinfectants may be Type 2.05.

Activities such as using preserved liquid soap for bathing and showering are addressed in a similar way to the statement for Type 1.

Primary exposure

User

The manufacture of preserved products is not included in this statement. Professionals are in catering, laundry and fibre processing, etc. Non-professional use is in residential activities (home laundry, washing up).

Plant & equipment

Professional catering and laundry equipment is effectively enclosed. Non-professional laundry and washing up may use machines, but the main concern for exposure estimation is hand operations.

Products

Detergents contain typical concentrations of 0.05% w/w biocide.

Delivery

There is no information about supply to the professional market. Retail size packs of laundry and washing products range from 500 ml to 5 litres.

Process & operations

There is no information about the professional handling of detergent products. Non-professionals may add product to water, water to product, and for laundry, can use neat product for spot treatment (e.g. collars) before washing manually or mechanically. Washing up concentrates are commonly used for cleaning food contact surfaces. Floor and wall cleaning fluids are diluted for use by cloth or mop, but are also used as concentrate for spot cleaning. Spot and window cleaners are supplied in trigger spray ready-for-use (r.f.u.) packs.

A common misuse scenario is the use of neat washing up detergent with abrasive to clean dirty hands of oil, soil, etc. and rinsing off under running water.

The following information relates to non-professional users. Weegels (TU Delft, 1997) has conducted research into dish washing at home and the US EPA holds data for home laundry work. There is some evidence for increased cleaning activity in springtime and the holidays, but the social desirability of cleanliness means that self-reporting can over-estimate cleaning activity. There may be an inverse correlation between the frequency and duration of cleaning (lower cleaning frequency

means longer cleaning jobs). 60% of residents doing washing up used a brush. Residues of washing up liquid were often noted around the cap of the bottle.

Frequency, duration & quantity

Home washing up:
- frequency - 1 use daily (range, 1 to 5 times daily, but no use on 50% of days).
- duration - 11 min, standard deviation (SD) 7 min (self reported).
- duration of washing up and cleaning with used suds - 14 min, SD 7 min.
- quantity used - 3 g per event (range 1 to 16 g)
- in-use concentration 0.9 g/l, SD 0.7 g/l. Volume used 9 l, SD 5 litres.
- misuse of concentrate - 1 per week, median value, for 6 min, SD 5 min..

Household cleaners:
- frequency - 1 use daily (range, 1 to 4, but no use on 80% of days)
- duration - median 7 minutes (range 1 min to > 4 hours)
- quantity used -median around 20 g (range 2 to 74 g).

Home laundry:
- by hand - frequency unknown (proposed value, 1 per day default).
- duration - 13 min $\pm$ 30 min (US EPA).
- by machine - 0.3 loads per person per day.

Maintenance, test & clean

No information

Removal & disposal

Disposal to mains drainage.

Controls

10% of domestic users wore protective gloves, the reminder used bare hands.

Market data

None available.

Secondary exposure

Population, route & time-frame

Residents - dried residues on plates - ingestion (acute)

Table: In-can preservatives - detergents

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Washing up	1.2.1		Hands - no protection
Laundry	1.2.1		Hands - no protection
Cleaning	1.2.1		Hands - no protection
Application phase			
Hand wash	1.4.2		Hands - no protection
Spot treatment	1.2.3		Hands - no protection
Brush and hand wash	1.2.3/1.4.1		Hands - no protection
Cleaning with cloth	1.2.2		Hands - no protection.
Post-application phase (includes disposal)			
Wipe down surfaces with used washing up suds	1.2.2		Hands

Type 6 In-can preservatives

6.02 Preservatives for other products

Background

This category covers a very wide range of products: - water-based paints, adhesives, dyes and inks, polishes, lubricants and fuels, enzyme solutions, starch sizes and concrete additives, (and water in water-beds). It includes preserved lubricant products used to coat yarn in spinning (spindle oil?), in food conveyors and in paper-mills, etc. and preserved ceramic slurries used in pottery.

Detergent and cleaning products are Type 6.01. Building products (other than wood), impregnated with insecticide, are addressed as Type 18. Oil in tank farms may be treated with slimicide (Type 12.03). Sealants are Type 7.

Primary exposure

User

Manufacture of preserved products in not included in this statement. Most users, both professional and non-professional, will be unaware that the product in use contains a preservative.

Plant & equipment

There is a very wide range of application plant, including textile and printing plant and concrete batch plant. Application equipment varies from oil applicators to fuel pumps, and brush and roller, to direct application from the container in which the product is marketed (e.g. adhesive stick).

Products

Products arrive at the point of use already dosed with biocide. It is unlikely that users will replenish products with biocide concentrate - products are used up rather than re-used. However, specific information from applicants for authorisation should make the supply criteria and fields of application clear.

Delivery

The range is too wide to generalise.

Process & operations

These range from the heavy industrial scale through to domestic and recreational uses. Recreational uses include home decorating and vehicle refuelling. Industrial processes show the greatest exposure risk during start up and maintenance operations - this includes emulsion products applied as surface coatings on production lines.

Non-professionals and professionals will apply paints by brush and roller. It is possible that professionals would spray paint.

Frequency, duration & quantity

There is no information on exposure frequency or duration for industrial scale operations, though it may be expected that these take place daily. Recreational uses of adhesive, fuelling of vehicles, etc. is likely to be short-term and intermittent. Tentative general values are proposed as:

Brush and roller applications:
- Professionals - 7 hours per day
- Non-professionals - 4 hours per day, 2 to 5 days per year.

The following examples are based on data from Weegels (TU Delft, 1997) and US EPA Activity Factors Handbook.

Household paints: (40% of paints used were water-based)
- general painting - 1 session per day (range 1 to 3 sessions), likelihood of use = 10%
- duration - -29 min, SD 29 min, 90% of time applying paint. (Window-frames - 45 minutes)
- quantity used - 75 g, range 10 to 500 g of water-based product.
- 90% used brush; 20% used roller and brush. 10% used roller only.

US EPA data - professional painters
- median 11 litres / day, 95th% 38 litres/day of water-based paint.

US EPA data, household (non-professional) uses (AM - arithmetic mean value).
- adhesive - AM 9 uses per year, AM 16 minutes' use, median 10 g per use.
- lubricant - AM 11 uses per year, AM 8 minutes' use, median 20 g per use.
- water-based paint - AM 4 uses per year, AM 300 minutes' use, median 3500 g per use.
- wood stains - AM 4 uses per year, AM 120 minutes' use, median 225 g per use.
- primer - AM 3 uses per year, AM 90 minutes' use, median 450 g per use
- water repellents - AM 2 uses per year, AM 105 minutes' use, 900 g per use
- engine degreaser - AM 4 uses per year, AM 13 minutes' use, 170 g per use.
- craft work at home - 1 per day, duration 11 min + 37 min.

Maintenance, test & clean

There is no information.

Removal & disposal

Paint brush cleaning - 120 seconds, range 72 to 189 seconds (solvent-based). Suggested values for hand-washing a paint brush (water-based paint) is 5 minutes and for a paint roller is 10 minutes.

Controls

Weegels found that 15% of household painters wore gloves, and that 50% of paint can exteriors were contaminated with paint spills. It is expected that users would wash their hands after use.

Market data

None available.

Secondary exposure

Population, route & time-frame

This depends on the location and type of application. A typical example is children contacting freshly coated surfaces - dermal (acute).

Table: In-can preservatives - other products (paint)

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Stir product	1.2.1		Hand
Application phase			
Apply product Spray Immersion (ceramics)	1.2.6/1.2.7 1.3.4 1.4.3		Hand, forearm - light clothing or coverall
Post-application phase (includes disposal)			
Clean brush / roller (non-professional only)	1.4.2		Hand

Type 7 Film preservatives

Background

The products include paints, mastics, sealants, fillers, and adhesives showing a preservative effect (e.g. wallpaper pastes). It also includes preservatives to prevent microbe infestation of plasticisers in plastics (e.g. flooring, shoes, vehicles, maritime equipment and toys). The most commonly preserved plastic is PVC. Carpet backing contains fungicide (Type 9.03).

Primary exposure

User

Professionals (decorators and builders) and non-professionals (Do It Yourself - DIY - wall coating, sealant replacement)

Plant & equipment

The equipment used is expected to be simple - sprayer (exterior coatings), mastic gun, paint brush and roller. There is no information on the type of sprayer that would be used.

There is no information on the industrial processes of manufacturing or moulding preserved plastics.

Products

Surface coating products are generally supplied ready for use, or lightly thinned. Wallpaper pastes are dispersed in water. The preservative is fungicidal in action, with up to 1% active substance in paint products (up to 2% w/w in the dry film). Sealants contain up to 0.5% w/w preservative.

Plasticiser preservatives include substances such as Kathon and OPBA.

Delivery

From wholesale or retail outlets, liquid paints in up to 25 l tubs, sealants in mastic gun cartridges or in dispenser tubes for DIY use, and wallpaper pastes in liquid or solid form in plastic packs.

Process & operations

There is no information on industrial processes: only surface coating is addressed in this statement.

Mixing and loading is minimal, e.g. product stirring, dispersion of paste in water.

Application of surface coatings and pastes is by brush (for more fluid products, rollers maybe used). Viscous products such as fillers are trowelled into place. Preserved silicone mastics are applied via a gun, and smoothed with a wetted finger. There is no information on sprayed products.

Post-application tasks include brush cleaning (non-professionals only)..

Frequency, duration & quantity

Information is limited and the following data should be regarded as highly tentative.

Spray applications:
- Professionals - 3 hours

Brush and roller applications:
- Professionals - 7 hours per day
- Non-professionals - 4 hours per day, 2 to 5 days per year.

There is no information on film removal.

Maintenance, test & clean

There is no information, though brush cleaning (see Type 6.02) will occur.

Removal & disposal

Removal of exhausted paint films by heat, chemical stripping or abrasive action may expose the worker to residual biocides.

Controls

Other than normal work-wear, there is little use of protective equipment, including hand protection, in the construction and decoration industries. Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

Non-professional users would not be expected to control exposure. Users could be expected to wash their hands after use.

Market data

There is no information.

Secondary exposure

Population, route & time-frame

Adults, children - contact with wet paint - skin contact (acute)
Children - contact with PVC flooring - skin contact (chronic)
Infants - ingestion of plastic plasticiser preservative (chronic)

Table: Film preservatives

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Product preparation - stirring	1.2.1		Hand - no protection
Dispersal in water	1.2.1		Hand - no protection
Application phase			
Spray application	1.3.1		Dermal - coveralls and RPE
Brush / roller application	1.2.6		Hand and forearm - no protection
Trowel application	1.2.4		Hand - no protection
Mastic gun and smoothing down	1.2.7		Hand - no protection
Manufacture of plastic articles	1.5.1		Hand - no protection
Post-application phase (includes disposal)			
Brush washing	1.4.2		Hand - no protection
Paint film removal	1.2.3		Hand - no protection

Type 8 Wood preservatives

8.01 Pre-treatment in industrial premises (pressure and vacuum impregnation and dipping)

Background

This type has been taken to cover all preventive treatments, including the use of antisapstain products. Much of the following statement has been condensed from an OECD review.

Primary exposure

User

Only professionals undertake preventive treatments in industrial plant. Non-professionals may undertake wood preservation at home (fences, sheds) and this is more fully addressed as Type 8.02.

Plant & equipment

Industrial plant:
- vacuum-pressure plant, used with water-based preservatives for roughly shaped wood.
- double-vacuum plant, used with solvent or water-based preservatives for shaped wood
- pressure plant, used with hot creosote for utility poles, etc.
- deluge / flood spray plant, used with water-based products for flat panels
- dipping in water or solvent-based preservatives for wooden articles (mechanical or manual)

Other plant:
- portable spray equipment and paint brushes to apply antisapstain products in forests
- spray gun and ventilated workstation to apply preservative to finished articles.

There is little information on the application of antisapstain products in industrial plant.

Products

For cyclical processes, product delivery is as kegs of concentrate paste, or as liquid concentrate in IBC or by tanker. Any dilution of concentrates is done in industrial plant.

Dipping processes are supplied in 200 l drums or by tanker. Solvent-based products are ready for use; water based products are supplied as concentrates.

Delivery

Bulk, IBC, drum (200 litre) and kegs of paste (copper chrome arsenic preservatives).

Processes and operations

Vacuum and pressure plant are operated on a cyclical basis and other processes on a batch process with continuous treatment. Anecdotally, wood preservation processes are more intensive during the spring.

In vacuum-pressure processes, wood absorbs 150 litres of preservative solution per m^3. In double vacuum processes, wood absorbs 10 to 50 litres of preservative solution per m^3. In pressure processes, wood absorbs around 300 litres per m^3. For dipping etc., wood appears to absorb 0.2 litres per 4 m^2 fence panel.

In all operations apart from manual dipping and deluge processes, fresh and treated wood is moved using lift trucks. However, the operators are closely involved with handling restraining straps and treatment machinery, in maintaining the door seals of treatment vessels, in removing fallen wood and sawdust sludge. Sites normally had one or two workers engaged in preservation, and one or two treatment vessels.

Frequency, duration & quantity

The following data have been taken from HSE surveys.

vacuum - pressure process:
- daily use - cycle time 3 hours, 3 cycles per day.

double-vacuum process:
- daily use - cycle time 1 hour, 6 cycles per day.

pressure process:
- daily use - cycle time 4 hours or overnight, up to 2 cycles per day.

deluge / flood spray process (conveyor line)
- used several days a week -, continuously for 2 hours

dipping process
- up to 30 minutes' immersion per batch (mechanical).

Maintenance, test & clean

Professional - greasing door seal, collecting fallen timber, clearing sludge.

Removal & disposal

Disposal of preservatives is normally as controlled waste

Controls

Work clothing (e.g. coveralls) and protective gloves and footwear. Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

Market data

There is no information.

Secondary exposure

Population, route & time-frame

Adults - cleaning work-wear at home - dermal (acute),
Adults - using preserved timber in construction - inhaled and dermal (acute and chronic)
Children - playing on preserved timber structures - dermal (chronic)
Infants - chewing preserved timber off-cuts - ingestion (acute)

Table: Wood preservatives - pre-treatment in industrial premises (preventive)

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Connect tanker transfer lines	1.1.3		Hands - protective gloves
Dilute concentrates in plant	1.5.2		None
Application phase			
Treatment vessels & dipping			
Load wood onto carrier	1.1.4		Dermal - gloves, coverall
Secure	1.1.3		
Push into treatment vessel	1.1.3		
Seal door, operate process	1.4.4		
Open door	1.1.3		
Remove carrier from vessel	1.1.4		
Release straps	1.1.3		
Convey treated wood to store	1.1.3		Gloves off to drive lift truck
Deluge			
Unload treated wood (conveyor)	1.1.3/1.4.4		Dermal, inhaled - waterproofs, gloves
Manual dipping			
Manual immersion	1.4.3		Dermal - gloves, coverall
Pour and scrub with product	1.2.3		
Remove to drip dry	1.1.3		
Post-application phase (includes disposal)			
Treatment vessels			
Grease / replace door seals	1.6.1		Hands - gloves, coverall
Remove fallen wood from vessel	1.6.1		Dermal - gloves, coverall
Clear sump / sludge	1.6.1		Waterproofs, wellingtons, gloves
Sampling	1.6.2		Hands - none
Disposal - tanker	1.1.3/1.5.2		Hands - protective gloves
Deluge			
Clean spray nozzles	1.6.1		Hands - no protection expected.
	1.6.1		

Type 8 Wood preservatives

8.02 Other wood preservatives

Background

This type has been taken to cover all curative treatments. Much of the following statement has been condensed from an OECD review.

Primary exposure

User

Both professionals and non-professionals can undertake most of the processes. However, some products are restricted to professional users.

Plant & equipment

- Spray equipment can be hired, though professionals may own their own equipment.

- Fumigation equipment held by professional fumigators.

Products

- These are solvent or water based products, supplied as concentrates for dilution on site, or ready for use. The nominal concentrations of active substances (fungicides and insecticides) for in-use product are less than 1% w/w. Retail outlets supply non-professional products in 1 to 10 litre cans.

- gas, volatile liquids.

Delivery

- These are normally obtained from wholesalers in containers up to 25 litres.

- ordered from suppliers.

Process and operations

Spraying (treating structures for rot and insect infestation of wood):
- low-medium pressure - 4 to 7 bar - electric or fuel driven pump and preservative reservoir
- low pressure - 1 to 3 Bar, - compression sprayer, garden spray equipment or powered sprayer.

Hand-held tool application to wooden structures and fences:
- brush for mobile fluids
- trowel, float or caulking tool (local damage
- wrapping with impregnated fabric (utility poles - professional use only, no use data)

Other:
- injection into woodworm holes with hand-held aerosol can
- preservative of furniture polishes
- sub-soil injection to halt rot in wooden foundations
- fumigation of structure infested with wood destroying insects

Many professional activities require considerable site preparation, and the use of preservative is less than half the time spent at the job.

Frequency, duration & quantity

Low to medium pressure spraying:
- a few days a week, maximum 2 uses daily.
- 40 minutes per use (range 6 to 100 minutes' spraying).
- quantity used - 0.35 litres per m^2 of wood surface, median quantity used per job, 47 litres.

Low pressure spraying (mostly non-professional uses):
- once or twice only, duration estimate - 40 minutes
- quantity used unknown, perhaps less than 10 litres.

Dipping:
- daily activity, 30 minutes per batch (1 per day), range 11 to 162 minutes
- about 1 litre consumed / m^2 fence panel, about 0.2 litre / m^2 window frame wood.

Fumigation:

- variable

Non-professionals normally wear gloves. Paint and paste applications, etc.
- paint - one or two days per year, 155 minutes per day (range 76 to 241 minutes)
- 4 litres of paint used (range 1 to 8.5 litres), median work rate 7.6 min / m^2.
- paste - no information, estimated duration 30 minutes, application rate 1 kg/m^2

Other applications:
- polishes and woodworm sprays - no information
- soil injection (mechanical) - one-off event

Maintenance, test & clean

Maintenance comprises unblocking spray nozzles. Hired equipment maybe returned to the hire shop while contaminated with wood preservative residues.

Removal & disposal

Fumigation: cylinders are returned to supplier.

Controls

Professionals will wear coveralls, protective footwear, gloves and may use eye and head protection. Where solvent-based products are used, they should wear RPE. Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

Non-professionals may wear gloves, for painting and when using irritant pastes.

Fumigation: professionals have SCBA breathing apparatus; warning signs and restricted access to fumigated structures.

Market data

None available

Secondary exposure

Population, route & time-frame

Adults, children - re-entry while surfaces are wet:
- dermal contact (acute)
- inhalation of volatilised residues, (chronic).

Table: Wood preservatives - other (curative)

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Dilution of concentrate	1.2.1		
Loading sprayer	1.1.2		
Priming pump and spray line	1.3.1		
Stirring paint / paste	1.2.1		
Application phase			
Spray (indoors)	1.3.1/1.3.6		
Apply by brush	1.2.6		
Apply by float / trowel etc.	1.2.4		
Caulk gun	1.2.7		
Fumigation			SCBA breathing apparatus; monitoring equipment
Post-application phase (includes disposal)			
Unblock spray nozzle	1.6.1		
Wash brush or wipe applicator	1.2.2/1.4.3		
Fumigation: aeration and re-entry			

Type 9 Fibre, leather, rubber and polymerised materials preservatives

9.01 Preservatives for textiles and leather

Background

Textile preservation covers preservation for storage, transport and use. Carpets contain insecticide and fungicide, tents and fabrics for outdoor use contain fungicide and shower curtains are also treated with fungicide. Carpet may be backed with latex which has been impregnated with fungicide, see Type 9.03. Textile spinning oil lubricant is Type 6.02. Mosquito net dipping is addressed under Type 18.02.

Leather preservation includes fungicides as part of the tanning process, as outlined below.

Primary exposure

User

Professionals only operate the processes stated below.

Plant & equipment

Certain raw fibres may require disinfection before processing to assure that they are free from communicable disease (e.g. formaldehyde fumigation). Textile mills and textile scouring plants use biocides in yarn treatment and finished textile treatment.

Tanneries and fellmongers use biocides in soak pits and large rotating drums.

Products & Delivery

Textiles: Insecticides and fungicides are supplied in 50 kg kegs typically. Fellmongers use 25 kg kegs or 200 litre drums - some products are supplied as powders. Tanneries are more likely to receive products in IBC.

Process & operations

The information source is an HSL report.

Textiles:
Insecticide and fungicide are applied to yarn as the final stage of dyeing. The concentration in finished fibre is 0.2 to 1.4% w/w. A stock solution of biocide is prepared manually, for metered addition to dye baths. Textiles made of woven fabric are either dipped in a biocide bath in the latter stages of manufacture, or biocide is applied as a spray or foam and dried in place. There is very little handling of treated fibre or fabric, though post-batch cleaning leads to significant exposure.

Leather:
Animal hides are supplied in the natural state or dried, and in either case boric acid may have been added. Hides are soaked / tumbled in water containing bactericide. Fellmongers remove wool and hair from the hides following enzyme treatment (Note - enzymes may contain preservative, type 6.02). Tanneries add fungicide at an early stage of the chrome tanning process. Tanned leather may also be conditioned by passing it through a biocide spray. The residual biocide in finished leather is estimated at 1% to 2%.

There appears to be little use of dispensing equipment. Biocide is dispensed to buckets, and stock solutions prepared, transferred manually to the soaking drums. After soaking, the hides are tipped to

the floor to drain. Conditioning (tanneries) involves manual dosing of biocide working solution into a sprayer, which sprays skins on conditioning tables. The hides are handled manually.

Frequency, duration & quantity

Textiles:

- Manual addition of stock solution to dye baths and machine minding - 1 per week
- Duration - biocide for treating fibre, 11 to 155 min; for treating textile. 46 - 250 min. general default 124 minutes.

Tanneries and Fellmongers:

- concentrate use - daily, about four times per shift
- concentrate handling, 10 minutes per use; diluted solution 120 minutes (68 to 163 min).
- Treated skin handling, diluted biocide - full shift (default)
- Conditioning - spraying - full shift.

Maintenance, test & clean

No information is available.

Removal & disposal

On-site effluent treatment plant and discharge consents in operation.

Controls

Coveralls, eye protection, gloves and wellington boots were worn. A respirator was used when dispensing powdered biocide. Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

Market data

No information.

Secondary exposure

Population, route & time-frame

Adults, children and infants, exposed principally to treated textiles (carpets, tents). Exposure by dermal contact (chronic) . The products have very low vapour pressures. Infants - ingestion of dust and carpet fibre (chronic).

Table: Type 9.01 Preservatives for textiles and leather

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Textiles			
Dilution of concentrate	1.2.1		Hand / forearm - gloves
Leather			
Handling concentrate	1.1.3/1.1.4		Hand / forearm - gloves; inhaled - RPE
Dilution of concentrate	1.2.1		Hand / forearm - gloves
Loading raw skins (boric acid)	1.1.3		
Application phase			
Textiles			
Addition to dye bath	1.1.1/1.1.2		Hand - gloves
Addition to dosing foam / spray	1.1.1/1.1.2		Hand - gloves
Leather			
Addition to treatment drum	1.1.1/1.1.2		Dermal - gloves and PPE
Draining treated skins	1.1.2		Dermal - gloves and PPE
Conditioning	1.3.1		Dermal and inhaled - gloves and PPE
Post-application phase (includes disposal)			
Handling treated fibre, textile and leather	1.1.4		Hand

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Type 9 Fibre, leather, rubber and polymerised materials preservatives

9.02 Preservatives for paper

Background

This product type is separate from paper mill slimicides (Type 12.01). Products are used to control fungi on non-food packing materials. There is very little information available. It is not certain whether paper conservation products (museums) are included within this product type.

Primary exposure

User

It is anticipated that users will be professionals only.

Plant & equipment

Industrial.

Products

These are supplied in drums and water-soluble packages.

Delivery

There is no information available.

Process & operations

Products are applied as the final stage in paper and cardboard manufacture. The products are applied at 0.1% to 1% of the paper by spray or roller. Where the mass of paper and cardboard requires preservation against challenging conditions, a 4% w/w loading is needed. However, there is no reliable information available.

Frequency, duration & quantity

It is anticipated that mixing and loading for spraying would be a daily, regular activity.

Maintenance, test & clean

Removal & disposal

Controls

Market data

There is no information on any of the above.

Secondary exposure

Population, route & time-frame

Adults and children handling preserved paper cartons - dermal contact (chronic) and infants chewing cardboard cartons - ingestion (chronic)

Table: Preservatives for paper

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Mixing concentrate for application	1.2.1		Hands, forearms - gloves, coveralls. RPE for dusty products
Application phase			
Spray or roller coating	1.3.1/1.4.4		None
Post-application phase (includes disposal)			
Clean down	1.6.1		Hands, forearms - gloves, coveralls

Type 9 Fibre, leather, rubber and polymerised materials preservatives

9.03 Preservatives for rubber and polymerised materials, and other biocidal products covered by product type 09.

Background

Rubber used in vehicle tyres, abrasive wheels, etc. does not contain preservative. Rubber and plastic products in contact with soil and water will contain preservative. Carpet backing, synthetic rubber geotextiles and pond liners, and water filtration and softening media contain preservatives.

Plasticiser preservatives are addressed under product type 7.

New rubber types, capable of activation with bleach to form biocidal rubber gloves, and products such as plastic chopping boards, doped with antimicrobial substances to kill surface bacteria, are not addressed within this product type.

Primary exposure

User

Biocide is incorporated at the manufacturing stage and it is anticipated that users will all be professionals. Users of preserved articles would be unlikely to know about the biocide content.

Plant & equipment

Products

Delivery

Process & operations

Frequency, duration & quantity

Maintenance, test & clean

Removal & disposal

Controls

Market data

There is no information on any of the above.

Secondary exposure

Population, route & time-frame

Adults, children and infants, exposed principally to treated textiles (carpet backing). Dermal contact, (chronic). Infants - ingestion of dust (chronic)

Table: Preservatives for rubber, polymerised materials, and other biocidal products

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Loading mixer	1.1.4		
Application phase			
-			
Post-application phase (includes disposal)			
-			

Type 10 Masonry preservatives

Background

This addresses products used to control lichen, fungi and algae on and in masonry, stone and concrete, in buildings, on paths and on roofs. Concrete additive preservatives are addressed as Type 6.02 and preservative coatings as Type 7. The products may include building materials such as impregnated plaster, but there is no information on the use of such articles.

Primary exposure

User

Professionals undertake in-situ curative treatments for fungal infestation of masonry and brickwork. The activity is often indistinguishable from in-situ curative wood preservation (Type 8.02) except for fluid injection. Minor uses include cleaning of fragile roofs made of reinforced cement , cleaning headstones in graveyards, and removing seaweed on dock steps and boat slipways. Typically, work is peripatetic. Abrasive cleaning treatments are not within scope.

Non-professionals undertake mould removal in bathrooms and path cleaning to reduce slipping risks.

Plant & equipment

Spray equipment can be hired, though professionals may own their own equipment. Minor tasks such as headstone cleaning is with brush and bucket. Non-professionals use garden or household pressure sprayers for path clearing. Household products for mould removal are ready-for-use trigger sprayers.

Products

Professional products are, commonly, water-based concentrates. These are supplied in pack sizes up to 25 litres. Non-professional products are water-based concentrates or soluble packs for application by spray and watering can, and as ready for use trigger sprayers.

Delivery

Purchased at need from wholesale or retail outlets.

Process & operations

Spraying (treating structures for professional treatment of fungal and algal infestation of masonry):
- low pressure spraying for fragile roofs, paths
- low-medium pressure - 4 to 7 bar - electric or fuel driven pump and preservative reservoir,
- also used at medium pressure (7-10 bar irrigation) to inject fluid in drilled holes in masonry.

Hand-held tool application:
- hand-brush or broom for small items
- watering can for paths
- trigger sprayer for bathroom and kitchen mould control

Mixing and loading is undertaken at the site of use, with products diluted for use in a spray reservoir or poured into a concentrate reservoir. Professional application is normally at sites where building redevelopment requires eradication of fungi. A considerable period of time is required at each site for lay bare the areas requiring treatment, so masonry biocide use is estimated to be only 10% to 50% of

the time spent on site. In general, all of the diluted product is used up in the treatment. Post-application, people should be excluded from the treated areas until surfaces are dry.

Non-professional application to paths requires either the path to be pressure washed before application of the biocide, or the biocide to be applied and left to kill algae with removal at a later date (e.g. by dry brushing). The use of sprayers is not relevant to this biocide use (though there maybe post-application exposure).

Frequency, duration & quantity

Professionals using spray equipment:
- Frequency - a few times a week, at two uses per day.
- Duration - 40 minutes per use (range 6 to 100 minutes)
- Quantity - 47 litres per job (range 6 to 600 litres

Professionals using brush equipment:
- There is no information on frequency or duration. It is unlikely that more than 10 litres of in-use product would be used on any occasion, with application lasting a suggested 30 minutes.

Non-professionals:
- clearing path - application with watering-can or low pressure sprayer:
- once monthly for (suggested) 15 minutes.
- mould treatment with trigger spray and cloth:
  once a fortnight for (suggested) 7 minutes.

Maintenance, test & clean

Professionals do not normally clean spray equipment. Seals and spray nozzle replacement would be the limit of likely maintenance. Non-professionals may wash out watering cans.

Removal & disposal

Killed algae (with biocide residues) are removed with a brush. This includes roofs of asbestos cement, where fibre release could occur through jet washing. Waste fluids from brushing are disposed to mains drainage or to the soil.

Controls

Professionals: coveralls, gloves and eye / face protection. RPE may be needed for solvent-based products. Persons should be excluded from treated areas until surfaces are dry.

Market data

No information

Secondary exposure

Population, route & time-frame

Adults and children - re-entry to areas with wet surfaces- dermal exposure by skin contact (acute) and adults and children - inhalation of volatilised residues (chronic).

Table: Masonry preservatives

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Dilution of concentrate	1.2.1		Hands and forearms - gloves
Application phase			
Spraying / irrigation	1.3.1/1.3.6		Dermal and inhalation - gloves, coveralls, face protection
Brushing (and broom)	1.2.3/1.2.8		Hands and forearms (and lower legs) - gloves, coveralls
Trigger spray and wipe	1.2.2/1.3.1		Hands - no protection
Post-application phase (includes disposal)			
Maintenance	1.6.1		Hands - no protection
Brush removal of dead algae	1.2.8		Hands, inhalation - no protection

Type 11 Preservatives for liquid cooling and processing systems

11.01 Preservatives used in once-through systems

Background

The products are used in assuring microbiologically clean water supplies to paper mills, food production, certain power station cooling systems, etc. The interface with Type 16 (molluscicides) is not clear. The shock disinfection and commissioning of domestic and office water systems for the supply of drinking water is covered here. There is very little information on the pattern of use but ozone (O_3) use is not is scope.

Primary exposure

User

Professionals only. Dosing systems are likely to require minimal intervention once set up, though cleaning in place procedures for inlets and holding tanks will be needed for sensitive systems such as those used in food and drink factories.

Plant & equipment

There is no information on dosing systems. Shock disinfection is a manual intervention.

Products

Common products include hypochlorite, in-situ generated vapour such as chlorine dioxide (ClO_2), and gases such as ozone or chlorine. Silver ion treatment in conjunction with residual chlorine is used in healthcare water supply systems. Cleaning in place products could involve a range of substances including peroxyacids. Pulp waste water treated with ClO_2 to remove effluent colouring is a non-biocidal use.

Delivery

There is no information - bulk delivery of dosing system products is probable.

Process & operations

There is no good information available on dosing and cleaning in place (CIP) other than under Type 4 disinfectants.

Shock disinfection is the introduction of elevated concentrations of biocide in order to disinfect existing pipework, and to recommission recirculating water systems. A measured quantity of biocide concentrate is mixed with the supply reservoir and the concentration profile determined through the water system over time.

Frequency, duration & quantity

Recirculating system strip-down, clean and recommissioning should take place twice a year. The water distribution systems in new homes are shock disinfected before first use. Office water pipes are disinfected at need.

Maintenance, test & clean

No information is available.

Removal & disposal

Used products in water are disposed to mains drainage or to the environment.

Controls

Market data

There is no information on the above.

Secondary exposure

There is insufficient information to make any estimate. Drinking water is tested (post shock treatment) to show that it is fit for consumption and free of disinfectant.

Table: Preservatives for once-through liquid cooling and processing systems

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Shock disinfection only: Dosing system – dip tube Addition of biocide, mixing	 1.1.3 1.2.1		 Hand - gloves
Application phase			
Permeation through system - bleed from discharge until biocide detected	1.5.2		Hand, inhaled - no protection
Post-application phase (includes disposal)			
Permeation through system - bleed from taps (domestic) Monitor biocide decay curve	1.5.2 1.6.2		Hand, inhaled - no protection Hand, inhaled - no protection

Type 11 Preservatives for liquid cooling and processing systems
11.02 Preservatives used in recirculating systems

Background

The products are used to treat wet cooling towers and evaporative condensers that are attached to air conditioning systems, food cooling systems, industrial processes and power supplies. The agents controlled are bacteria, algae and fungi. Small units are attached to dry cleaning establishments and mobile skating rinks. The type includes the control of algae in decorative fountains and in circulating aquaria water. It does not include biofilm dispersants, scale and corrosion inhibitors, or products immobilised in deioniser units.

Primary exposure

User

Professionals only use such products.

Plant & equipment

Large and medium sized systems (500 to 1000 m^3) are normally dosed from biocide reservoirs, with the supply and maintenance of dosing systems under the control of biocide suppliers. The suppliers may also train user company workers in use of their system.

Products

These are supplied in liquid form, and as solid tablets.

Delivery

Large systems have tanker delivery. Medium-sized systems' products are delivered in 200 l drums or 1000 l IBC.

Process & operations

Warm water (30 to 40 ^oC) is dispersed as a spray through an updraught of fresh air. The water cools by forced evaporation with aerosol drift minimised through the use of "drift eliminators" on cooling towers. Biofilms can form on wet surfaces, detritus within the cooling tower sump, and within scale. Biocide addition to medium sized systems is by intermittent (1 per week) or continuous dosing. For very small and very large systems, the biocides are added by shock dosing.

Biocide addition is by dosimeter, or by manual addition as a measured dose, e.g. by graduated jug or (for very large systems) pouring several entire drums into the sump. Exposure can occur through manual addition, or in metering systems, through changing the drum of concentrate, moving the dispensing tube.

Workers inspect and test the system to check for scale or biofilm accumulation, check that the heater and thermostat to prevent the sump freezing in cold weather is working, and to take dip-slides.

Systems are drained down before the biannual maintenance. The number of installations per site ranges from 1 to 20 or more. A default is proposed as 3 systems per site.

There is little information on the control of food cooling systems. For example, hot food is shock cooled by evaporation of water within the product into a partial vacuum. The condensate, recycled as part of the cooling process, is rich in nutrient and can carry a high microbiological load.

Frequency, duration & quantity

Biocide addition (concentrate):
- manual - one per installation (3), once a week, for 2 minutes
- dosing system drum change - service company, 4 installations per day, (12 units), 2 minutes

Plant workers:
- no exposure.

Maintenance, test & clean

Plant workers (diluted in-use fluid):
- inspect and test - one per installation (3) per week, for 2 minutes

Removal & disposal

Bleed-off water from cooling towers and drain-down waste are discharged to mains drainage. Drums are returned to the supplier for re-use.

Controls

Effective drift eliminators prevent exposure to cooling tower aerosols and volatilised biocides are released to the environment. Very large systems do not use drift eliminators, but the release source is many tens of metres above ground level.

Service personnel wear protective equipment and gloves, and where necessary, RPE, when changing the dosing drum supply tube. Maintenance of dosing pumps requires the cleaning of these items before dismantling.

Where skin sensitising biocides are used, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

Market data

There is no EU level information.

Secondary exposure

Population, route & time-frame

Adults and children - misuse (public bathing in decorative fountains) and aerosol drift thereof - dermal contact and (if downwind) inhalation - (chronic)

Table: Preservatives for recirculating liquid cooling and processing systems

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Manual dispensing into measure and into sump	1.1.2		Hands and forearms - gloves and coverall. If volatile, RPE needed.
Auto-dispense – change dip tube	1.1.3		Hands and forearms (and if volatile, inhaled) - gloves, coveralls, (RPE)
Application phase			
-			
Post-application phase (includes disposal)			
Sample process liquid (dip slide)	1.6.2		Hands - none
Inspect interior of cooling tower	1.6.2		Hands, inhaled - RPE if running
Clean dispensing pump for maintenance	1.6.1		Hands and forearms - (and if volatile, inhaled) - gloves, coveralls, (RPE)

Type 12 Slimicides
12.01 Slimicides for paper pulp

Background

The stages of paper-making involving biocide addition are fresh-water supply (Type 11.01), at pulp storage (virgin or recycled fibre), in stock preparation, in paper process water, in water recovery, and in additives and coatings (Type 6.02). Fibre contains a range of naturally occurring aerobic and anaerobic bacteria and fungi which, if not controlled, cause slime deposits, malodour, discoloration, corrosion and fungal mat formation.

Surface applied fungicides added to finished paper (Type 9.02), and to machinery lubricants (Type 6.02) are addressed elsewhere. Catalase inhibitors (e.g. glutaraldehyde, for peroxide de-inking in paper recycling) and biofilm inhibitors (e.g. biodispersants, surfactants, enzymes) are non-biocidal. Some specialised paper making processes use no biocide.

Primary exposure

User

There are two levels of professional user: service companies who manage the addition of concentrate, and wet-end paper mill workers, making and drying paper. There are no non-professional users.

Plant & equipment

As an industrial scale operation, paper making consumes <10 to 100 tonnes of water per tonne of paper. A typical production rate is estimated at 500 to 1000 tonnes of paper per day.

Products

Supply is in liquid form, representing most of the biocide used in paper-making. A few products are supplied in granular form, dissolved on site. Chlorine dioxide is generated on site from sodium chlorite or hypochlorite, which are not biocides.

Delivery

Industry trends are towards returnable intermediate bulk container (IBC) and bulk (tanker) delivery. Drum (200 l) supply is reducing in importance.

Process & operations

Chemically and mechanically separated fibre is suspended in water as slurry, typically containing 4% solids. The slurry is deposited as a paper web, with the water (white water) recycled. Biocide addition involves decisions on what product to add (knowing the target micro-organism), when and where to add it, monitoring of microbial activity and deposit formation, and machine performance. This must be without harm to waste water treatments, etc. An estimated of the rate of biocide use is 20 to 200 g per tonne of paper.

Biocide addition is by dosimeter from a drum, IBC's or on-site bulk storage. Some mills add biocide manually as a measured dose, e.g. using a bucket. Automatic dosing is indicated if manual addition is required more frequently than once a week.

Exposure to biocide concentrate occurs in manual dispensing and addition, particularly where this involves dilution and mixing before addition; and moving the dosing pump inlet tube between drums or IBC's.

In almost all companies, biocide concentrate addition is managed by the specialist biocide supply and service company, using trained operators, service engineers and consultants. Where microbial populations shift or resistance development is suspected, process biocides may be alternated within the day or every other day.

Exposure to in-use process fluids containing dilute biocide involves all workers in the process.

Frequency, duration & quantity

Concentrate handling:
- Manual addition frequency, 1 per week per site;
- manual duration estimate - 5 minutes dispensing, mixing and loading.
- Automatic dosimeter - frequency of changing reservoir, 1 per week (or less)
- automatic dosimeter change dosing pump. 5 minutes maximum.

Process operation at in-use concentration:
- several hours through the day - suggested value 4 hours;
  elevated skin exposure if wet clothing dries on the body.

(Many biocides degrade in paper-making, so in-use concentrations are lower than the nominal values).

Maintenance, test & clean

Maintenance and repair of dosing pumps require decontamination before handling as protective equipment is not practicable for such tasks.

Maintenance workers are exposed to process water that has dried, with concentrations above the nominal in-use value.

Sampling for microbial counting and examination involves transient hand contact with process water.

Deep cleaning using pressurised washers etc. is undertaken during process shut-down. The duration of use is expected to be prolonged (e.g. full shift exposure to dilute biocide spray).

Removal & disposal

Process water is either recycled or discharged to waste treatment. Drums may be returned or recycled, and IBC's are returned to the supply company.

Controls

Exposure of exposure to concentrate requires the use of personal protective equipment suitable for the hazard. RPE may be needed for volatile biocides. Process workers may wear waterproof work clothing and wellingtons. Drying machinery vapour is ducted outside the workplace.

Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected to be in place.

Market data

No information on the EU market size.

Secondary exposure

Population, route & time-frame

The scenario is skin contact with residual biocide within paper (20 to 200 ppm). Volatile or reactive biocides will have disappeared by the time paper is used.

Table: Slimicides for paper pulp

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Manual dispensing, pouring – automixing	1.1.2		Hand and forearm - gloves, coveralls. Inhalation (product dependent) - RPE.
Change concentrate reservoir	1.1.3		Hand and forearm - gloves, coveralls. RPE if necessary.
Application phase			
Process operation	1.5.2		Waterproof clothing, eye protection. RPE if needed for aerosols or vapour
Post-application phase (includes disposal)			
Process water sampling	1.1.2		Hand - gloves
Equipment maintenance	1.6.1		Dermal - gloves, waterproofs, eye protection, RPE if necessary
Dispense pump - clean for maintenance	1.6.1		Dermal - gloves, coveralls, eye protection, RPE if necessary.
Shut down deep clean	1.31		Dermal - gloves, waterproofs, eye protection, RPE if necessary

Type 12 Slimicides
12.02 Slimicides for mineral oil extraction

Background

These products control slime forming organisms in drilling mud, and suppress the proliferation of sulphate-reducing bacteria within the well and in pipelines. This includes the use of biocides in well injection water to control iron-reducing and sulphate-reducing bacteria (SRB). An estimated 40% of drilling muds are water-based, and up to 25% of these are treated with biocide.

Onshore non-oil drilling also uses slimicides; these uses could be considered as similar.

Primary exposure

User

There are three levels of professional user.
- Mud engineers, who manage the formulation of drilling mud and other specialist fluids which includes concentrate handling;
- Labourers - mixers who control mud supplies and operate the separation of mud from drilling shale (shaker screens), and
- Drill floor workers, who become extensively contaminated with drilling mud

There are no non-professional users.

Plant & equipment

An oil-rig may hold up to 4 mud pits (total volume around 60 m^3), with 75 m^3 of mud "active" in the drilling system at any time.

Products & Delivery

These are supplied in IBC's and drums, typically fitted with snap connectors.

Process & operations

From the pit, mud is pumped to the drill. On emerging from the well, mud passes over a shale shaker to remove debris and returns to the mud pit. Around 50 litres of biocide concentrate is added to a mud mix to give a biocide concentrations around 0.1%.

Well injection brine is dosed to a concentration around 0.03%. Injection into oil pipelines and underwater storage tanks to suppress SRB is automated.

Oil-rig operators typically work 12 hour shifts. The labourers tend to blockages and keep the shaker screens operational. In this area there are substantial mud aerosols.

Frequency, duration & quantity

Mud mixing:
- there is no information on the typical frequency or duration

Mud cycling screen operation
- this is a daily activity - the duration of time working in shale shaker rooms is not known.

Drill floor
- this a daily activity with exposure to mud for 12 hours.

Maintenance, test & clean

There is little information available. Samples of mud and fluids are taken for testing.

Removal & disposal

Water-based drilling muds are disposed to the environment.

Controls

It is anticipated that labourers and drill floor workers wear impermeable work wear (for protection against drilling products and weather), gloves and impermeable footwear. The use of RPE is anticipated to occur in screen rooms, though there is no information on this.

Skin disorders are not uncommon. Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording by a trained individual) is expected.

Market data

No EU level data available.

Secondary exposure

Population, route & time-frame

Other than rig workers incidentally exposed, secondary exposure is not anticipated.

Table: Slimicides for mineral oil extraction

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Mud mixing	1.1.2/1.2.1		Inhaled aerosol: RPE
Application phase			
Screening/separation	1.5.2		Dermal, inhaled - impermeable coveralls, gloves, RPE
Post-application phase (includes disposal)			
Sampling	1.6.2		Hand - gloves

Type 12 Slimicides
12.03 Other slimicides

Background

The type is not defined. It may include scenarios such as the control of microbial agents in water-backed spray booths and abrasive machinery, to minimise particulate emissions. Oil tank control of sulphate-reducing bacteria may be type 6.02.

Primary exposure

User

Professional - sprayer using spray booth; leather worker using abrasive machinery.

Plant & equipment

Water-backed plenum extraction system.

Products

Delivery

There is no information.

Process & operations

Particulate laden air is drawn through a water curtain before discharge outside the workplace. The water becomes progressively laden with organic residues.

Frequency, duration & quantity

Maintenance, test & clean

Removal & disposal

Controls

Market data

There is no useful information on any of the above.

Secondary exposure

Population & time-frame

People outside the workplace - inhalation (chronic)

Table: Other slimicides

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Application phase			
Post-application phase (includes disposal)			

Type 13 Metalworking fluids

Background

Biocides are added to water-based fluids, to preserve these in their action of cooling, lubricating and carrying cuttings from mechanical cutting operations. Metalworking fluids are supplied containing biocide. Biocide concentrate may be added at intervals to fluids as shock doses.

Primary exposure

User

Professionals in tool making and other metalworking operations.

Plant & equipment

Cutting fluids are used in lathes, milling machines and other machinery for cutting and shaping metal. These are of varying degrees of sophistication, but all require human intervention that implies exposure. Small and medium sized companies operate an average of 10 cutting workstations.

Products

Metalworking fluids based on emulsifiable oil concentrates are supplied containing biocides. Refined and synthetic fluids do not contain biocide (though these do become infected with microbes in use). The fluids with a biocide content around 0.1% are diluted to concentrations about 1% to 20%, typically 5%, of the original fluid in water.

When bacterial counts are rising above normal levels, biocide concentrate may be added to make a 0.01% to 0.2% concentration in the in-use fluid.

Delivery

Typically, in 200 l drums or IBC's.

Process & operations

Metal is shaped by moving past a cutting tool, or the cutting tool moves around or past metal. Metalworking fluid is supplied at the cutting tool for cooling, lubrication and swarf removal. The process is common, from making small screw threaded items to large aircraft parts.

There are several operations undertaken:

- tool setting - setting the machine for a production run;
- metal-working and handling worked pieces;
- dismantling the tool setting
- sump maintenance - cleaning filters, removing tramp oil, swarf removal, sump emptying
- fluid monitoring (refractive index, dip slides)
- metalworking fluid dilution for use and biocide replenishment

A single company may have a single sump supplying all machines, up to 100 m^3 capacity, or individual sumps, or a mixture of these.

An estimate (UBA-INFU, 2000) is that 2% of the emissions from metalworking deposit on work clothing. The risk of dermal and inhalation exposure has been related to the microbiological and

endotoxin content of the fluid. Aerosol emissions have mass median diameter up to 80 micron, diminishing to about 3 microns through evaporation (Thornburg and Leith, Appl. Occup. Env. Hyg. 15(8):618-628, 2000) and airborne concentrations in metalworking was at 1.9 mg/m^3 (HSE). Wearing gloves for metalworking caused them to become grossly contaminated inside the glove within a short period of time (HSL report).

Frequency, duration & quantity

Despite a considerable number of reports concerning exposure to metalworking fluids (e.g. HSE, EH74/4), there is very little information on the frequency and duration of operations. Exposure is by inhalation and skin contact. The following are suggestions only:

- tool setting and dismantling - 4 per day, 10 minutes per event
- metalworking - operator near to machine - 1 hour per day

Maintenance, test & clean

The scope for dermal exposure is very. However, there is practically no information on the patterns of work and the following are suggestions only:

- sump maintenance - 1 per month, 4 hours
- fluid monitoring - 1 per week, 10 minutes
- fluid dilution and/or biocide addition - 1 per week, 10 minutes.

Removal & disposal

This is possibly by contract. The products are not suitable for discharge to mains drainage.

Controls

Splash-guards in metalworking operations appear to have little effect on airborne concentrations, though they will help to reduce general contamination. All surfaces in workshops, and all articles produced, are contaminated with metalworking fluids until the latter are degreased.

Skin disorders are common in the industry. Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected.

Market data

There is no information

Secondary exposure

Population, route & time-frame

Adult - home laundry of work-wear - dermal (chronic).

Table: Metalworking fluids

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Diluting concentrate Adding biocide	1.2.1 1.1.2		Skin - coverall and gloves
Application phase			
Metalworking	1.1.3/1.5.1/ 1.5.2		Skin - coveralls
Post-application phase (includes disposal)			
Sump maintenance Fluid monitoring	1.6.1 1.6.2		Skin - gloves, coveralls Skin

Type 14 Rodenticides

Background

The scope is limited to rodents; this product type is closely linked with Type 23, for the control of other vertebrates. Typical sites of use are domestic, retail, industrial and recreational premises, and near animal housing, and sewers, docks, waste sites and embankments. Products to protect foodstuff in transport or storage (e.g. grain) are not included, but may fall under the scope on the Biocidal Products Directive.

Primary exposure

User

Professional pest controllers (private companies and local authorities) and non-professionals (using retail products ready-for-use (r.f.u.).

Plant & equipment

Mechanical equipment used by professionals is limited to phosphide pellet dispensers and blowers to apply toxic dusts. Other equipment includes bait stations protected from interference by children and non-target animals, such as bait boxes and tubes.

Products

Grain bait is the most commonly applied product, loose, in pellet form, and in a waterproof sachet for use in wet environments. Concentrates, for preparation of drinking water or specific food baits, are the next most common products. Contact (tracking) dusts, wax blocks and caulks, phosphide pellets and cyanide dusts are available. Non-professional products are normally r.f.u. bait stations, often containing grain in a pellet or wax block.

Delivery

There is no reliable information available. Pellets of phosphide bait are supplied in moisture resistant tubes or canisters.

Process & operations

Professional users place loose grain baits by scooping. All other solid baits are placed either manually, by blowing or dusting (rodent runs), or by pellet dispenser. Bait boxes are simply located and fixed in place. Bait mixing gives the highest potential for exposure, and professionals may undertake mixing on a medium scale using mechanical mixers.

Outdoor treatments are seasonal. Products relying on body heat loss are of most use in the winter. In general, the highest usage is in the autumn. Indoor treatments, particularly in cities, are year-round.

Mixing is restricted to self-preparation of bait using concentrate. Blowers and pellet dispensers require a reservoir to be filled with pesticide. Gassing (cyanide powder and phosphide pellets, liberating gas on contact with moisture), takes place outdoors and >10 metres away from inhabited buildings. Powders are either blown or introduced with a long-handled spoon. Pellets are placed with an applicator. In both cases, burrow entrances are blocked post-application.

Application is placing bait in bait stations, sewers, burrows, etc. and dispersive operations such as caulking and blowing.

Post application tasks include checking bait boxes, decontamination of applicator equipment, and the collection of uneaten solid and liquid baits, and dead animals, to minimise the risks to non-target animals.

Frequency, duration & quantity

Workers are peripatetic and much time is spent travelling to treatment sites and surveying. It is expected that rodenticide use is daily. In an HSE survey of pest controllers (1994) it was estimated that the median duration "using pesticides" was 120 minutes, range 40 to 330 minutes, with no further time budget detail. Treatment times are stated as:

- up to 100 minutes - pastes, mouse tubes and pellet placement;
- 300 to 400 minutes - cereal baits, sachets, dusts, liquid baits
- >500 minutes - wax blocks.

However, it is probable that the time actually handling, dispensing and clearing up is a fraction of these durations.

A Danish review (2001) proposed the following:

- sites treated once per week, visiting 8 sites per day (6 to inspect, 2 to treat)
- private gardens - 30 minute job
- heavy infestation - 8-hour job
- wax bait placing - 5 minutes, 4 per site
- loose grain placement - 5 minutes, 6 per site
- pellet placing - 8 to 16 per site, over 30 minutes - 8 hours (1600 pellets) for large sites
- bait mixing and application - 5 minutes (apple pieces), 2 applications per site
- phosphide 0.6 g pellets (56% AlP) - 2 to3 per burrow, 2 burrows per site
- powders - 10 minutes per application, 2 burrows per site.

Mouse infestations are treated more swiftly than rat infestations

Maintenance, test & clean

Cleaning of mechanical applicators (with water) takes place outdoors. A Danish review proposed 1 job per day, 5 minutes.

Removal & disposal

Collection of uneaten bait, empty packages and dead animals, disposed as controlled waste.

Controls

Professionals normally wear a work uniform or coveralls, and protective gloves. Contact powder and other applications are indicated with warning signs.

Market data

None available at EU level.

Secondary exposure

Population, route & time-frame

Children, contact with exposed baits and dead animals - dermal (chronic)

Table: Rodenticides

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Mix concentrate bait	1.1.2/1.2.1		Hands - gloves. Large scale - RPE, gloves, coveralls, eye protection
Load dust or pellet applicator	1.1.4		Hands - gloves. Outdoors.
Application phase			
Place loose grain bait	1.1.4/1.2.5		Hands - gloves, coverall
Place pellet or wax bait	1.1.4		Hands - gloves, coverall
Place gassing product (powder, pellet)	1.1.4/1.2.5		Hands, inhaled - gloves, coverall, RPE
Blow gassing or contact product	1.3.2		Dermal, inhaled - gloves, coverall, RPE - decontaminated after use
Place bait station	1.1.4		None
Post-application phase (includes disposal)			
Clean applicator	1.6.1		Dermal, inhaled - gloves, coverall, RPE, outdoors
Collect uneaten bait / dead animal	1.1.4		Dermal - gloves, coverall, RPE for sweeping.

Type 15 Avicides

Type 16 Molluscicides

Type 17 Piscicides

Background

The only information appears to be a TNO review (BIOEXPO, 1997). Avicides appear to be limited to pigeon control. The criteria for non-agricultural, non-water molluscicides are unclear. Piscicides appear to be limited to use in fish farms at the end of a fish harvest, to clear any large fish that would eat newly introduced fry.

There is practically no information on which to base any pattern of use statement. Avicide products are baits or contact poisons. Piscicide products are pellets or pour-in liquids.

Primary exposure

User

Plant & equipment

Products

Delivery

Process & operations

Frequency, duration & quantity

Maintenance, test & clean

Removal & disposal

Controls

Market data

Secondary exposure

Population, route & time-frame

Table: Avicides, Molluscicides & Piscicides

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Application phase			
Post-application phase (includes disposal)			

Type 18 Insecticides, acaricides and products to control other arthropods
18.01 Products used by professionals

Background

This product type excludes medicines used for the control of parasites etc. on animals. Insects in wood are addressed as Type 8.02 and in grain store cleaning, Type 4. All other scenarios are covered, including stored product pests, and infestations of commercial and residential property and transport.

Primary exposure

User

These are professional pest controllers (private companies and local authorities). People at work that - incidentally - use pesticides from retail outlets are classed as non-professional users (18.02).

Plant & equipment

The equipment used in insect control is portable or transportable, and includes the following:

- knapsack and compression sprayers for liquids and dusts
- dust applicators (blowers, bellows, piston pumps, compression dusters)
- controlled droplet applicators (CDA) and fogging machines
- tractor-trailer systems for waste tip spraying
- pre- and post-construction sub-soil injection apparatus (termite control)
- fumigant smoke and gas treatments
- baits (gels applied by caulking, bait stations)
- lacquers

Fixed installations include remotely operated low-volume misting equipment for warehouse and other "knock-down" space treatments. These are also used for Type 4 products.

Ready-for-use applications include:
- hand-held pre-pressurised aerosol sprays, for aircraft space treatment on landing
- adhesive papers and traps (biocidal)

Other applications include building materials (not wood), pre-impregnated with Type 18 biocide, and the professional impregnation of bed-nets for mosquito control (see 18.02).

Products

Sprayers use concentrates (liquid, emulsion, wettable powder, micro-encapsulated) diluted for use. Dusting equipment uses ready-for-use (r.f.u.) dusts. Misting and fogging machines use r.f.u. liquids or diluted concentrates. The liquids and dusts are marketed in a variety of containers. Fumigants are smoke generators (pyrotechnic devices, r.f.u.) and volatile liquids vapours applied via evaporator.

Delivery

Products are generally ordered at need from a supplier. It is common for user companies to stock a restricted range of products (e.g. one type of pyrethroid, organophosphate, etc. for liquid spray application).

Process & operations

The types of treatment are:

- space treatment - to knock down flying insects.
- nest and harbourage (crack and crevice) treatments
- blanket treatment - to cover a horizontal and/or vertical surface
- band treatment - to cover insect access routes along floor-wall junctions etc.
- injection - to treat sub-soil to protect foundations from termites
- fumigation - to treat stacked commodities or freight containers
- cracks and crevice

Mixing and loading is a process that is often difficult to segregate from application because it is often very short term and does not occur for every application. Post-application tasks such as cleaning out sprayers are not common - the application equipment tends to be dedicated to a range of uses with one type of product.

Frequency, duration & quantity

Workers are peripatetic and much time is spent travelling to treatment sites and surveying. Daily use is anticipated. In an HSE survey of pest controllers (1994) it was estimated that the median duration "using pesticides" was 120 minutes, range 40 to 330 minutes. Specific values are:

- professional use daily, several times per day
- unspecified task - 40 minutes' duration, range 3 to 150 minutes
- blanket spraying (biting insects) - 32 minutes, range 3 to 105 minutes
- band spraying and dusting (crawling insects) - 48 minutes, range 10 to 120 minutes
- wasp nest eradication - 3 minutes
- aerosol space spraying - 6 second discharge per location, 1 g per second emitted
- stack fumigation and pyrotechnic treatments - 2 hours (user remote from point of use)
- termite treatments (surface spray, sub-soil injection at 6 bar) - 4 hours, range 1 to 11.5 hours (Cattani et al, Ann. Occup. Hyg. 2001, 45(4), 299-308)

Suggested values for other activities are:

- waste-tip treatment - 40 minutes
- CDA and fogging - 40 minutes
- lacquer application - 20 minutes
- bait caulking - 10 minutes, in place for 2 weeks (RIVM)
- soil injection - 4 hours (1 to 11.5 hours)

Maintenance, test & clean

This is limited to unblocking nozzles and replacing seals.

Removal & disposal

Products are generally used up. Packaging is returned to the supplier or treated as special waste.

Controls

As wall as a work uniform and coveralls, operators wear disposable and non-disposable protective gloves. Respiratory protective equipment (RPE) is nearly always available if needed. Washing facilities are often found on pest controllers' vans.

Warning signs should be posted on fumigated containers and on all access routes to treated areas. Fixed installation mist treatments (permit to work rules) must have areas free of people before treatment. Smoke treatments should have the space checked that it is smoke-free before re-entry.

Market data

There is no information on the size of the EU market.

Secondary exposure

Population, route & time-frame

Adults, children - inhaled, skin contact immediate post-application (acute)
Adults, infants - inhaled, (infants) ingested - post application (chronic)

Fumigation: bystanders

Table: Insecticides, acaricides and products used by professionals

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Mixing and loading liquids	1.2.1		Hand, forearm - gloves, coverall
Loading dusts	1.1.4		Hand, forearm - gloves, coverall
Loading remote space treatment	1.1.2		Coverall, RPE
Application phase			
Spraying and dusting - surfaces	1.3.1/1.3.2		Dermal, inhaled - gloves, coverall, RPE
Space treatment includes smoke and vapour fumigation	1.3.5/1.5.1		Remote - none. Otherwise none.
Injection	1.3.6		Dermal, inhaled - gloves, coverall
Caulking	1.2.7		Hand - gloves, coverall
Baiting	1.1.4		None
Lacquers	1.2.6		Hand, forearm - gloves, coverall
Post-application phase (includes disposal)			
Re-entry air test (fumigant, smoke)	1.6.2		RPE, coverall

Type 18 Insecticides, acaricides and products to control other arthropods
18.02 Products used by non-professionals

Background

This product type excludes medicines used for the control of parasites etc. on animals. Insects in wood are addressed as Type 8.02.

Primary exposure

User

Non-professional users are residents, consumers and people at work who use products incidentally.

Plant & equipment

Equipment commonly available to non-professionals includes hand operated ready-for-use (r.f.u.) packs and plug-in vaporisers. While non-professionals can hire spray equipment, this is not generally envisaged.

Products

Most products are supplied ready-for-use, as follows:

- space treatments - pre-pressurised aerosol cans, trigger sprayers, impregnated mats, smoke coils, vapour strips, mothballs, plug-in vaporisers
- nest and harborages treatments - dust puffer packs, aerosol cans, caulk paste tube
- spot, band and broadcast treatments - aerosol cans, trigger sprayers, dust puffer packs

"Total release aerosols / foggers" are often reported in literature, though their use in the EU is uncertain. These products discharge their full contents after a short delay, as a space and broadcast treatment. Some liquids are supplied ready for use in pump sprayers. Bed-net emulsion concentrates are supplied for dilution. Fly papers may also contain biocide.

Delivery

Products are generally purchased from a retailer and stored for extended periods in the home.

Process & operations

The types of treatment are:

- space treatment - to knock down flying insects.
- nest and harbourage (crack and crevice) treatments
- broadcast treatment - to cover a horizontal surface
- spot and band treatment - to cover insect access routes along floor-wall junctions etc.

Products may also be supplied to impregnate bed nets with insecticide to control mosquito bites.

There is no mixing and loading except where liquids are put into pump sprayers, or where bed-net solutions for hand-dipping are made. Application covers the use of the product - some products remain detectable for considerable periods of time. Bed-nets are treated by hand washing. There is no post-application activity other than net drying and container disposal.

Frequency, duration & quantity

The following information (non-professional use) is derived from research (HSL), 1997-2001:

- diluting concentrates - single event to produce 5 litres of in-use product
- air-space aerosol spray indoors - 4 uses daily, 6 sec discharge, 90 sec exposure per event
- air-space trigger spray indoors - 4 uses daily, 6 sec discharge, 90 sec exposure per event
- pumped sprayer indoors - 4 uses daily, 60 sec discharge, 90 sec exposure per event
- surface aerosol spray indoors - 1 use per week, 7 min
- surface trigger spray indoors - 1 use per week, 7 min
- surface dusting crack and crevice - 1 per week, 7 min
- surface dusting broadcast - 1 per month, 7 min; 11 min vacuuming up
- plug-in vaporisers and smoke coils - 1 per day, 2 to 8 hours
- vapour strips, mats, mothballs - continuous

Bed-net impregnation - 1 per month, 10 min (proposal only)

Weegels (TU Delft 1997) found general insecticide mixing and loading operations at 80 sec, range 77 to 104 sec and aerosol blanket spraying (fleas) duration at 5 minutes.

ECETOC proposes values (trigger or aerosol spray) as follows:

- spot treatment - total exposure 5 min, released at 100 cm height
- air space treatment - total exposure 1 min, released at 180 cm height
- crack and crevice treatment - total exposure 10 min, released at 25 cm height
- general band / blanket treatment, total exposure 10 min, released at 75 cm height

with all treatments persisting for 2 weeks.

CONSEXPO uses 1 min discharge for aerosol sprays. For trigger sprays, 5 min for spot uses and 10 min for blanket uses and 10 min for surface dusting cracks and crevices are implemented.

Industry data suggest that aerosol can applications last about 2 minutes continuous spraying and that the evaporation rate from vaporising devices is 2 to 6 mg / hour.

Maintenance, test & clean

This is not expected to occur.

Removal & disposal

Containers are disposed to domestic waste.

Controls

Users may wear gloves, though this should not be assumed.

Market data

There is no EU-level information.

Secondary exposure

Population, route & time-frame

Adults and children - exposure during and immediate post application - inhaled, (acute)
Adults, children and infants - inhaling vapour from vaporisers - inhaled (acute)
Adults, children and infants - contact with treated bed-nets - dermal, (chronic)
Infants - skin contact and ingestion of residues - dermal, ingested - (chronic)

Table: Insecticides, acaricides and products used by non-professionals

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Diluting bed net solution	1.2.1		Hand, forearm - no protection
Loading pump sprayers	1.1.2		Hand - no protection
Application phase			
Air-space treatments	1.3.5		Inhaled, dermal - no protection
Surface treatments	1.3.1/1.3.2		Dermal - no protection
Net impregnation	1.4.3		Dermal, no protection
Post-application phase (includes disposal)			
Net drying	1.1.4		Dermal - no protection

Type 19 Repellents and attractants
19.01 Repellents applied directly on human or animal skin

Background

There is very sparse information concerning these products.

Primary exposure

User

Professional and non-professional.

Plant & equipment

Products & Delivery

No information.

Process & operations

Spray or paint or pour on exposed skin - spread by hand.

Frequency, duration & quantity

No information

Maintenance, test & clean

This is not anticipated.

Removal & disposal

Wash off, dislodge to clothing (human products), evaporation.

Controls, Market data

No information

Secondary exposure

Population, route & time-frame

Protected adults handling infants - dermal route, (acute)

Table: Repellents applied directly on human or animal skin

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
-			
Application phase			
Pour on hand and spread on exposed skin	1.2.2		Skin
Post-application phase (includes disposal)			

Type 19 Repellents and attractants
19.02 Attractants and repellents not applied directly on human or animal skin

Background

There is very sparse information concerning these products. Impregnated textiles are addressed in Types 9.01 and Type 18.02. Bird repellents are mentioned in Type 15. It is probable that a substance such as tiger dung or orange peel (to repel cats) is out of scope.

Primary exposure

User

Professionals and non-professionals

Plant & equipment

Products & delivery

Process & operations

Vaporising systems are used to disperse natural oils as insect repellents, e.g. candles, heated blocks. Bone oil is painted on surfaces to repel vermin. Granule packs for scattering are used to repel domestic pests. Pre-formed pheromone traps are used with adhesive boards or insecticides as attractants.

It is uncertain whether substances to deter humans from consuming household products (e.g. BITREX) is within scope.

Frequency, duration & quantity

Adults handle articles to set them in operation. Scattering, painting.

Maintenance, test & clean

This is not anticipated.

Removal & disposal

Disposal in domestic or trade waste.

Controls

Market data

No information.

Secondary exposure

Population Route & time-frame

Adults, children and infants - inhalation (acute); dermal - granules - (chronic)

Table: Attractants and repellents not applied directly on human or animal skin

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Application phase			
Paint	1.2.6		Inhaled, hand - gloves
Vaporiser	1.3.5/1.5.1		Inhaled
Granule scattering	1.1.4		Hand - no protection
Post-application phase (includes disposal)			

Type 20 Preservatives for food or feedstocks

Background

Salad disinfection is addressed as Type 4. Possible professional use scenarios are the dipping of fruit in fungicide for storage, the treatment of cheese rind with antibiotic spray, to prevent infection with unwanted spores, and the protection of air-cured ham from maggot infestation with an insecticide coating. Meat preservation with saltpetre and pickling is believed to be out of scope.

Primary exposure

User

Plant & equipment

Products

Delivery

Process & operations

Frequency, duration & quantity

Maintenance, test & clean

Removal & disposal

Controls

Market data

Secondary exposure

Population, route & time-frame

There is no information on any of the above

Table: Preservatives for food or feedstocks

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Application phase			
Post-application phase (includes disposal)			

Type 21 Antifouling products

Background

This statement concerns application to vessels and to nets used in aquaculture. There is no information on application of antifouling products to permanently immersed structures or for stripping expired antifoulant coatings.

Primary exposure

User

Professionals - sprayers, pot-men and ancillary workers in dockyards and slipways;
Professionals - chandlers in marinas and on hard-standing
Non-professionals - leisure craft in marinas and on hard standing
Professionals - dipping nets in antifoulant (and washing old nets)
Professionals - installing treated nets at fish farms

Plant & equipment

Professionals use equipment such as high pressure airless sprayers and mobile access platforms. net dipping requires the use of lifting machinery.

Products

Three-quarters of the products in a survey (1994 - HSE) were free-association (the active substance leaches from the coating); one quarter were self-polishing (active ingredient in a copolymer coating which hydrolyses slowly in water - requires reapplication every 5 years). There are no reliable data for the military sector. It is estimated that 30% of the coating active substance remains when coatings are removed (UBA-INFU).

Net dipping is in viscous solvent or waterborne preparations.

Delivery

Products for professional use on ships are delivered to the vessel in cans up to 25 litres. Supply in the UK is often via the ship owner, and data sheets are not necessarily transmitted. There is no thinning or dilution.

Products for use in marinas are purchased at need from a chandler, who may offer a service in applying antifoulant to leisure craft.

Products for use on nets are supplied in 200 litre drums.

Process & operations

Antifoulant is applied only to areas of vessels intended for immersion. Bare metal surfaces are prepared with sprayed coatings such as corrosion inhibitors. Antifoulant is sprayed using airless spray equipment at or above 100 bar. As a rule, sufficient sprayers are employed to ensure that one full coat is applied in one day. Rarely are more than two coats applied. The pot man attends to mixing and loading the antifoulant to the high-pressure pump reservoir.

Net dipping is the repeated immersion of nets (up to 100 m long) in a reservoir. Nets are packed damp and are still in this state when installed.

Professional sprayers, etc spraying ships:
- antifoulant reservoir supplying high-pressure pump, operated by pot-man
- sprayer, often working from a mobile platform,
- others, e.g.. mobile platform operator
- coating removal by high pressure water or abrasive

Professional chandlers painting boats:
- coating by brush and roller or (small areas) by hand-held aerosol can
- coating removal using powered sanding equipment

Non-professionals painting boats:
- coating by brush and roller
- removal by hand-held abrasive

Professional net-dipping:
- coating by crane-assisted dipping in a water or solvent dispersion of antifoulant
- cleaning by pressure washer and large scale washing machine.

Professional net installer:
- handling freshly coated nets, still damp with antifoulant.

Frequency, duration & quantity

Professional antifouling is not seasonal, whereas non-professional application normally takes place in springtime. Much of the time spent by a vessel in dry dock is for refitting and maintenance. Hence, the application of antifoulant is irregular with intervals between exposure. Net deployment is most intensive in the springtime, and net dipping takes place year round.

Professionals spraying antifouling:
- all workers - 2 to 3 consecutive days per month, duration 184 min, range 40 to 360 min
- using 240 litres of product (25 to >800 litres) over an area of 1600 m^2 (600 to 4000 m^2).

An estimate (UBA-INFU) is for 5 to 45% of antifoulant as overspray.

Professionals and non-professionals - brush and roller application
- 1 or 2 consecutive days (per year - non-professionals), duration 90 min (62 to 135 min)
- using 4 litres per session (2 to 5 litres) over an area of 20 m^2 (7 to 30 m^2)

Professionals coating nets
- 1 or 2 nets per day, some days a week, 60 minutes' contact (range 30 to 200 minutes)
- 8 hours' drying per net (no contact). Contact - dipping and packing damp nets.

Professionals deploying nets
- 3 to 7 nets per day, up to 6 persons to deploy one net
- 80 to 300 minutes per work session per day.

Maintenance, test & clean

There is no information on removing residues from reservoirs, pumps or supply lines.

Removal & disposal

There is no information on the patterns of use for removing coatings.

Controls

Professionals spraying antifouling take care to avoid the products depositing on their skin. Custom in the industry is for operators to coat exposed skin with petroleum jelly. Two sets of coveralls are used, with protective gloves and respiratory protective equipment (preferably air-fed).

Where skin sensitising biocides are used in products, a system of health surveillance (regular skin inspection and recording, by a trained individual) is expected.

Market data

No data available.

Secondary exposure

Population, route & time-frame

Bystanders (adult workers) during vessel coating operations - inhaled, dermal (acute)

Table: Antifouling products

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Load antifoulant reservoir	1.1.2		Dermal - gloves, coveralls
Prime spraying lines	1.3.1		Dermal - gloves, coveralls
Application phase			
Spray	1.3.1		Dermal, inhaled - gloves, double coveralls, RPE (air fed)
Dip	1.1.3/1.4.4		Dermal - gloves, coverall
Paint (brush or roller)	1.2.6		Dermal - gloves
Manoeuvre work platform	1.3.1		Dermal, inhaled - gloves, double coveralls, RPE
Post-application phase (includes disposal)			
Clean equipment	1.3.1		Dermal - gloves, coveralls
Remove expired coatings	1.2.3		Dermal, inhaled - gloves, coveralls, RPE (air fed)
Install new net	1.1.3/1.1.4		Dermal - gloves, coverall

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Type 22 Embalming and taxidermist fluids

Background

The type includes cadaver preparation and tissue samples in healthcare, as well as conventional embalming and taxidermy. Preserved animal specimens are conserved in museums and used in education. Products used in cleaning are covered under type 2.01.

Primary exposure

User

Professionals, principally. There are two main groups:
- those involved in preserving tissue
- those involved in using preserved tissue.

Plant & equipment

This is limited to dispensers and pumps connected to trochars for inoculating cadaver arteries and cavities with preservative fluids.

Products and Delivery

Supply is as 10 or 25 litre drums, fitted with taps.

Process & operations

Danish and Aberdeen University reviews stated that temporary preservation (embalming) requires 3 to 5 litres of solution pumped at around 1.2 bar, through arteries and (following aspiration) into cavities. Sprays may be used to help preserve skin.

Permanent preservation requires 11 litres, per adult cadaver followed by prolonged immersion in aqueous ethanol to strip out aldehyde preservatives. This process applies also to animal specimens used in education.

Some animal taxidermy preparations are pastes mixed of active substances that are commodity chemicals. There may be links with product type 9.01 - leather preservatives.

Mixing and loading is restricted to diluting concentrate within the pump reservoir, or mixing taxidermy paste. Application of fluid is by injection and of pastes by manual spreading. Post-application tasks are cleaning and (pathology laboratories) tissue sectioning and staining.

Pathological tissue samples are placed in a small vessel into which preservative has been dispensed, and transported to laboratories for examination.

Frequency, duration & quantity

Embalming:
- daily, 2 procedures per day (range 0 to 6)
- peripatetic embalmers who visit many funeral parlours and conduct many more than two corpses per day; more than six may be unrealistic.
- mixing and loading - 10 minutes

- application (excludes aspiration, when no biocide used) - 15 minutes
- handling and cleaning - 10 minutes

Taxidermy
- There is no useful information available. Post application - mounting in display cases.

Pathological specimen handling - estimates only
- frequency - estimate 5 per day by one scrub nurse, 10 per day per pathologist
- dispensing preservative and adding tissue - 1 minute
- tissue washing, sectioning, etc - unknown.

Maintenance, test & clean

Equipment is cleaned and disinfected after use (Type 2.1)

Removal & disposal

Preserved cadavers and tissues are removed for burial or long-term storage.

Controls

Embalmers usually wear a cotton theatre suit with wellingtons, apron, protective gloves and forearm protectors, and some head and face protection. Facemasks are medical rather than respiratory protective equipment. There may be exhaust ventilation around the embalming table, and there is general ventilation

Market data

There is no information.

Secondary exposure

Population, route & time-frame

This is not envisaged.

Table: Embalming and taxidermist fluids

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Decant concentrate	1.1.2		Hands, inhaled - gloves, coveralls
Dilute and mix in pressure vessel	1.2.1		Hands - gloves
Mix taxidermy paste	1.2.1		Hands - gloves
Application phase			
Connect to artery and inject	1.3.6		Hands, - gloves, eye protection, apron
Massage cadaver / animal	1.1.4		Hands, - gloves, eye protection, apron
Connect to cavities and inject	1.3.6		Hands, - gloves, eye protection, apron
Spray cadaver skin	1.3.1		Hands, - gloves, eye protection, apron
Post-application phase (includes disposal)			
Cleaning	1.6.1		Hands - gloves, eye protection
Moving cadaver	1.1.4		Hands - gloves
Pathology dissection	1.1.3		Hands, inhaled - gloves, LEV

Type 23 Control of other vertebrates

Background

Much of this statement repeats that for Type 14. Products will include those for use in emergencies e.g. rabies outbreak. The scope is excludes rodents and birds. Typical target species are burrowing animals, squirrels and other creatures classed as vermin.

Primary exposure

User

Professional pest controllers (private companies and local authorities

Plant & equipment

Mechanical equipment used by professionals is limited to pellet dispensers.

Products

Phosphides are marketed as gassing products and toxic pellets in water-resident packages. Cyanide is available as an encapsulated powder. Other products reported include pyrotechnic fumigants and strychnine (treating worms for mole bait).

Delivery

There is no reliable information available. Pellets of phosphide bait are supplied in moisture resistant tubes or canisters.

Process & operations

Professional users place bait by pellet dispenser. Outdoor treatments are seasonal. Products relying on body heat loss are of most use in the winter. In general, the highest usage is in the autumn

Mixing is restricted to self-preparation of bait using concentrate. Bait mixing gives the highest potential for exposure, and professionals may undertake mixing on a small or medium scale using mechanical mixers. Pellet dispensers require a reservoir to be filled with pesticide

Application is placing bait in, burrows, etc. Poison gas generators should be used >10 metres away from inhabited buildings and burrow entrances are blocked post-application. Cyanide powders are blown into rabbit warrens.

Post-application tasks include the collection of uneaten baits, and dead animals, to minimise the risks to non-target animals.

Frequency, duration & quantity

Workers are peripatetic and much time is spent travelling to treatment sites and surveying. It is expected that rodenticide use is daily

A Danish review (2001) proposed the following:

- sites treated once per week, visiting 8 sites per day (6 to inspect, 2 to treat)
- private gardens - 30 minute job
- heavy infestation - 8-hour job
- loose grain placement - 5 minutes, 6 per site
- pellet placing - 8 to 16 per site, over 30 minutes - 8 hours (1600 pellets) for large sites
- bait mixing and application - 5 minutes (apple pieces), 2 applications per site
- phosphide 0.6 g pellets (56% AlP) - 2 to3 per burrow, 2 burrows per site
- powders - 10 minutes per application, 2 burrows per site.

This includes rodenticide applications.

Maintenance, test & clean

Cleaning of mechanical applicators (with water) takes place outdoors. A Danish review proposed 1 job per day, 5 minutes.

Removal & disposal

Collection of uneaten bait, empty packages and dead animals, disposed as controlled waste.

Controls

Professionals normally wear a work uniform or coveralls, and protective gloves.

Market data

None available at EU level.

Secondary exposure

Population, route & time-frame

Children, contact with exposed baits and dead animals - dermal (acute)

Table: Control of other vertebrates

Scenario outline	Task code	Time %	Exposure route and controls
Mixing & loading phase			
Mix concentrate bait	1.1.2/1.2.1		Hands - gloves. Large scale - RPE, gloves, coveralls, eye protection
Load pellet applicator	1.1.4		Hands - gloves. Outdoors.
Application phase			
Place bait	1.1.4		Hands - gloves, coverall
Place gassing product (powder, pellet)	1.1.4		Hands, inhaled - gloves, coverall, RPE
Blow gassing product	1.3.2		Dermal, inhaled - gloves, coverall, RPE - decontaminated after use
Place bait station	1.1.4		None
Post-application phase (includes disposal)			
Clean applicator	1.6.1		Dermal, inhaled - gloves, coverall, RPE, outdoors
Collect uneaten bait / dead animal	1.1.4		Dermal - gloves, coverall, RPE for sweeping.

3.3 Database models

Database models are based on experimental exposure data, collected in surveys of worker exposure, and studies of exposure for specific tasks in laboratory or workshop simulations. Database models are familiar in the risk assessment of plant protection products, where they have been used for many years. This section reports those models that are considered adequate for human exposure assessment and gives references. It is notable that:

- many database models relate to workplace situations and few to home use;
- some are valid for specific scenarios only;
- the models relate to exposure by inhalation and skin contact.

Guidance is presented in Part 2.1.6 on the selection of values from databases for use in risk assessment.

Database models - advantages and drawbacks

The advantages include:

- the data set is clearly linked with a scenario or task;
- the inputs and outputs can be simply documented;
- they are self-validated, provided the underlying studies are well enough reported.

But the disadvantages include:

- many - if not most - scenarios have not been monitored or measured
- there is reliance on critical factors such as the pattern of use or clothing penetration;
- the underlying studies may have been closely controlled;
- the data ranges can be very wide and data sets very sparsely populated.

Model reference

The models in this section are allocated a reference name - the index is on the next page. As state-of-the-art at the end of 2001, the models reported are or are not recommended for use in the tiered approach to exposure assessment. In the latter case, they are only acknowledged.

At this moment, no clear guidance is presented in this report regarding the choice between models for specific scenarios other than the one involved. Such guidance needs to be prepared at a later stage (recommendation).

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Index of database models

Introduction

Exposure is a consequence of contact with a substance. All of the above models relate to inhalation exposure and/or skin contact, and most apply to biocidal products (RE_X contains some plant protection models and EUROPOEM contains many such models).

Most of these models state indicative percentiles (or central tendency and worst case), and/or produce single values from deterministic routines. The input values should be selected from pattern of use data, default values and stated assumptions, as recommended in Part 2.1. Where the data set is sparse, there will be no quoted percentile and exposure assessment should use the top value in that data set (but if that is a clear outlier, then the next highest value may have been taken). A more detailed analysis of choosing surrogate data from databases is discussed elsewhere in this document.

The 'probability' term in the descriptions that follow indicate just the distribution of detectable and non-detectable amounts in the respective underlying studies.

Great care needs to be taken in modelling reasonable worst cases where there are a number of scenarios undertaken per day - in such situations, probabilistic routines are preferred. None of the models addresses aggregated exposure (that is, exposure resulting from the full range of sources where an active substance might be used), nor exposure through dietary intake. That is also best approached through probabilistic modelling, the detailed description of which is beyond the scope of this report.

Simple databases

Mixing and loading Model 1

User: Professionals at work
Task: Loading quantities around 50 kg
Data source: Dutch model, Agricultural pesticide database
Reference: van Golstein Brouwers et al., Assessment of occupational exposure to pesticides in agriculture Part IV, TNO Report V96, Zeist, NL.

Exposure to the hands is expressed as in-use product being transferred, handling around 50 kg
(liquid density = 1.0 g/ml)

Potential dermal exposure, liquid	90^{th} % value	300 mg / hour
Exposure by inhalation, liquid	90^{th} % value	0.02 mg / hour
Potential dermal exposure, powder	90^{th} % value	2000 mg / hour
Exposure by inhalation, powder	90^{th} % value	15 mg / hour

The model is based on data extracted from the open literature. Better databases for liquid formulations are now available for estimation of exposure during mixing/loading of agricultural pesticides, such as EUROPOEM (model 3).

Mixing and loading Model 2

User: Non-professionals / anyone
Task: Diluting concentrate from 1 litre can with water in bucket (200 ml to 2.5 litres)
Data source: HSL 2001
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure (hands and forearms) expressed as mg concentrate
density assumed at 1.0 g/ml

Water-based fluid concentrate, no foaming		**Solvent-based viscous concentrate**, foaming	
Dispensing and dilution, skin exposure <u>averaged over 4 events</u> for bare hands and forearms			
Probability	80%	Probability	70%
Range	0.33 to 3.2 mg / event	Range	0.3 to 1.7 mg / event
50^{th} % value	1.1 mg / event	50^{th} % value	0.8 mg / event
Worst case	3.2 mg / event	Worst case	1.7 mg / event
Dispensing and dilution, skin exposure <u>worst case single event</u> for bare hands and forearms			
Probability	33%	Probability	26%
Worst case	12.8 mg / event	Worst case	6.7 mg / event

(Subsequent uses of a container increase the probability of container contamination, hence hand contamination).

Mixing and loading Model 3

User: Professionals at work
Task: Loading agricultural pesticides

Data source: EUROPOEM
Reference: BIBRA TNO, Carshalton, UK, 1996.

Exposure expressed as mg a.s./kg a.s. per operation (75th percentile).
(portable equipment and machine reservoir)

Liquid concentrate loading		**Portable reservoir**	**Machine reservoir**
Potential dermal exposure	75^{th} % value	230 mg/kg a.s.	20 mg/kg a.s.
Exposure by inhalation	75^{th} % value	0.1 mg/kg a.s. (95^{th} %)	0.005 mg/kg a.s.

The model is developed for the loading of agricultural pesticides and covers relatively large amounts.

Mixing and loading Model 4

User: Professionals at work
Task: Pouring fluid from container into receiving vessel
Data source: UK POEM model
Reference: Guide 1992, PSD, York, UK

Exposure expressed as ml of in-use product per operation as 75th % value

Container of unspecified design		**Wide-necked container**	
Container volume	Contamination	Container	Contamination
1 litre	0.01 ml	1 litre, D = all	0.01 ml
5 litre	0.2 ml	2 litre, D = all	0.01 ml
10 litre	0.5 ml	5 litre, D = 45 / 63 mm	0.01 ml
20 litre	0.5 ml	10 litre, D = 45 mm 10 litre, D = 63 mm	0.10 ml 0.05 ml
		D = neck diameter	

The model is developed for the loading of agricultural pesticides and covers relatively large amounts.

Mixing and loading Model 5

User: Professionals at work
Task: Pouring from container into receiving vessel
Data source: German model
Reference: Lundehn et al., Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Heft 277, Berlin, Germany

Exposure expressed as mg a.s./kg a.s. per operation
(portable equipment and machine reservoir)

		Portable reservoir	**Machine reservoir**
Potential dermal exposure, liquid	50th % value	205 mg/kg a.s	2.4 mg/kg a.s.
	90th % value	1195 mg/kg a.s	50 mg/kg a.s.
Exposure by inhalation, liquid	50th % value	0.05 mg/kg a.s.	0.001 mg/kg a.s.
	90th % value	0.10 mg/kg a.s.	0.005 mg/kg a.s.
Potential dermal exposure, powder	50th % value	50 mg/kg a.s. (nominal)	6 mg/kg a.s.
	95th % value	-	14.3 mg/kg a.s.
Exposure by inhalation, powder	50th % value	0.8 mg/kg a.s.	0.07 mg/kg a.s.
	95th % value	2.4 mg/kg a.s.	0.55 mg/kg a.s.
Potential dermal exposure -granule	50th % value	21 mg/kg a.s.	2 mg/kg a.s.
	95th % value	122 mg/kg a.s.	5.6 mg/kg a.s.
Exposure by inhalation, granule	50th % value	0.02 mg/kg a.s.	0.008 mg/kg a.s.
	95th % value	0.06 mg/kg a.s.	0.24 mg/kg a.s.

The model is developed for the loading of agricultural pesticides and covers relatively large amounts. Only exposure to the hands is involved.

A better model for liquid formulations is now available (EUROPOEM, model 3).

Mixing and loading Model 6

User: Professionals at work
Task: loading liquid antifoulant into reservoir for airless spray application
Data source: HSE surveys 1995-6, IOM study on PPE, 1996
Reference: EH74/3 (excludes data for other ancillary workers)

Exposure expressed as mg/min in-use product, and *estimate mg a.s. / kg a.s.*

Probability of potential dermal exposure		100%	23 data, 0 data = zero
Range of non-zero values		0.27 to 252 mg/min	*0.96 to 351 mg/kg a.s.*
	50^{th} % value	43 mg/min	*13 mg/kg a.s.*
	75^{th} % value	92 mg/min	*71 mg/kg a.s.*
	95^{th} % value	222 mg/min	*292 mg/kg a.s.*
Probability of clothing penetration		59%	17 data, 7 data =-zero
Range of non-zero values		1% to 28%	-
	50^{th} % value	3%	-
Probability of hand exposure inside gloves		100%	17 data, 0 data = zero
Range of non-zero values		0.003 to 10.8 mg/min	-
	50^{th} % value	0.6 mg/min	-
	75^{th} % value	2.7 mg/min	-
	95^{th} % value	8.2 mg/min	-
Deposition on outside of protective gloves		100%	4 data, 0 data =-zero
Range of non-zero values		7.6 to 30 mg/min	-
	50^{th} % value	25 mg/min	-

Exposure by inhalation, exposure as mg/m^3 in-use product, *estimate* mg/m^3 *a.s.*

Probability of exposure by inhalation		100%	20 data, 7 data = zero
Range of non-zero values		0.04 to 42* mg/m^3	*0.01 to 2.1 mg a.s./*m^3
	50^{th} % value	0.8 mg/m^3	*0.2 mg a.s./*m^3
	75^{th} % value	1.9 mg/m^3	*0.4 mg a.s./*m^3
	95^{th} % value	17 mg/min	*1.4 mg a.s./*m^3

Context of model

Inhalation exposure

For the anti-fouling pot-men, exposure to spray aerosol is intermittent and unusual. Results indicate that the normal range (18 of 19 results) is between 0.2 and 4.0 mg/m^3 of product. One exceptional result (the highest recorded) has been recalculated at 24 mg/m^3 (previously 42 mg/m^3, but closer inspection of the proportion of active material in the paint has caused abatement of this particular result). However, it is considered to be unlikely that even a result of this magnitude would be a true reflection of the personal exposure of a pot-man to aerosol. The individual result showed no elevated potential dermal exposure and associated inhalation of the sprayer was below the level recorded for the pot-man. HSE has judged that, when considered in the context of the other samples taken at the same time, that datum resulted from a minor splash of product depositing on the sampling filter, and should be discounted as an outlier.

Potential dermal exposure
The model is based on assumed concentrations of active substance (usually copper) at the bottom end of the published range. This leads to worst case estimates of deposition rates.

The data have been collected using a seven patch methodology and the results calculated by applying a factor of two to take account of the unexposed areas of clothing where patches are not normally worn. This approach has been proposed as a result of independent research by the Institute of Occupational Medicine.

The model is considered to provide a fairly accurate representation of typical rates of contamination that may be found in a wide range of anti-fouling applications, from small through to very large vessels.

Mixing and loading Model 7

User: Professionals at work
Task: Pouring and pumping liquid, and dumping solids into systems
Reference: Popendorf et al., Am. Ind. Hyg. Ass. J. 56:993-1001, 1995.

Exposure expressed as mg/min and mg/m^3 concentrate.

		Task	
Potential dermal exposure		**Pour liquid**	**Pump liquid**
Probability of exposure		100% (15 data)	93% (14 data, 1 = zero)
	Range	0.002 to 10.4 mg/min	0.001 to 1.76 mg/min
	50th % value	0.04 mg/min	0.12 mg/min
	75th % value	0.10 mg/min	0.60 mg/min
Probability of exposure by inhalation		27% (15 data, 11 = zero)	21% (14 data, 11 = zero)
	Range	0.09 to 0.94 mg/m^3	1.1 to 22 mg/m^3
	50th % value	0.29 mg/m^3	3.9 mg/m^3
Potential dermal exposure		**Weigh / dump solid**	**Place solid**
Probability of exposure		91% (11 data, 1 = zero)	100% (3 data)
	Range	0.008 to 3.05 [a] mg/min	0.02 to 1.35 mg/min
	50th % value	0.27 mg/min	0.08 mg/min
	75th % value	1.15 mg/min	-
Probability of exposure by inhalation		18% (11 data, 9 = zero)	33% (3 data, 2 = zero)
	Range	2.6, 7.2 mg/m^3	- mg/m^3
	50th % value	5.0 mg/m^3	1.0 mg/m^3

a. highest value for weighing / dumping at 56.5 mg/min is an outlier.

Note, these data include an element for hand exposure inside gloves. It is not possible to tease these data out of the data set as presented. Consequently , this model will over-predict.

Task information (potential dermal exposure per task):

Pour: range 0.01 to 73.1, 50th % at 0.65 75th % at 1.74 mg/cycle
Duration range 1 to 78 min, 50th % at 12, 75th % at 22 min/cycle

Pump:		range 0.04 to 30,	50^{th} % at 2.45 75^{th} % at 8.60 mg/cycle
	Duration	range 3 to 51 min,	50^{th} % at 18, 75^{th} % at 32 min/cycle
Dump :		range 0.05 to 833,	50^{th} % at 2.55 75^{th} % at 6.7 mg/cycle
	Duration	range 2 to 70 min,	50^{th} % at 13, 75^{th} % at 33 min/cycle
Place:		range 0.0.04 to 9.0,	50^{th} % at 0.68 mg/cycle
	Duration	range 0.5 to 12 min,	50^{th} % at 2 min/cycle

The same data set can be re-expressed in terms of biocidal product type (next page)

Model 7 (re-expressed)

Exposure expressed as mg/min and mg/m^3concentrate.

		Product type	
Potential dermal exposure		**In-can preservative**	**Wood, paper & pulp**
Probability of exposure		87% (15 data, 2 = zero)	100% (7 data)
	Range	0.008 to 3.05 [a] mg/min	0.001 to 1.38 mg/min
	50^{th} % value	0.10 mg/min	0.17 mg/min
	75^{th} % value	0.43 mg/min	0.37 mg/min
Probability of exposure by inhalation		13% (15 data, 13 = zero)	29% (7 data, 5 = zero)
	Range	2.6, 7.2 mg/m^3	1.1, 3.9 mg/m^3
	50^{th} % value	5.0 mg/m^3	2.5 mg/m^3
Potential dermal exposure		**Cooling water**	**Metalworking fluid**
Probability of exposure		91% (11 data, 1 = zero)	100% (10 data)
	Range	0.03 to 10.5 mg/min	0.002 to 1.35 mg/min
	50^{th} % value	0.11 mg/min	0.04 mg/min
	75^{th} % value	0.74 mg/min	0.10 mg/min
Probability of exposure by inhalation		27% (11 data, 8 = zero)	30% (10 data, 7 = zero)
	Range	0.16 to 0.94 [b] mg/m^3	0.09 to 1.0 mg/m^3
	50^{th} % value	0.94 mg/m^3	0.42 mg/m^3

a. highest value at 56.5 mg/min b. highest value at 22. (Outliers)

The present paper describes a series of measurements for pouring and pumping liquid and solid (powder or flakes) biocidal products. The data have been recalculated by HSE from the data described in the paper. There is a large variation in the packages and scenario's involved and the amounts handled.

The data indicated above should just guide the exposure assessor. The most relevant data for the scenario under consideration should be taken from the paper. It must be emphasised that the exposures should only be used as indicative values in view of the small database.

Spraying Model 1

User: Professionals, principally
Task: Mixing and loading liquids and powders in compression sprayers or dusting applicators, and applying at 1 to 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards. Scenario: low-pressure insecticide application.
Data source: HSE surveys 1992-3, IOM study on PPE, 1996
Reference: EH74/3

Exposure expressed as mg/min in-use product, and *estimate mg a.s. / kg a.s.*

Probability of potential dermal exposure		84%	102 data, 18 data = zero
Range of non-zero values		0.63 to 692 mg/min	*9.4 to 12500 mg/kg a.s.*
	50^{th} % value	24.5 mg/min	*164 mg/kg a.s.*
	75^{th} % value	92 mg/min	*462 mg/kg a.s.*
	95^{th} % value	251 mg/min	*3280 mg/kg a.s.*
Probability of clothing penetration		41%	61 data, 36 data =-zero
Range of non-zero values		2% to 78%	-
	50^{th} % value	44%	-
Probability of hand exposure inside gloves		50%	71 data, 35 data = zero
Range of non-zero values		0.08 to 120 mg/min	-
	50^{th} % value	1.3 mg/min	-
	75^{th} % value	10.7	-
	95^{th} % value	39.4	-
Deposition on outside of protective gloves		100%	5 data, 0 data =-zero
Range of non-zero values		12 to 181 mg/min	-
	50^{th} % value	31 mg/min	-

Exposure by inhalation, exposure as mg/m^3 in-use product, *estimate* mg/m^3 *a.s.*

Probability of exposure by inhalation		28%	97 data, 70 data = zero
Range of non-zero values		0.2 to 631 mg/m^3	*0.01 to 2.1 mg a.s./*m^3
	50^{th} % value	104 mg/m^3	*0.2 mg a.s./*m^3
	75^{th} % value	130 mg/m^3	*0.4 mg a.s./*m^3
	worst case value	405 mg/m^3	*1.4 mg a.s./*m^3

(Professionals often use disposable gloves for public hygiene insecticide applications).

Context of model

The above model relates in particular to products applied in public hygiene areas (e.g. schools, restaurants, swimming pools, hospitals, nursing homes). In the domestic setting they are used on insect nests, both indoors and out, on indoor surfaces, in cracks and crevices, on soft furnishings, as space sprays, and in clothing storage. Uses in work environments include food factories and on waste tips. Products are mostly used in a dispersive manner to knock down insects, or leave residual active substance to eradicate populations of insects or prevent reinfestation. Fumigation is a separate and specialised activity.

The work is peripatetic, with lone working most common. Typically, less than two hours a day is spent using pesticides, with some applications being seasonal (e.g. wasps in midsummer) and some year-round (e.g. bakeries).

The tasks for which HSE hold data are mixing and loading of liquids and powders, and spraying by compression sprayer (i.e. at 1-3 bar). HSE also holds data for application of powders. There is detailed information about the particular exposure scenario, but very often the data sets are too sparse to draw satisfactory conclusions about specific tasks, e.g. differentiating between the exposure at blanket, band and pin-stream spraying.

The quantities used per treatment for liquid insecticide spraying ranged from 1 to 20 litres, with a median quantity of 5 litres of fluid. Concentrations of active substance ranged from 0.03 to 1% w/w, usually using water as the solvent or dispersing liquid (71 data). For insecticidal dusting, operators used between 60 - 2200g of dusting powders at nominal in-use concentrations between 0.5 - 1.0% active substance (15 data).

The model represents the data arising from 100 separate studies of pest control operators using public hygiene insecticides. The jobs are mainly application through the use of fine sprays emanating from low pressure compression sprayers. Other results relate to application of dusts. Public hygiene insecticide application is often of short duration (a matter of minutes) and the use of any one particular product or active substance may also be infrequent.

Two HSE projects (permethrin and bendiocarb *technical development surveys , TDS*) and part of a contract project (validation of surface sampling techniques) by the Institute of Occupational Medicine, contributed to the data-set. The data cover similar ranges when translated to a rate of contamination (mg diluted formulation per minute of application).

The results apply to both dusting and spraying, indoors and outdoors, whether in an overhead or downward direction, and include a contribution to exposure from mixing and loading operations which ensure the spraying aspect of the model over-predicts deposition to a marginal degree.

This public hygiene insecticide model may also be termed a low-pressure spraying model as it may apply to many operations where the emission profile is similar to that during application of dilute non-agricultural pesticide products. For instance, it could be applied to

any operation involving a hand-held compression sprayer or even an industrial process where there is a low-level fine spray emission.

There may be some uncertainty over the in-use concentrations used to establish this model but the calculations have been made on the basis of operators applying products at preferred concentrations and according to prescribed conditions of use.

Spraying Model 2

User: Professionals, principally
Task: Mixing and loading liquids in reservoir for powered spray application at 4 to 7 bar pressure as a coarse or medium spray, indoors, overhead and downwards. Scenario - medium pressure spray applications, e.g. for remedial biocides.
Data source: HSE survey 1988, BPCA 1990, ECoS 1996, IOM study on PPE, 1996
Reference: EH74/3 and Ann. Occ. Hyg. 42(3):159-165, 1998

Exposure expressed as mg/min in-use product, and *estimate mg a.s. / kg a.s.*

Probability of potential dermal exposure		100%	55 data, 0 data = zero
Range of non-zero values		2.3 to 36300 mg/min	*0.6 to 2360 mg/kg a.s.*
	50^{th} % value	45 mg/min	*63 mg/kg a.s.*
	75^{th} % value	222 mg/min	*278 mg/kg a.s.*
	95^{th} % value	2100 mg/min	*2090 mg/kg a.s.*
Probability of clothing penetration		71%	51 data, 15 data =-zero
Range of non-zero values		1% to 85%	-
	50^{th} % value	6%	-
Probability of hand exposure inside gloves		90%	50 data, 5 data = zero
Range of non-zero values		0.11 to 358 mg/min	-
	50^{th} % value	2.4 mg/min	-
	75^{th} % value	7.8 mg/min	-
	95^{th} % value	191 mg/min	-
Deposition on outside of protective gloves		100%	6 data, 0 data =-zero
Range of non-zero values		13.9 to 273 mg/min	-
	50^{th} % value	35 mg/min	-
Probability of feet exposure inside shoes		94%	17 data, 1 data = zero
Range of non-zero values		0.15 to 260 mg/min	-
	50^{th} % value	2.04 mg/min	-
	75^{th} % value	5.4 mg/min	-

Exposure by inhalation, exposure expressed as mg/m^3 in-use product, *estimate mg/m^3 a.s.*

Probability of exposure by inhalation		84%	61 data, 10 data = zero
Range of non-zero values		0.98 to 813 mg/m^3	*0.01 to 21 mg a.s./m^3*
	50th % value	20 mg/m^3	*0.08 mg a.s./m^3*
	75th % value	76 mg/m^3	*0.25 mg a.s./m^3*
	95th % value	198 mg/m^3 *	*5.4 mg a.s./ m^3*

* 95th % inhaled omits two highest data at >10x higher than next highest data point

Context of model

Application of remedial biocides in the range of industrial, recreational, and residential settings, and in the remediation of old buildings prior to their conversion to domestic premises, form the basis for this model. These products are applied to interior and exterior structural timber, masonry and surfaces, to wooden articles (fences, sheds, seating) and to exterior monuments, pathways and stairways.

Products may be applied by spraying, as a surface wash using a brush, or by a variety of manual methods. Pastes, for instance, may be applied by brush, trowel, caulking tool, palette knife, or by gloved hand. Monument, exterior brickwork and path cleaners are either sprayed or washed, with vigorous agitation using a scrubbing brush or stiff broom.

Although products may be applied using a wide range of techniques, the HSE work has concentrated on those areas where exposure has been subjectively assessed to be highest, i.e. during spray application. Other data have been collected which address some of the other methods of application, such as application of timber treatment fluids by brushing, but these data are not represented here within this model.

Four studies contributed to the data set - an early HSE study, a sponsored study by Tilt *et al* (both on remedial timber treatment), a contract study (surface biocide and remedial timber) by ECoS Environmental and a contract project (validation of surface sampling techniques) by IOM. The data are reasonably coherent - they cover similar ranges when transformed as a contamination rate *(mg diluted formulation per minute application).*

Some data for gloves have been omitted because the experiment determined what fell on the outside of gloves, not what had penetrated. The early HSE study data for surface deposition was omitted because it reported only what had penetrated.

The findings from over 50 separate investigations of operator exposure during the application of remedial treatment fluids are used. Most in-use solutions were water based and studies investigated treatment of timber and masonry. Concentrations of concentrate and in-use fluid were provided through chemical analysis. Typically, the work entailed much initial preparation to clear areas prior to treatment and to expose masonry and timbers - it was estimated that this phase could account for 50-90% of the time on site. Mixing, loading, and application are done as a single scenario. Solvent or water-based treatment products are applied, through an electrical- or fuel-driven pump-pressurised sprayer, supplied from a reservoir.

The top end of the model represents contamination rates arising from use of high pressure hosing of large areas and the operators became visibly drenched over a period of time. It is difficult to imagine higher rates of contamination arising from other processes.

Spraying Model 3

User: Professionals
Task: Airless spraying viscous solvent-based liquids at >100 bar pressure, overhead and forwards. Scenario - high-pressure spraying of antifoulants.
Data source: HSE surveys 1993, 1996, IOM study on PPE, 1996
Reference: EH74/3

Exposure expressed as mg/min in-use product, and *estimate mg a.s. / kg a.s.*

Probability of potential dermal exposure		100%	27 data, 0 data = zero
Range of non-zero values		0.88 to 1240 mg/min	*0.63 to 1140 mg/kg a.s.*
	50^{th} % value	103 mg/min	*87 mg/kg a.s.*
	75^{th} % value	250 mg/min	*177 mg/kg a.s.*
	95^{th} % value	745 mg/min	*984 mg/kg a.s.*
Probability of clothing penetration		93%	14 data, 1data =-zero
Range of non-zero values		1% to 41%	-
	50^{th} % value	5%	-
Probability of hand exposure inside gloves		100%	19 data, 0 data = zero
Range of non-zero values		0.003 to 4.22 mg/min	-
	50^{th} % value	1.0 mg/min	-
	75^{th} % value	2.04 mg/min	-
	95^{th} % value	3.95 mg/min	-
Deposition on outside of protective gloves		100%	6 data, 0 data =-zero
Range of non-zero values		21.7 to 119 mg/min	-
	50^{th} % value	76 mg/min	-

Exposure by inhalation, exposure expressed as mg/m^3 in-use product, *estimate mg/m^3 a.s.*

Probability of exposure by inhalation		91%	21 data, 2 data = zero
Range of non-zero values		0.04 to 79.4 mg/m^3	*0.01 to 16.2 mg a.s./m^3*
	50^{th} % value	6.6 mg/m^3	*0.92 mg a.s./m^3*
	75^{th} % value	17.3 mg/m^3	*2.8 mg a.s./m^3*
	95^{th} % value	64.6 mg/m^3 *	*6.2 mg a.s./m^3*

Context of model

High pressure airless spraying of paints has been studied to assist with the assessment of exposure at operations such as application of antifouling paints to ships. The data are equally applicable to many high-pressure paint spraying operations. The limited available data have arisen from three main sources. 40 exposure data were provided by 9 surveys in a 1994 HSE study. 20 exposure data were provided by 5 surveys in a 1996 HSE study and 10 exposure data were produced from 4 surveys in a 1996 IOM study investigating the validity of surface sampling techniques.

Painting tasks usually involve a sprayer and ancillary workers who may tend the paint reservoir and others who may assist by managing the trailing paint lines and moving the platform from which the painter operates. All groups of workers can expect exposure and it has been possible to differentiate the distributions for each category. Two sets of data are presented, one for spray painting and the second related to all ancillary tasks other than paint spraying.

Antifouling paint application

Professionals apply antifoulant paint to vessels by airless spraying, by roller and brush. Application of antifoulants is usually only one part of a general overhaul and refitting of a vessel. Professional painters work year-round but applying antifouling is intermittent. Once dry-docked, the vessel is cleaned, usually through the use of high-pressure water-jets (for self-polishing coatings) or with abrasive grit (for erodable coatings). Bare metal surfaces are prepared with other coatings such as corrosion inhibitor before application of an antifouling topcoat. The antifouling is applied `using airless spray techniques at up to 100 bar.

The frequency of exposure to any particular ingredient is very important - painters rarely apply antifouling coatings more often than one or two days in a month - and even then the active substances may not be the same in each case.

During application of antifoulant HSE studies have indicated paint usage to range from 25 to over 800 litres during a spray session. The vessel surface areas ranged between 600 to 4000m^2. The duration of the work ranged from 40 to 360 minutes (median about 180 minutes).

Most of the contamination arises from impingement of the paint aerosol with the operator, but a contribution from contact with painted surfaces will almost always occur. Environmental conditions, such as wind speed and turbulence around the vessel being painted are important variables affecting exposure. Other factors which impact on the measured levels of contamination are the proximity to the coated surface and the confinement of the job. Exposures will always be maximised if the painter has to work in a confined area such as in a well beneath the bottom of a vessel.

Spraying Model 4

User: Professionals
Task: Airless spraying viscous solvent-based liquids at >100 bar pressure both inside and outside a container.
Reference: Brouwer et al., Ann Occ. Hyg. 44(7):543-549, 2000

Exposure expressed as Uvitex at 39 to 109 mg/litre, mean 64.8 mg/litre (mass concentration 0.0074% mg Uvitex OB/kg paint)

Duration 4 to 21 min		**Spray activity**	
Potential dermal exposure (coverall/body)		**Spray inside**	**Spray outside**
Probability of exposure		100% (5 data)	100% (21 data)
Arithmetic mean		0.558 mg	0.144 mg
Standard deviation		0.294 mg	0.127 mg
Actual dermal exposure (uncovered/ hands and face)			
Arithmetic mean		0.011 mg	0.007 mg
Standard deviation		0.012 mg	0.013 mg

Percentile estimates as in-use spray, assuming 65 mg/litre:

Spray inside 50th % at 7540 mg/min, 75th % at 10600 mg/min, 95th % at 17500 mg/min
Spray outside 50th % at 1690 mg/min, 75th % at 2770 mg/min, 95th % at 5540 mg/min
Penetration: no data available

Deposition pattern:
Head - 2% Arms - 9% Torso - 13% Legs - 72% (Hands - 4%)

For comments see after model 5.

Spraying Model 5

Airless pressure spraying model

User: Professionals
Task: Airless spraying viscous solvent-based liquids at >100 bar.
Reference: Brouwer et al., Ann Occ. Hyg. 45(1):15-23, 2001

This model is available as an Excel spreadsheet "spray paint model"

Models 4 and 5 Potential dermal exposure during airless spray painting

Context of the models
The data for these models were generated in a field study during airless spraying a large container. All conditions were similar to field practice, however the paint was colourless to enable detection of a fluorescent tracer that was added to the paint at a concentration of appr. 65 mg/L. Model 4 consists of a dataset shops of 21 datapoints collected in three different paint and includes two repeated measurements for10 spray painters and one single data point for one spray painter) for airless spraying the outside of the container, and 5 datapoints during spraying the inside of the container. All data reflect exposure (mg tracer) resulting from actual spraying, *i.e.* a single spray task, where the duration of exposure is similar to the actual duration of the emission of paint from the spray gun.

The amount of tracer (Uvitex OB) that was deposited onto a Tyvek coverall or the uncovered skin (hands and face) was quantified by a image acquisition and processing technique (VITAE).

Model 5 predicts potential whole body dermal exposure (mg) of non-volatile substances in paint during actual spraying. It is a structured approach of the mass transport processes that are involved in the processes of generating aerosols through the deposition of aerosols onto the spray painters body. The model uses several defaults for key parameters, *e.g.* immission and spray deposition efficiency, and assigned vales for factors which are considered to modify deposition, *e.g.* object structure or size, ventilation etc.
The model predicts potential whole body exposure based on actual data of the concentration of non-volatile substances in the paint, but does not generate a distribution of the exposure over the body.

The model has not been validated, however the output of the model for airless spray painting has been compared with the data set of model 4. The predicted exposure correlated reasonably well with the measured exposure (R_{SP} = 0.82). This was remarkably better compared to the correlation between one single parameter of the model (amount of paint sprayed) and measured exposure (R_{SP} = 0.15).

Both the dataset ‘model 4’ (for airless spray painting) and model 5 (all kinds of spray painting) can be used as a first Tier exposure assessment of potential body exposure of non-volatile substances. The percentage of non-volatile substances in the paint for extrapolations (‘model 4’), since the date are based on a concentration of 0.0074% tracer in paint. For use of model 5 the spray rate should be known, in addition to the percentage of non-volatile substances in the paint, and the assigned values for all other parameters can be kept 1. If more

information on these parameters is available the estimate may be improved, as indicated by the improved correlation between measured and predicted exposure.

The advantages of model/dataset 4 and 5 the relatively easiness of use and the limited information that is needed for a first tier exposure assessment. The application of both ‘models ‘ is limited to estimate dermal exposure to non-volatile substances that were generated as part of mixed-phase aerosols and were deposited on the painters body during actual spraying. Other mass transport processes that may result in additional exposure, *e.g.* transfer from contaminated surfaces or direct contact with paint, are not included. Model 5 is not validated.

Models 4 and 5 predict deposition of non volatile substances of paint onto paint sprayers body, face and hands during actual spraying. Since the data generated by model 4 are based on very low mass concentrations of a tracer in paint (<0.01%) very large extrapolation factors, resulting in inaccurate estimates of predicted exposure to biocides. Model 5 has not been validated.

Spraying Model 6

User: Professionals
Task: Disinfection by spraying surfaces at 140 bar – animal husbandry (pig and poultry units). Duration 3 to 126 min (median at 9 min).
No mixing or loading.
Reference: Popendorf and Selim, Am. Ind. Hyg. Ass. J. 56:1111-1120, 1995

Expressed as mg/cycle and mg/cycle in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		100%	10 data, 0 = zero
Range of non-zero values		4.28 to 317 mg/min	
	50^{th} % value	21.4 mg/min	
	75^{th} % value	90 mg/min	
		Task-based data	
Range of non-zero values		120 to 1800 mg/task	
	50^{th} % value	442 mg/task	
	75^{th} % value	1100 mg/task	

No data for hand exposure.

The present paper describes a series of measurements for high-pressure spraying of ceilings, walls and floors of empty livestock production buildings for swine or poultry. The data have been recalculated by HSE from the data described in the paper.

The data indicated above should just guide the exposure assessor. It must be emphasised that the exposures should only be used as indicative values in view of the small database and the possible mismatch between techniques and geometry of the buildings in the USA and Europe.

Spraying Model 7

User: Professionals
Task: Disinfection by spraying surfaces at up to 14 bar or with hand-held compression sprayer (up to 3 bar) – carpets, walls, ceiling voids. Duration 17 to 141 min (median at 47 min). No mixing or loading.
Reference: Popendorf and Selim, Am. Ind. Hyg. Ass. J. 56:1111-1120, 1995

Expressed as mg/cycle and mg/task in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		100%	8 data, 0 = zero
Range of non-zero values		4.63 to 200 mg/min	
	50th % value	48.0 mg/min	
	75th % value	100 mg/min	
		Task-based data	
Range of non-zero values		80 to 23000 mg/task	
	50th % value	2150 mg/task	
	75th % value	9500 mg/task	

No data for hand exposure.

The present paper describes a series of measurements for low-pressure spraying of carpets, walls and the area above ceiling tiles, in institutional, commercial and residential settings. The data have been recalculated by HSE from the data described in the paper.

The data indicated above should just guide the exposure assessor. It must be emphasised that the exposures should only be used as indicative values in view of the small database and the possible mismatch between techniques and geometry of the buildings in the USA and Europe.

Spraying Model 8

User: Professionals
Task: Using aerosol spray can for disinfecting dental chairs, plumbing fixtures, walls. Duration 1 to 43 min (median at 17 min). No mixing or loading.
Reference: Popendorf and Selim, Am. Ind. Hyg. Ass. J. 56:1111-1120, 1995

Expressed as mg/cycle and mg/task in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		63%	8 data, 3 = zero
Range of non-zero values		3.43 to 40.6 mg/min	
	50^{th} % value	5.55 mg/min	
	75^{th} % value	6.33 mg/min	
		Task-based data	
Range of non-zero values		7 to 780 mg/task	
	50^{th} % value	12 mg/task	
	75^{th} % value	90 mg/task	

No data for hand exposure.

The data have been recalculated by HSE from the data described in the paper.

The data indicated above should just guide the exposure assessor. It must be emphasised that the exposures should only be used as indicative values in view of the small database and the possible mismatch between techniques and geometry of the buildings in the USA and Europe.

Spraying Model 9

User: Professionals

Task: Disinfection of slaughterhouses and meat processing industry by spraying or foaming.

Reference: Preller and Schipper, respiratory and dermal exposure to disinfectants: a study in slaughterhouses and the meat producing industry, TNO Report V98.1306, Zeist, Netherlands.

The authors have measured exposures during mixing and loading, as well as application. The mixing and loading was done manually or by using automated dosing systems. The compound measured was alkyldimethyl-benzylammonium chloride. The total duration of the mixing, loading and applications was between 14 and 108 minutes, with a median of 32 minutes. The treated area (up- and downward spraying) varied between 125 and 3650 m^3. The median was 375 m^3. The study involved 15 workers in 10 companies.

The range of inhalation exposure was 11.4-424 $\mu g/m^3$, with a GM of 53.6 $\mu g/m^3$.

The potential body exposure was expressed in various units, considering with and without hands, as well as measurements underneath gloves.

For modelling purposes, the authors suggest a 90th percentile. For inhalation exposure this amounts to 2 ml spray/m3. The potential dermal exposure amounts to 800 ml spray/hr (including hands).

The data can be used in a first tier exposure assessment. The used techniques are not differentiated in the above numbers and may therefore be used for a mixture of mixing/loading and spraying techniques.

Spraying Model 10

User: Professionals

Task: Low-pressure spraying by pest control operators

Reference: De Cock and Van Drooge, Field study on occupational exposure during spraying of biocidal products by pest control operators using deltamethrin and cyfluthrin, TNO Report V3806, 2001, Zeist, Netherlands.

The spraying techniques used were manual spraying (< 3 bar) and spray can, with the inclusion of the preparation part (mixing/loading). Both techniques were used for up- and downward spraying and used indoors and outdoors. A total of sixteen workers was considered in this study.

The authors propose to use the 90th-percentile of their exposure data for risk assessment purposes. The total duration varied between 30 and 159 minutes, with an average of 81 minutes.

For inhalation exposure, the spread in the data was from 0.3-342 µg/m^3, with a 90th-percentile of 65 µg/m^3.

The potential dermal exposure to the body alone varied from 50-5900 mg/kg a.s., with a 90th-percentile of 1200 mg/kg a.s. The potential hand exposure varied from 21-10100 mg/kg a.s., with a 90th-percentile of 4700 mg/kg.

Spraying Model 11 (compound-specific)

User: Professionals
Task: Disinfection by foam coating surfaces - food production.
No mixing or loading.
Reference: Hygiene et Securite de Travail 1999 term 3, 176, 5-9

Estimated **exposures by inhalation**:

Chlorine:
Range 0 to 1.33 mg/m^3, 50th % at 0.1 mg/m^3, 75th % at 0.16 mg/m^3, 95th % at 0.65 mg/m^3

Nitrogen trichloride
Range 0 to 1.96 mg/m^3, 50th % at 0.06 mg/m^3, 75th % at 0.15 mg/m^3, 95th % at 0.80 mg/m^3

Formaldehyde:
Range 0.06 to 0.62 mg/m^3, 50th % at 0.3 mg/m^3, 75th % at 0.4mg/m^3

Glutaraldehyde;
Range 0.01 to 0.25 mg/m^3, 50th % at 0.05 mg/m^3, 75th % at 0.10 mg/m^3

The applied foam contained only a small %-age of active substance. The exposure is linked to spray model 2 (medium pressure, 4-7 bar coarse spraying droplets).

Handling Model 1

User: Professionals
Task: Industrial wood preservation - intermittent manual handling of water-wet or solvent-damp wood and associated equipment.
Data source: HSE surveys 1989, 1993, 1996, AEAT survey 1997-8
Reference: EH74/3, and Ann. Occ. Hyg. (43):543-555, 1999

Expressed as mg/cycle in-use product at assumed density = 1.0 g/ml

Process		**Water-based**	**Solvent-based**
Probability of potential dermal exposure		100% (45 data)	89% (19 data, 2 = zero)
Range of non-zero values		63.6 to 132000 mg/cycle	7 to 450 mg/cycle
	50^{th} % value	3990 mg/cycle	95 mg/cycle
	75^{th} % value	8570 mg/cycle	158 mg/cycle
	95^{th} % value	32200 mg/cycle	450 mg/cycle
Probability of clothing penetration		98% (43 data, 1 = zero)	60% (15 data, 6 =- zero
Range of non-zero values		1% to 100%	1% to 100%
	50^{th} % value	12%	21%
Probability of hand exposure inside gloves		100% (43 data)	91% (23 data, 2 = zero)
Range of non-zero values		42 to 7570 mg/cycle	0.5 to 1330 mg/cycle-
	50^{th} % value	783 mg/cycle	11.6 mg/cycle
	75^{th} % value	1080 mg/cycle	88.8 mg/cycle
	95^{th} % value	2410 mg/cycle	260 mg/cycle
Probability of hand exposure - new gloves		100% (29 data)	64% (14 data, 5 = zero)
Range of non-zero values		10.2 to 2330 mg/cycle	0.5 to 106 mg/cycle
	50^{th} % value	135 mg/cycle	23.6 mg/cycle
Probability of feet exposure inside shoes		88% (43 data, 6 = zero)	38% (23 data, 15 = zero)
Range of non-zero values		7.3 to 2670 mg/cycle	1.01 to 18.7 mg/cycle
	50^{th} % value	125 mg/cycle	2.7 mg/cycle
	75^{th} % value	501 mg/cycle	2.9 mg/cycle

Exposure by inhalation, exposure expressed as mg/m^3 in-use product

Probability of exposure by inhalation		73% (49 data, 17 = zero)	21% (24 data,19 = zero)
Range of non-zero values		0.02 to 7.96 mg/m^3	0.25 to 0.75 mg/m^3
	50^{th} % value	1.0 mg/m^3	0.6 mg/m^3
	75^{th} % value	1.9 mg/m^3	-
	95^{th} % value	5.5 mg/m^3 *	-

(vacuum-pressure - water based products - typical cycle time 180 min:
double-vacuum process - solvent or water based products - typical cycle time 60 min)

(continued)

The above values can be re-expressed through the metric "mg/min" as follows:

Water-based vacuum pressure process (27 data)

	Range	50^{th} %	GM	GSD
Potential dermal exposure:	6.52 to 99.4 mg/min,	25.7	26	2.06
Hands inside gloves	0.11 to 15.3 mg/min	2.76	2.19	3.06
Feet inside shoes	0.05 to 6.54 mg/min	0.51	0.53	3.88

Water-based double vacuum process (7 data)

Potential dermal exposure:	0.67 to 117 mg/min	46.9	16.7	7.69
Hands inside gloves	0.24 to 80.2 mg/min	3.24	3.29	10.2
Feet inside shoes	0.19 mg/min			

Solvent-based double vacuum process (11 data)

Potential dermal exposure:	0.06 to 6.41 mg/min	2.14	0.88	5.69
Hands inside gloves	0.003 to 8.0 mg/min	0.19	0.18	8.37
Feet inside shoes	0.02 to 0.04 mg/min	0.03		

Context of the models

In all cases samples of the in-use fluid were analysed to allow for derivation of the associated rates of contamination.

Timber is treated industrially to protect it against insect and fungal attack when in use. Typically timber will be treated with either water- or solvent-based formulations. Standard methods are used, typically complying with British Standards, BS 4072, BS 5268 part 5, BS 5589, and BS 5707. Usually timber is treated in sealed treatment vessels and the job entails a cycle of loading, waiting, unloading and removal of treated timber to storage. Dermal contamination occurs through direct contact with the surface of treated timber and through contact with ancillary equipment and contaminated process plant. Dermal exposure may also arise from the spread of contamination into areas such as control rooms and from secondary sources such as previously contaminated overalls and gloves.

Traditionally, the water-based formulations have been mixtures of copper, chromium and arsenic compounds (commonly referred to as CCA), sometimes with the addition of organic chemicals to provide a degree of early protection against sap stain fungi. In recent years some water-based formulations have foresaken CCA and incorporated synthetic organic biocidal substances as the main active ingredient. There are a variety of modes of action and ways in which substances migrate through, and leach out of, the timber. Water-based processes usually tend to enhance penetration of the timber by application of pressure (10 to 14 Bar) in the treatment vessel. The treatment cycle, which may take several hours, inevitably results in the treated timber being removed from the vessel in a wet state, sometimes with small pools of treatment fluid being evident.

Solvent-based processes appear similar to water-based processes to the casual observer. After loading and sealing of the treatment vessel, the process involves the application of vacuum to the timber, addition of the treatment fluid for a pre-set time at around atmospheric pressure, followed by draining of the fluid and final application of vacuum to remove much of the available solvent from surfaces. The vessel is reopened, timber removed and placed in a suitable covered store. The timber tends be touch dry but there may be small pools of liquid. The timber slowly releases residual solvent to atmosphere during the period of storage.

As may be seen from the data sets illustrated below the profiles of exposure resulting from the two processes are rather different. In both cases primary exposure to timber preservatives in industrial pre-treatment is through dislodging residues from contaminated surfaces, with a small contribution to exposure from inhalation. HSE data have been gathered from 4 separate studies involving 56 timber treatment sites around the UK between spring 1996 and spring 1998.

Water-based timber treatment

CCA timber treatment operators may carry out 2-3 cycles of treatment in any day. The workload is variable, being seasonal and demand driven. Results may be presented as ***rates of contamination per cycle*** or as ***rates of contamination per minute*** to allow comparison with other models.

Rates of contamination per cycle have been used to present the results. Water-based treatments average around 3 hours, but some accelerated fixation methods may take longer - indicating fewer treatments per day. The exposure may be best described as intermittent contact with wet objects. Exposure appears to be a function of wetness.

The values for *penetration of gloves* need to be interpreted with caution when used in risk assessment. Hand exposure is dependent on a number of contributory elements. Highest exposures will be seen when inappropriate gloves are used in an inappropriate way, where the barrier (if there is any) has been compromised and when exchange for new ones is infrequent. Much of the exposure may result from pre-existing contamination. Proportionately much lower levels of exposure are seen where new gloves are used and careful hygiene practices are followed. The timber treatment data provide some insight into the way gloves may act as a potential source of exposure.

Handling Model 2

User: Professionals
Task: installing fish cages using lifting equipment and handling, nets damp with sticky product.
Data source: HSE survey 2000
Reference: JS2002033, HSE report

Expressed as mg/min in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		100%	9 data, 0 data = zero
Range of non-zero values		3.34 to 56.9 mg/min	
	50^{th} % value	6.43 mg/min	
	75^{th} % value	7.55 mg/min	
Probability of hand exposure inside gloves		89%	9 data, 1 data = zero
Range of non-zero values		0.08 to 0.50 mg/min	-
	50^{th} % value	0.19 mg/min	-
	75^{th} % value	0.21 mg/min	-
Probability of feet exposure inside shoes		50%	6 data, 3 data = zero
Range of non-zero values		0.002 to 0.03 mg/min	-
	50^{th} % value	0.01	

Context of model

The data, from which the above model derive, were collected as part of a HSE sponsored survey of the major treaters and users of nets in the UK. The results reflect the true nature of the net deployment activity – an intermittent handling of treated nets at various stages of dryness. The work includes semi-automated handling of the nets during the process of reconstructing the cages around fish farms. The model is very specific to that activity and thought to be a reasonable predictor of rates of contamination during the task.

In all cases the in-use concentration of fluids were evaluated through chemical analysis.

Handling Model 3

User: Professionals
Task: Handling wood - gluing with phenol-formaldehyde resin
Reference: Mäkinen et al., Int. Arch. Occ. Environ. Health (72):309-314, 1999

Expressed as mg/min in-use product at assumed density = 1.0 g/ml and 0.3% free phenol

Probability of potential dermal exposure		100%	
	Range	1.71 to 14.8 mg/min	
	mean value	5.67 mg/min	
Probability of hand exposure inside gloves		100%	
Range of non-zero values		up to 0.71 mg/min	
	mean value	0.23 mg/min	

The occupational hygiene data are limited with only a few measurements. Standard deviation is very high. These single cases are difficult to generalise. The model is suitable only in limited cases for very similar agents (biocides with same viscosity) and the same kind of processes. For these particular processes studied, the measurements performed are representative, no other applications could be found.

Handling Model 4

User: Professionals
Task: Handling synthetic mineral fibre filament spray coated with size, and handling winding reels
Reference: Mäittälä et al., Int Arch Occ. Environ. Health (72):539-545, 1999

Expressed as 3-gycidoxypropyltrimethylsilane active substance

		Forming	**Winding**
Probability of potential dermal exposure		69% (5 data = zero)	86% (1 data = zero)
	Range	5.33 to 176 mg/min	7.67 to 19 mg/min
	50^{th} % value	40.3 mg/min	13.3 mg/min
	75^{th} % value	41.3 mg/min	15.3 mg/min
Probability of hand exposure inside gloves		100% (8 data)	100% (6 data)
Range of non-zero values		10.2 to 38.5 mg/min	18.8 to 44.8 mg/min
	50^{th} % value	24.2 mg/min	28.3 mg/min
	75^{th} % value	29.7 mg/min	38.8 mg/min

There is no data as to the quantity of size on the coated filament (bulk analysis).

The occupational hygiene data are limited with only a few measurements. Standard deviation is very high. These single cases are difficult to generalise. The model is suitable only in limited cases for very similar agents (biocides with same viscosity) and the same kind of processes. For these particular processes studied, the measurements performed are representative, no other applications could be found.

Handling Model 5

User: Professionals
Task: Embalming
Reference: University of Aberdeen report and
Bennett et al., Am. Ind. Hyg. Ass. J. (57):599-609, 1996

Expressed as inhaled formaldehyde

Duration 50 to 92 min, median 65 min.
Exposure by inhalation: Range 0.37 to 3.02 ppm formaldehyde, 50^{th} % at 1.37 ppm
University of Aberdeen

TWA formaldehyde, 60-100 minute procedure with all exposure in second half:
Exposure 50^{th} % at 2.3 ppm, 75^{th} % at 3.9 ppm, 95^{th} % at 5.5 ppm.

This ‘model’ can only be used for estimation of exposure to formaldehyde.

Dipping Model 1

User: Professionals
Task: Dipping wooden articles (fences, window frames) in tanks and coating with fluid by pouring and scrubbing.
Data source: HSE survey 1999
Reference: 3830 / R51.169 HSE report

Expressed as mg/min in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		100%	5 data, 0 data = zero
Range of non-zero values		6.26 to 178 [a] mg/min	
	50th % value	16.7 mg/min	
	75th % value	178 mg/min	
Probability of hand exposure inside gloves		80%	5 data, 1 data = zero
Range of non-zero values		1.12 to 25.7 mg/min	-
	50th % value	7.56 mg/min	-
	75th % value	12.7 mg/min	-
Probability of feet exposure inside shoes		80%	5 data, 1 data = zero
Range of non-zero values		0.10 to 25.8 mg/min	-
	50th % value	2.57 mg/min	-
	75th % value	4.87 mg/min	-

a. highest data point at 2780 is an outlier.

Exposure by inhalation, exposure expressed as mg/m^3 in-use product

Probability of exposure by inhalation	0%	5 data, 5 data = zero
Range of non-zero values	-	

Context of model

The data for this model were generated during a survey of dipping activities. The methods for determining deposition on clothing utilised a seven patch technique and rates of contamination have been calculated using findings from an earlier IOM study on comparisons between patch and whole garment sampling. The model (though of very few data points) is thought to be reflective of conditions at a range of dipping tasks where operators may contact treatment fluids and certainly falls within the expected ranges.

In all cases the in-use concentration of fluids were evaluated through chemical analysis.

Dipping Model 2

User: Professionals
Task: Fellmongers and tanners, mixing and diluting, and loading, and unloading treatment vessels.
Data source: HSE survey 1999
Reference: 3830 / R51.169 HSE report

Expressed as mg/min in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		100%	5 data, 0 data = zero
Range of non-zero values		0.19 to 178 [a] mg/min	
	50th % value	15.0 mg/min	
	75th % value	168 mg/min	
Probability of hand exposure inside gloves		80%	5 data, 1 data = zero
Range of non-zero values		0.05 to 39.9 mg/min	-
	50th % value	0.20 mg/min	-
	75th % value	0.22 mg/min	-
Probability of feet exposure inside shoes		20%	5 data, 4 data = zero
Range of non-zero values		0.05 mg/min	-
	50th % value	-	-

a. . highest data point at 3050 is an outlier.

Exposure by inhalation, exposure expressed as mg/m^3 in-use product

Probability of exposure by inhalation		20%	5 data, 4 data = zero
Range of non-zero values		424 mg/m^3	*(SPLASH)*
	50th % value	-	

Context of model

The data for this model were generated during a survey of dipping activities. The methods for determining deposition on clothing utilised a seven patch technique and rates of contamination have been calculated using findings from an earlier IOM study on comparisons between patch and whole garment sampling. The model (though of very few data points) is thought to be reflective of conditions at a range of dipping tasks where operators may contact wet objects and treatment fluids and certainly falls within the expected ranges.

The in-use concentrations of fluids were evaluated through chemical analysis.

Dipping Model 3

User: Professionals
Task: Textile treatment - mixing, diluting and machine minding.
Data source: HSE survey 1999
Reference: 3830 / R51.169 HSE report

Expressed as mg/min in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		100%	5 data, 0 data = zero
Range of non-zero values		0.02 to 23.8 mg/min	
	50^{th} % value	1.37 mg/min	
	75^{th} % value	7.49 mg/min	
Probability of hand exposure inside gloves		80%	5 data, 1 data = zero
Range of non-zero values		0.07 to 1.60 mg/min	-
	50^{th} % value	0.25 mg/min	-
	75^{th} % value	0.34 mg/min	-
Probability of feet exposure inside shoes		80%	4 data, 3 data = zero
Range of non-zero values		0.32 mg/min	-
	50^{th} % value	-	-

Exposure by inhalation, exposure expressed as mg/m^3 in-use product

Probability of exposure by inhalation		91%	6 data, 4 data = zero
Range of non-zero values		80, 122 mg/m^3	*splash ?*
	50^{th} % value	101 mg/m^3	

Context of model

The data for this model were generated during a survey of dipping activities. The methods for determining deposition on clothing utilised a seven patch technique and rates of contamination have been calculated using findings from an earlier IOM study on comparisons between patch and whole garment sampling. The model (though of very few data points) is thought to be reflective of conditions at automated dipping activities where there is little scope for operator contact with treated materials.

The in-use concentration of fluids were evaluated through chemical analysis.

Dipping Model 4

User: Professionals
Task: Aquaculture - net dipping, dispensing to pit from IBC, stirring and crane-assisted dipping, solvent-based and water-based products.
Data source: HSE survey 1999
Reference: 3830 / R51.169 HSE report

Expressed as mg/min in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		100%	8 data, 0 data = zero
Range of non-zero values		0.67 to 221 [a] mg/min	
	50th % value	11.9 mg/min	
	75th % value	19.3 mg/min	
Probability of hand exposure inside gloves		100%	9 data, 0 data = zero
Range of non-zero values		0.11 to 16.7 mg/min	-
	50th % value	1.02 mg/min	-
	75th % value	2.98 mg/min	-
Probability of feet exposure inside shoes		100%	9 data, 0 data = zero
Range of non-zero values		0.04 to 5.66 mg/min	-
	50th % value	0.92	
	75th % value	2.18	-

a. highest data point at 5620 is an outlier.

Exposure by inhalation, exposure expressed as mg/m^3 in-use product

Probability of exposure by inhalation		100%	9 data, 0 data = zero
Range of non-zero values		0.05 to 0.20 mg/m^3	
	50th % value	0.07 mg/m^3	
	75th % value	0.11 mg/m^3	

Context of model

The data from which the above model derive were collected as part of a HSE sponsored survey of the major treaters of nets in the UK – there are only four companies carrying out this work. The results reflect the true nature of the net dipping activity – an intermittent handling of treated nets at various stages of dryness. The work includes semi-automated immersion of the nets in large vats of fluid and similar retrieval at the conclusion of the process. This work is then followed by the preparation of the nets and wrapping prior to transportation to the ultimate customer.

In all cases the in-use concentration of fluids were evaluated through chemical analysis. This model could be used for a number of operations involving intermittent, but close, handling of immersed objects.

Dipping Model 5

User: Professionals (Hospitals and healthcare)
Task: Disinfection of articles in trough or ventilated cabinet / auto-disinfector
Reference: Pisaniello et al., Appl. Occ. Environ. Hyg. 12(3):171-177, 1997

Glutaraldehyde vapour.

No LEV	GM 0.034 ppm	GSD 2.7
LEV	GM 0.014 ppm	GSD 2.4

These map to percentiles:

No LEV	50^{th} % at 0.04 ppm, 75^{th} % at 0.06 ppm, 95^{th} % at 0.18 ppm
LEV	50^{th} % at 0.02 ppm, 75^{th} % at 0.03 ppm, 95^{th} % at 0.06 ppm

This ‘model’ can only be used for glutaraldehyde.

Surface disinfection (manual) Model 1

User: Professionals
Task: Dilution and mixing of disinfectant and cleaning surfaces with a wrung cloth or mop and wringer bucket
Reference: Schipper et al., 1996, TNO Report V96.314

Exposure inside protective gloves, expressed as mg/min in-use product at assumed density = 1.0 g/ml

Probability of hand exposure inside gloves		100%	16 data, 0 data = zero
Range of non-zero values		1.08 to 15.5 mg/min	-
	50^{th} % value	3.96 mg/min	
	75^{th} % value	10.3 mg/min	
Deposition on bare hands		100%	2 data, 0 data =-zero
Non-zero values		1.7 and 70.2 mg/min	-
	Average	36 mg/min	

Exposure by inhalation, exposure expressed as mg/m^3 in-use product

Probability of exposure by inhalation		39%	18 data, 11 data = zero
Range of non-zero values		5 to 55.6 mg/m^3	-
	50^{th} % value	22.2 mg/m^3	-
	75^{th} % value	28.9 mg/m^3	-

The duration of the work considered per shift was on average 22 minutes for an operation room and 79 minutes for an isolation room in hospitals.

The authors have calculated 90th-percentile values, which they consider relevant for registration purposes. For the preparation of a solution this amounts to 500 mg/kg; for the actual washing/cleaning and mopping/wiping this amounts to 2000 mg/kg for potential dermal exposure.

Surface disinfection (manual) Model 2

User: Professionals
Task: Washing and wiping floors with mob, bucket and wringer (e.g. hospitals, schools). Duration 8 to 39 min (median at 15 min). No mixing or loading.
Reference: Popendorf and Selim, Am. Ind. Hyg. Assoc. J. (56):1111-1120, 1995

Expressed as mg/cycle and mg/task in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		100%	6 data, 0 = zero
Range of non-zero values		0.45 to 4.50 [a] mg/min	
	50th % value	2.97 mg/min	
	75th % value	4.11 mg/min	
		Task-based data	
Range of non-zero values		11 to 786 mg/task	
	50th % value	32.5 mg/task	
	75th % value	91.5 mg/task	

a. outlier at 68.7 mg/min

No data for exposure of hands.

The data have been recalculated by HSE from the data described in the paper.

The data indicated above should just guide the exposure assessor. It must be emphasised that the exposures should only be used as indicative values in view of the small database and the possible mismatch between techniques and geometry in the USA and Europe.

Surface disinfection (manual) Model 3

User: Professionals
Task: Wiping plumbing fixtures and surfaces with rag washed in bucket. Duration 8 to 78 min (median at 15 min). No mixing or loading.
Reference: Popendorf and Selim, Am. Ind. Hyg. Assoc. J. (56):1111-1120, 1995

Expressed as mg/cycle and mg/task in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		88%	8 data, 1 = zero
Range of non-zero values		8.62 to 87.6 mg/min	
	50th % value	23.8 mg/min	
	75th % value	56.6 mg/min	
		Task-based data	
Range of non-zero values		87 to 3900 mg/task	
	50th % value	886 mg/task	
	75th % value	1550 mg/task	

No data for exposure of hands.

The data have been recalculated by HSE from the data described in the paper.

The data indicated above should just guide the exposure assessor. It must be emphasised that the exposures should only be used as indicative values in view of the small database and the possible mismatch between techniques and geometry of the buildings in the USA and Europe.

Sub-soil treatment

User:	Professionals
Task:	treating subsoil against termites by injection, spraying foundations and sub-building crawl spaces
Reference:	Fenske & Elkner, Tox. Indust. Health 6(3-4):349-371, 1990

This study is interesting, since it covers a typical application. The compound was applied by sub-slab and soil injection to houses. This included in some cases crawl space application.

Exposure was measured on a few outer patches and a few inner patches, as well as by biological monitoring (chlorpyrifos).

From the data no potential dermal exposure data for the whole body can be estimated.

Inhalation exposure over the whole work time varied between 1.8 and 35.4 µg/m^3, with a median of 10.1 µg/m^3 active substance. This amounts to 12.6 to 247.8 µg/m^3 and 70.7 µg/m^3 in-use product..

Sub-soil treatment Model 2

User: Professionals
Task: Mixing and loading, and treating soil by watering and subsoil by injection, spraying foundations and sub-building crawl spaces
Reference: Cattani et al., Ann. Occ. Hyg. 45(4):299-308, 2001. Full data set will be at www.pesticide-research.curtin.edu.au and revision will be needed.

Expressed as mg/min in-use product at assumed density = 1.0 g/ml, in-use concentration 1%

Task		**Ground spraying pre-construction**	
Probability of potential dermal exposure		100%, 3 data	3.3 to 38.2 mg/min
	50th % value	20 mg/min	
	75th % value	29.2 mg/min	
Probability of hand exposure inside gloves		100%, 4 data	3.17 to 48.8 mg/min
	50th % value	3.50 mg/min	-
	75th % value	15.0 mg/min	-
Probability of exposure by inhalation		100%, 4 data	0.58 to 4.15 mg/m^3
	50th % value	2.16 mg/m^3	
	75th % value	3.81 mg/m^3	
Task		**Post-construction injection**	
Probability of potential dermal exposure		94%, (18 data, 1 = zero)	0.3 to 69.8 mg/min
	50th % value	14.7 mg/min	
	75th % value	25.8 mg/min	
Probability of hand exposure inside gloves		94% (17 data, 1 = zero)	0.20 to 144 mg/min
	50th % value	4.0 mg/min	-
	75th % value	8.0 mg/min	-
Probability of exposure by inhalation		100%, 17 data	0.07 to 5.83 mg/m^3
	50th % value	0.33 mg/m^3	
	75th % value	0.57 mg/m^3	
Task		**Under-floor spraying, post-construction**	
Probability of potential dermal exposure		100%, 6 data	5.3 to 54.6 mg/min
	50th % value	32.2 mg/min	
	75th % value	42.2 mg/min	

Probability of hand exposure inside gloves		100%, 6 data	1.83 to 77.8 mg/min
	50^{th} % value	13.3 mg/min	-
	75^{th} % value	19.0 mg/min	-
Probability of exposure by inhalation		100%, 5 data	1.70 to 21.9 mg/m^3
	50^{th} % value	4.0 mg/m^3	
	75^{th} % value	20.6 mg/m^3	

Dust and soil adhesion Model 1

Finley et al., Risk Analysis (14):555-569, 1994

The authors propose source terms for use in probabilistic modelling:

Adult	mean	0.49 mg soil / cm^2 skin	95^{th} %	1.6 mg soil / cm^2 skin
Child	mean	0.63 mg soil / cm^2 skin	95^{th} %	2.4 mg soil / cm^2 skin

All log-normal distributions, arithmetic mean = 0.52, SD 0.9 mg/ soil / cm^2 skin
50^{th} % = 0.52 mg soil / cm^2 skin

Dust and soil adhesion Model 2

User: Professionals
Task: Bagging treated seed (active substance 0.01 to 5.05% of dust generated, 50^{th} % = 0.06%)
Reference: HSL report, work in progress on Phase 2 - cleaning.

Expressed as mg/min dust, calculated from related inhalation results. The final concentration of dressing on the treated seed is not known, but it lays mostly on the seed coat).

		Dust	**Concentrate**
Probability of potential dermal exposure		100%, 17 data	100%, 22 data
Range of non-zero values		0.37 to 84.9 [a] mg/min	0.006 to 0.75 mg/min
	50^{th} % value	11.4 mg/min	0.15 mg/min
	75^{th} % value	33.6 mg/min	0.38 mg/min
Probability of hand exposure inside gloves		100%, 16 data	100%, 20 data
Range of non-zero values		0.3 to 44.9 [b] mg/min	0.002 to 0.26 mg/min
	50^{th} % value	4.68 mg/min	0.04 mg/min
	75^{th} % value	25.3 mg/min	0.09 mg/min

a. two outlier data discarded - highest value 6910 mg/min
b. outlier at 383 mg/min.

Exposure by inhalation, exposure expressed as mg/m^3 dust or concentrate

		Dust	**Concentrate**
Probability of exposure by inhalation		100%, 21 data	86% (22 data,3 = zero)
Range of non-zero values		0.61 to 19.4 mg/m^3	0.001 to 0.34 mg/m^3
	50^{th} % value	1.79 mg/m^3	0.006 mg/m^3
	75^{th} % value	2.7 mg/m^3	0.02 mg/m^3
	95^{th} % value	10.6 mg/m^3 *	-

Dust and soil adhesion Model 3

User: Professionals
Task: mixing and loading dusty bags, weighing and bag crushing
Reference: TNO report V96.064 (Lansink et al., 1996)

Expressed as mg/min in-use product, assumed from stated data ranges

Task		**Transporting bags**	
Dust on gloves	50th % value	135 mg/min	
	75th % value	205 mg/min	
	95th % value	363 mg/min	
Task		**Manual scooping and weighing**	
Dust on gloves	50th % value	221 mg/min	-
	75th % value	373 mg/min	
	95th % value	647 mg/min	-
Task		**Dumping into vessel**	
Dust on gloves	50th % value	117 mg/min	
	75th % value	224 mg/min	
	95th % value	552 mg/min	
Task		**Bag collection and crushing**	
Dust on gloves	50th % value	142 mg/min	
	75th % value	228 mg/min	
	95th % value	496 mg/min	

Context of the model

The data for this model were gathered in a survey of several types of handling of calcium carbonate used from bags in 10 different paint factories. Sampling was done using cotton gloves only over the period that the activity actually took place. The method of analysis was specific to calcium carbonate. Results are applicable to manual handling of dusty powders packaged in cardboard bags of approximately 25 kg. Particle sizes of calcium carbonate varied from < 0.1 µm to a median diameter of 30 µm for different varieties of calcium carbonate. Manual weighing was generally done with local exhaust ventilation of questionable effectiveness. Dumping in vessels was done with local exhaust ventilation of reasonable to very good effectiveness. Duration of measured tasks was between 1 and 15 minutes. Each measurement regarded activities for only one batch of paint. The model is considered appropriate for transporting bags, dumping into vessel and bag collection and crushing. The number of measurements for manual scooping and weighing is small (n=6) and the model for this activity is only indicative. The model can be used for estimating exposure if up to 25 bags (or 1000 kg) of dusty powder are handled. Extrapolation to substantially

longer duration of tasks, more batches, higher numbers of bags or larger amounts of powder should be done very cautiously, due to the expectation that the adherence of powder to either skin or cotton slopes to a maximum. The model cannot be used for very coarse or non-dusty powders (e.g. median diameter > 100 µm), granules or flakes. It can also not be used for handling of powders in containers (drums) with inner lining. It may provide only indicative results for handling of polymer bags that are substantially more “dust-tight” than cardboard bags, especially for the transporting of bags.

Fogging and misting

Misting Model 1

User: Professionals
Task: misting at low level using CDA wand (CDA low level sprayer). No mixing or loading.
Data source: HSE survey 1999
Reference: Ann. Occ. Hyg. (to be published), ACP paper 70 (283/01).

Expressed as mg/cycle in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		100%	12 data, 0 data = zero
Range of non-zero values		0.05 to 13.8 mg/min	
	50^{th} % value	2.21 mg/min	
	75^{th} % value	8.08 mg/min	
Probability of hand exposure inside gloves		100%	12 data, 0 data = zero
Range of non-zero values		0.003 to 0.98 mg/min	-
	50^{th} % value	0.06 mg/min	-
	75^{th} % value	0.12 mg/min	-
Probability of feet exposure inside shoes		100%	12 data, 0 data = zero
Range of non-zero values		0.002 to 0.76 mg/min	-
	50^{th} % value	0.02 mg/min	
	75^{th} % value	0.05 mg/min	-

Exposure by inhalation, exposure expressed as mg/m^3 in-use product

Probability of exposure by inhalation		33%	12 data, 8 data = zero
Range of non-zero values		22 and 26 mg/m^3	*2 data very high outliers*
	50^{th} % value	24 mg/m^3	

6 data relate to ready for use product and 6 for diluted concentrate

Deposition pattern - head - 0.3%; arms - 1.3%; torso - 13.7%; legs - 84.7%

Context of model

Data collected from a survey of application of amenity herbicides by controlled droplet application. The data are specific to this type of activity. In-use concentrations of product were established through chemical analysis.

Misting Model 2

User: Professionals
Task: misting at waist level using CDA (ULV) mist blower. No mixing or loading.
Data source: HSE survey 2000
Reference: HSL report in press

Expressed as mg/cycle in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		100%	8 data, 0 data = zero
Range of non-zero values		6.11 to 35.5 mg/min	
	50^{th} % value	13.8 mg/min	
	75^{th} % value	21.8 mg/min	
Probability of hand exposure inside gloves		100%	8 data, 0 data = zero
Range of non-zero values		0.02 to 0.20 mg/min	-
	50^{th} % value	0.03 mg/min	-
	75^{th} % value	0.04 mg/min	-
Probability of feet exposure inside shoes		25%	8 data, 6 data = zero
Range of non-zero values		0.03 and 0.04 mg/min	-
	50^{th} % value	0.04 mg/min	

Exposure by inhalation, exposure expressed as mg/m^3 in-use product

Probability of exposure by inhalation		100%	8 data, 0 data = zero
Range of non-zero values		31.0 to 79.5 mg/m^3	
	50^{th} % value	47.7 mg/m^3	
	75^{th} % value	70.2 mg/m^3	

Context of model

Simulation of misting activity but using services of professional operator in a realistic building. In-use concentrations determined by chemical analysis. Data specific to mode of application.

Fogging Model 3

User: Professionals
Task: Fogging at mid level using fogging machine. No mixing or loading.
Data source: HSE survey 2000
Reference: HSL report in press

Expressed as mg/cycle in-use product at assumed density = 1.0 g/ml

Probability of potential dermal exposure		100%	4 data, 0 data = zero
Range of non-zero values		0.60 to 1.13 mg/min	
	50^{th} % value	0.74 mg/min	
	75^{th} % value	0.79 mg/min	

Exposure inside protective gloves, expressed as mg/min in-use product

Probability of hand exposure inside gloves		100%	4 data, 0 data = zero
Range of non-zero values		0.03 to 0.33 mg/min	-
	50^{th} % value	0.16 mg/min	-
	75^{th} % value	0.29 mg/min	-

Exposure inside shoes, expressed as mg/min in-use product

Probability of feet exposure inside shoes		100%	4 data, 0 data = zero
Range of non-zero values		0.003 to 0.009mg/min	-
	50^{th} % value	0.006 mg/min	
	75^{th} % value	0.009 mg/min	-

Exposure by inhalation, exposure expressed as mg/m^3 in-use product

Probability of exposure by inhalation		0%	4 data, 4 data = zero
Range of non-zero values		-	

Context of model

Simulation of fogging activity but using services of professional operator in a realistic building. In-use concentrations determined by chemical analysis. Data specific to mode of application.

Metalworking fluid

MWF Model 1

User: Professionals
Task: Mounting and demounting hard metal saw blades in a sharpening machine using lubricant fluid
Reference: Linnainmaa and Kiilunen, Int. Arch. Occ. Env. Health (69):193-200, 1997

The report quotes hand-wash data for cobalt on workers' hands following hard metal working. Protective gloves were not worn.

In-use fluid		1.2 to 5100 mg / litre cobalt, mean 696 mg / litre density unknown, assumed 0.9 to 1.1 g / ml
Hand washes	wash 1	0.39 to 6.5 mg cobalt removed
	wash 2, 3	no data, reported "exponential decline"
	wash 4	0.022 to 0.212 mg

The ranges for washes 2 and 3 were interpolated from a simple plot of wash number against $\log_{10}$(mg cobalt).

All washes were assumed as uniform distributions between the ranges.
Wash 2 was 0.75 correlated with wash 1, etc. until wash 4 was correlated 0.75 with wash 3.
The in-use fluid was assumed as a triangular distribution, most likely value at 696 mg / l.
The concentration was a uniform distribution.

A Crystal Ball probabilistic estimate for **fluid on the hands**:

50th %	2.8ml
75th %	5.1 ml
95th %	13.1 ml

The 95th % value is very similar to the default 6 ml spill model which assumes 6 ml of fluid adhering to a bare hand.

The occupational hygiene data are limited with only a few measurements. Standard deviation is very high. These single cases are difficult to generalise. The model is suitable only in limited cases for very similar agents (biocides with same viscosity) and the same kind of processes. For these particular processes studied, the measurements performed are representative, no other applications could be found, except probably spilling or splashing of liquids to hands.

MWF Model 2

User: Professionals
Task: using water and oil based metal working fluids (MWF)
Reference: HSE report EH74/4

Expressed as mg/m^3 in-use oil or water based MWF

Exposure by inhalation		**Oil based MWF**	**Water-based MWF**
Range of values		0.03 to 3.7 mg/m^3	0.01 to 13.0 mg/m^3
	50^{th} % value	0.78 mg/m^3	0.12 mg/m^3
	75^{th} % value	2.18 mg/m^3	0.33 mg/m^3
	95^{th} % value	3.35 mg/m^3	1.58 mg/m^3
		Total inhalable particulate	
Range of non-zero values		0.05 to 4.4 mg/m^3	0.02 to 23mg/m^3
	50^{th} % value	0.55 mg/m^3	0.32 mg/m^3
	75^{th} % value	1.84mg/m^3	0.65 mg/m^3
	95^{th} % value	3.26 mg/m^3	1.91 mg/m^3

The oil or water mist particle sizes were not determined.

Context

A study of 31 companies ranging from multinationals to small independent engineering workshops handling mineral oils, semi-synthetic oils and synthetic fluids. In excess of 300 personal samples were collected.

MWF Model 3

User: Professionals
Task: Using cutting fluids in case and valve making, and assembly
Reference: Abrams et al., Appl. Occ. Environ. Hyg. 15(16):492-502, 2000

Expressed as mg/m^3 MWF

Case-making	GM 0.54 mg/m^3	GSD 1.58
Valve-making	GM 0.30 mg/m^3	GSD 1.61
Assembly	GM 0.12 mg/m^3	GSD 1.40

Percentile estimates:

Case-making	50^{th} % at 0.55 mg/m^3, 75^{th} % at 0.75 mg/m^3, 95^{th} % at 1.09 mg/m^3
Valve-making	50^{th} % at 0.31 mg/m^3, 75^{th} % at 0.41 mg/m^3, 95^{th} % at 0.63 mg/m^3
Assembly	50^{th} % at 0.01 mg/m^3, 75^{th} % at 0.06 mg/m^3, 95^{th} % at 0.49 mg/m^3

These data should not be read as a model; it just indicated levels of exposure to metal working fluids observed by inhalation.

Pyrotechnic aerosol settlement

User: Professionals
Task: Settlement of aerosols (vacated space - fumigation with biocide smoke)
Data source: HSL 2001
Reference: ACP 23/2 (284/01)

Test	**Air changes per hour**	**Maximum airborne concentration, mg/m^3**	**Settled surface concentration, mg/m^2**
Phase 1 dicloran - test 1	0.4	31	17
Phase 1 dicloran - test 6	0	37	295
Phase 1 permethrin - test 2	0	8	5
Phase 1 permethrin - test 4	0	10	7
Phase 1 red smoke - test 7	0	48	18
Phase 2 dicloran - test 9	0.4	92	135
Phase 3 dicloran - test 1	3.2	47	19.5
Phase 3 dicloran - test 2	0.3	90	59.6
Phase 3 dicloran - test 3	0	78	63.1
Phase 3 dicloran - test 5	0.3	133	96.5

(omits failed tests)

Deposit from a given airborne aerosol concentration (particle size 2 microns and below

Other than the outlier (Phase 1 dicloran - test 6), the data follow a straight line with a formula

$mg/m^2 = 0.073 \times mg/m^3$

Further formulae link the **quantity** used, the **deposit** and the **maximum concentration**:

- The maximum concentration of airborne biocide aerosol = 65 mg/m^3 per 100 mg of biocide in the unburned smoke generator per m^3 of enclosure. (That is, 100 mg of biocide in a smoke generator, fired in a 10 m^3 enclosure, would produce a maximum airborne concentration of 6.5 mg/m^3). In default of any other data, a worst case value in any space is 15 mg/m^3 at 4-hours post-firing.

- The maximum deposit of aerosol on upward-facing surfaces = 13.3 micrograms per cm^2, per gram of biocide in the unburned smoke generator, per square metre of

surface. (That is, 100 mg of biocide in a smoke generator, fired in an enclosure with 10 m^2 horizontal area would produce a maximum deposit of 0.13 micrograms per cm^2). In default of any other data, a worst case value in any space is 14 micrograms per cm^2.

PPE penetration and deposition

User: Professionals
Task: all.
Data source: HSE surveys 1991-2000
Reference: EH74/3 and Ann. Occ. Hyg. 45(1):55-60, 2001

Probability of clothing penetration		62%	231 data, (87 data = zero)
Range of non-zero values		1 to 100%	
	50^{th} % value	11%	
	75^{th} % value	42%	
Probability, hand exposure inside new gloves		95%%	47 data
Probability, hand exposure inside old gloves		95%	190 data
	50^{th} % value	1.36 mg/min	
	75^{th} % value	4.21 mg/min	
	95^{th} % value	71.9 mg/min	
Probability of feet exposure inside shoes		Assume 100%	
Range of non-zero values		0.05 to 14.8 mg/min	68 data
	50^{th} % value	0.28	
	75^{th} % value	1.44	-
	95^{th} % value	4.57 mg/min	

Non-professionals: assume 20% clothing penetration (light clothing)
50% or 100% penetration (minimal clothing)

New gloves reduce hand-in-glove exposure by a factor of 0.6.

Creely & Cherrie (Ann Occup Hyg 2001 45(2) 137-143)

Probability of exposure of hands inside gloves = 83%
Protection factor versus the challenge to the outside of gloves > 220.

Deposition pattern (next page)

Deposition patterns

The following data are taken from workplace surveys only (omits data for hands)

Survey	**% head**	**% arms**	**% trunk**	**% legs**
Industrial preservation - water	1	5	8	86
Industrial preservation - solvent	1	3	4	93
Remedial spray - much overhead work	2	11	12	75
Brush wood preservative	4	19	29	48
Brush / roller antifoulant - some overhead	19	12	26	43
High pressure airless spray - some overhead	9	18	40	33
Mixing and loading antifoulant	3	12	21	64
Insecticide spraying - downwards	4	10	21	65
Insecticide spraying - around and overhead	9	13	34	44
Orchard - tractor spraying - overhead	4	9	36	52
Dipping - immersing articles	3	7	18	73
Sheep dipping - immersing	-	12	23	65
Sheep dipping - handling	-	8	17	75
Normalised 50th % value	*4*	*11*	*21*	*65*
Whole body - areas for comparison	*7*	*11*	*46*	*36*

Consumer product spraying and dusting

Spraying - air space spraying Model 1

User: Non-professionals
Task: air space spraying with pre-pressurised aerosol cans, trigger sprays and pumped sprayers
Data source: HSL 2001
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure of forearms and hands / legs, feet and face, as mg/min in-can product at nominal density = 1.0 g/ml; Inhaled as mg/m^3 in-can product

Pre-pressurised aerosol spray cans

Task
Intermittent discharge of a hand-held aerosol can into the air of a small sealed room, a sum of four events. The subjects remained in the room for 30 seconds after each event before exiting. The aerosol continuous discharge rate was 2.3 g/sec.

Exposure assessment note
The predicted inhalation exposure is highly sensitive on the dwell time within the area sprayed and careful judgement is required in the interpretation of both the measured airborne concentrations and the dermal exposure values. In practice the dermal exposure probably occurs mainly during the period of aerosol release. The value of the inhalation component results from a 36 second exposure (6 second release + 30 second dwell time).

Dermal deposition rates relate to actual dermal exposure.

Results all based on strontium washings, actual dermal exposure to in-use product, sum of 4 spraying events

		Hand and forearm	**Legs, feet & face**	**Inhaled**
Probability of exposure		100%	100%	100%
		10 data	10 data	10 data
Range of non-zero values		21.6 to 432 mg/min	24.5 to 233 mg/min	64 to 374 mg/m^3
	50th % value	108 mg/min	79.2 mg/min	167 mg/m^3
	75th % value	156 mg/min	113 mg/min	234 mg/m^3

Hand-held trigger spray

Task
Discharge of a hand-held trigger spray into the air of a small sealed room, a sum of four events. The subjects remained in the room for 30 seconds after each event before exiting. The sprayer discharged up to 1.1 g of product per trigger pull.
(Note, hand muscles experience rapid fatigue after very few minutes' use of these devices)

Results all based on strontium washings, actual dermal exposure to in-use product, 4 spraying events (adjusted for blanks)

		Hand and forearm	**Legs, feet & face**	**Inhaled**
Probability of exposure		100%	100%	90%
		10 data	10 data	10 data (1 = zero)
Range of non-zero values		47.5 to 173 mg/min	8.5 to 90.8 mg/min	27 to 129 mg/m^3
	50th % value	89.5 mg/min	19.7 mg/min	66.2 mg/m^3
	75th % value	136 mg/min	42.4 mg/min	90.2 mg/m^3

Hand-held pumped sprayer (averaged over 4 events)
Task
Discharge of a hand-held pump sprayer into the air of a small sealed room, a sum of four events. The subjects remained in the room for 30 seconds after each event before exiting. The sprayer was pre-loaded and given to the subject, who paused to re-pressurise the device every few seconds.

Results all based on strontium washings, actual dermal exposure to in-use product, 4 spraying events (adjusted for blanks)

		Hand and forearm	**Legs, feet & face**	**Inhaled**
Probability of exposure		100%	100%	100%
		10 data	10 data	10 data
Range of non-zero values		17 to 189 mg/min	7.1 to 39.3 mg/min	19.1 to 110 mg/m^3
	50th % value	30 mg/min	18 mg/min	63.3 mg/m^3
	75th % value	98.4 mg/min	22.7 mg/min	76.3 mg/m^3

Median 9% of the legs etc. deposit was on the face

The use of consumer deposition and exposure models demands a full explanation of the proposed in-use scenario and will vary from product to product. The conditions of the simulation exercises may not be a true representation of the way a product is meant to be used. The selection of application period, followed by dwell period is the key determinant of predicted deposition and dose through inhalation. The data presented in these models are a

reflection of the specific scenarios used in the experiments.

Consumer product spraying and dusting Model 2

User: Non-professionals
Task: surface spraying (soft furnishings, skirting boards, shelves) with pre-pressurised aerosol cans, trigger sprays and dust applicator packs; also vacuum cleaning dust deposits.
Data source: HSL 2001
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure of forearms and hands / legs, feet and face, as mg/min in-can product at nominal density = 1.0 g/ml; Inhaled as mg/m^3 in-can product

Pre-pressurised aerosol spray can
1995 study: spraying a small room including a sofa, 6 metres of skirting board, 2 dining chairs and 6 m^2 of carpet. Hand and forearm dermal measurements only were taken.
1998 study: spraying a living room containing a 3-piece suite, 6 m^2 of carpet and a pet bed.

		Hand and forearm	**Legs, feet & face**	**Inhaled**
Probability of exposure		100%	100%	93%
		15 data	6 data	15 data (1 = zero)
Range of non-zero values		1.7 to 156 mg/min	17 to 45.2 mg/min	0.33 to 49.5 mg/m^3
	50th % value	33.4 mg/min	28.4 mg/min	30.5 mg/m^3
	75th % value	64.7 mg/min	35.7 mg/min	35.9 mg/m^3

Hand-held trigger spray
Hand-held trigger spraying 13 m skirtings, 2 m^2 of shelves and 8 m^2 of horizontal and vertical laminate surfaces. The sprayer discharged up to 1.1 g of product per trigger pull. (Note, hand muscles experience rapid fatigue after very few minutes' use of these devices)

Results all based on strontium washings, actual dermal exposure to in-use product

		Hand and forearm	**Legs, feet & face**	**Inhaled**
Probability of exposure		100%	100%	100%
		11 data	11 data	11 data
Range of non-zero values		3 to 68.2 mg/min	1.9 to 12.4 mg/min	2.6 to 19.5 mg/m^3
	50th % value	24 mg/min	7.2 mg/min	8.7 mg/m^3
	75th % value	36.1 mg/min	9.7 mg/min	10.5 mg/m^3

Hand-held dusting applicator pack for crack and crevice

Task

A Crack and crevice powders for fleas and ants, indoor and outdoor use

The products were found to be particles of inert filler such as fine talc or chalk (median, 45% of dust less than 75 µm) in a flexible canister with a single dispense hole, diameter 2 to 2.5 mm. This is the group on the left of the illustration. A synthetic mixture reproduced the finest grade of powder found from six different products, with 5% Tinopal and 1% strontium.

Volunteers wearing minimal clothing applied dust in a simulated ant treatment in a kitchen, including 13 m of skirtings, 2 m^2 of shelves and 3 m^2 of horizontal laminate surfaces.

B Broadcast powders for fleas, indoor carpet / furnishings use.

Products specified for use on soft furnishings were fine powders as (a), above. Other products, exclusively for use on carpets, were found to be coarse granules (median, >95% of granules greater than 180 µm) in a hard container with either one large or several small dispense holes, diameter up to 4.8 mm. The likelihood and level of contamination was considered to be higher for the finer dusts and the same synthetic mixture and dispenser were used as for (a).

Volunteers wearing minimal clothing applied the powder in a simulated flea treatment of a living room, then removed it with an inefficient (i.e. not cyclone) vacuum cleaner.

		Hand and forearm	**Legs, feet & face**	**Inhaled**
Probability of exposure		100%	100%	100%
		10 data	10 data	10 data
Range of non-zero values		0.4 to 4.18 mg/min	0.22 to 6.56 mg/min	0.21 to 8.01 mg/m^3
	50^{th} % value	2.39 mg/min	1.34 mg/min	1.42 mg/m^3
	75^{th} % value	2.83 mg/min	2.15 mg/min	1.78 mg/m^3
Hand-held dusting applicator pack, broadcast powder (3 data only)				
Range of non-zero values		0.8 to 2.5 mg/min	2.4 to 3.2 mg/min	0.8 to 1.9 mg/m^3
Vacuuming after dusting application, non-cyclone vacuum cleaner (3 data only)				
Range of non-zero values		0.6 to 1.0 mg/min	1.0 to 3.2 mg/min	0.6 to 0.8 mg/m^3

Median 5% of the legs etc. deposit was on the face

Consumer product spraying and dusting Model 3

User: Non-professionals
Task: Surface spraying (underside of joists indoors with hand-held pressurised sprayer; fence outdoors with electric powered sprayer), i.e. refillable pressure spray equipment.
Data source: HSL 2001
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure of forearms and hands / legs, feet and face, as mg/min in-use product at nominal density = 1.0 g/ml; Inhaled as mg/m^3 in-can product

Hand-held pressurised 3-litre garden sprayer, spraying 16 m^2 joists overhead

Task

Spraying 16 m^2 of rough wooden joists and the undersides of floorboards, overhead indoors, with water-based product using a hand-held pumped pressurised 3-litre garden sprayer (includes loading).

		Hand and forearm	**Legs, feet & face**	**Inhaled**
Probability of exposure		100% (10 data)	100% (10 data)	100% (10 data)
Range of non-zero values		19.2 to 219 mg/min	6.9 to 138 mg/min	7.8 to 160 mg/m^3
	50th % value	109 mg/min	79.7 mg/min	73.8 mg/m^3
	75th % value	176 mg/min	120 mg/min	115 mg/m^3

Electric powered sprayer outdoors - all types of fence

		Hand and forearm	**Legs, feet & face**	**Inhaled**
Probability of exposure		100% (6 data)	100% (6 data)	100% (6 data)
Range of non-zero values		32.4 to 144 mg/min	13.4 to 84 mg/min	1.1 to 6.5 mg/m^3
	50th % value	52.8 mg/min	36.3 mg/min	2.0 mg/m^3
	75th % value	72.6 mg/min	39.9 mg/min	3.3 mg/m^3

Median 7% of the legs etc. deposit was on the face
Skin deposit - spraying lattice fences 50th% = 120 mg/min, solid fences 50th% = 70 mg/min

Consumer product painting

Brush painting Model 1

User: Non-professionals
Task: Brush painting 16 m^2 of rough wooden joists and the undersides of floorboards, overhead indoors, with water-based product (includes decanting).

Data source: HSL 2001
Reference:: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure of forearms and hands / legs, feet and face, as mg/min in-use product at nominal density = 1.0 g/ml; Inhaled as mg/m^3 in-can product

		Hand and forearm	**Legs, feet & face**	**Inhaled**
Probability of exposure		100% (11 data)	100% (11 data)	100% (11 data)
Range of non-zero values		43.2 to 239 mg/min	8.0 to 54.6 mg/min	0.6 to 11.4 mg/m^3
	50^{th} % value	110 mg/min	18.8 mg/min	1.7 mg/m^3
	75^{th} % value	150 mg/min	35.7 mg/min	3.1 mg/m^3

Median 18% of the legs etc. deposit was on the face

Consumer product painting Model 2

User: Non-professionals
Task: brush painting sheds and fences
Data source: Ann. Occ. Hyg. 41(3):97-312, 1997
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure of hands and whole body minus hands, as mg/min in-use product
at nominal density = 1.0 g/ml

Laboratory studies - lattice fence painting, water-based product			
		Hands	**Body (less hands)**
Probability of exposure		100% (12 data)	92% (8 data)
Range of non-zero values		0.05 to 17 mg/min	1.18 to 28.1 mg/min
	50^{th} % value	2.54 mg/min	5.61 mg/min
	75^{th} % value	6.32 mg/min	13.8 mg/min

Laboratory studies - lattice fence painting, solvent-based product			
		Hands	**Body (less hands)**
Probability of exposure		100% (12 data)	100% (7 data)
Range of non-zero values		0.03 to 87.3 mg/min	3.83 to 133 mg/min
	50^{th} % value	6.18 mg/min	24.6 mg/min
	75^{th} % value	19.5 mg/min	30.2 mg/min

Consumer product painting Model 3

User: Non-professionals
Task: Brush painting sheds and fences using household gloves or no gloves
Data source: Ann. Occ. Hyg. 44(6):421-426, 2000
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure as mg/min in-use product at nominal density = 1.0 g/ml

Probability of potential dermal exposure		100%	15 data, 0 data = zero
Range of non-zero values		0.06 to 63.3 mg/min	
	50^{th} % value	5.06 mg/min	
	75^{th} % value	16.9 mg/min	
Probability of hand exposure inside gloves		83%	6 data, 1 data = zero
Range of non-zero values		0.01 to 3.24 mg/min	-
	50^{th} % value	0.02 mg/min	-
	75^{th} % value	0.3 mg/min	-
Deposition on bare hands		100%	9 data, 0 data =-zero
Range of non-zero values		0.11 to 56.3 mg/min	-
	50^{th} % value	3.47 mg/min	-
	75^{th} % value	5.91 mg/min	-
Probability of feet exposure inside shoes		53%	15 data, 7 data = zero
Range of non-zero values		0.01 to 0.24 mg/min	-
	50^{th} % value	0.02 mg/min	-
	75^{th} % value	0.05 mg/min	-

Exposure by inhalation, exposure expressed as mg/m^3 in-use product

Probability of exposure by inhalation		40%	15 data, 9 data = zero
Range of non-zero values		0.5 to 8.03 mg/m^3	
	50^{th} % value	1.63 mg/m^3	
	75^{th} % value	4.15 mg/m^3	

Consumer product painting Model 4

User: Non-professionals
Task: brush and roller painting antifoulant on the underside of small boats (leisure craft) using household gloves. Field survey data. The product was mixed and applied by brush direct from the can, or poured to a paint tray and applied by roller. The task was mostly done outdoors in a cramped position, with the single-hull boat (one double-hull) on a sling, cradle or trailer.

Data source: Ann.. Occ. Hyg. 44(6):421-426, 2000
Reference: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products

Exposure as mg/min in-use product at nominal density = 1.0 g/ml

Probability of potential dermal exposure		100%	11 data, 0 data = zero
Range of non-zero values		3.53 to 108 mg/min	
	50^{th} % value	15.7 mg/min	
	75^{th} % value	50.8 mg/min	
Probability of hand exposure inside gloves		89%	9 data, 1 data = zero
Range of non-zero values		0.07 to 18.5 mg/min	-
	50^{th} % value	0.74 mg/min	-
	75^{th} % value	3.77 mg/min	-
Deposition on outside of protective gloves		100%	2 data, 0 data =-zero
Range of non-zero values		70 and 76.6 mg/min	-
	50^{th} % value	73.3 mg/min	-
Probability of feet exposure inside shoes		100%	2 data, 0 data = zero
Range of non-zero values		0.1 and 0.11 mg/min	
	50^{th} % value	0.1 mg/min	-

Exposure by inhalation, exposure expressed as mg/m^3 in-use product

Probability of exposure by inhalation		40%	11 data, 7 data = zero
Range of non-zero values		0.03 to 0.11 mg/m^3	
	50^{th} % value	0.04 mg/m^3	
	75^{th} % value	0.05 mg/m^3	

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

References:

1 Hand press data: Roff (in press) – HSL reports IR/ECO/00/11 and IR/ECO/01/02
2 Houghton, thesis 1997
3 Brouwer et al., Appl. Occ. Env. Hyg. 14:231-239, 1999
4 Lu & Fenske, Env. Health Perspect. 107(6):463-467, 1999
5 Ross et al., Chemosphere 22(9-10):975-984, 1991
6 Jazzercise data - Ross et al., Chemosphere 20(3-4):349-360, 1990
7 Fogh et al., Riso Lab, Roskilde, Denmark 1999
8 Rodes et al., JEA & E, in press
9 Coldwell and Corns, 2001, HSL report OMS/2001/14

Household products - secondary exposure

The following data appear in the identified publications.

Substance	Matrix	Conc. max	Reference no.
Bendiocarb	Air	0.05 µg/m^3	3
	Air	2 µg/m^3	6
	Dust	0.9 µg/g	9
Carbaryl	Air	0.03 µg/m^3	3
Chlorothalonil	Air	0.001 µg/m^3	3
Chlorpyrifos	Air	0.5 µg/m^3	1
	Air	0.13 µg/m^3	3
	Air	4 µg/m^3	6
	Air	1.6 µg/m^3	8
	Dust	22 µg/g	1
	Dust	3.1 µg/g	4
	Dust	119 µg/g	5
	Dust	15 µg/g	8
Deltamethrin	Air	0.005 µg/m^3	2
	Dust	50 µg/g	2
DDT	Dust	data	9
Diazinon	Air	0.02µg/m^3	1
	Air	0.32 µg/m^3	3
	Air	35 µg/m^3	6
	Dust	0.4 µg/g	1
	Dust	66 µg/g	5
	Dust	5.8 µg/g	8
Dichlofluanid	Air	0.14 µg/m^3	1
Dichlorvos	Air	0.15 µg/m^3	3
	Dust	1.7 µg/g	8
Glyphosate	Dust	3.5 µg/g	9
Lindane	Air	0.02 µg/m^3	3
	Dust	9.4 µg/g	9
Malathion	Air	0.01 µg/m^3	3
Pentachlorophenol	Dust	3.3 µg/g	4

Permethrin	Air	0.02 µg/m^3	1
	Air	0.1 µg/m^3	2
	Dust	320 µg/g	1
	Dust	800 µg/g	2
	Dust	284 µg/g	9
Permethrin (vacuuming)	Air	0.10 µg/m^3	1
o-Phenyl phenol	Dust	0.8 µg/g	8
Piperonyl butoxide (pyrethroid synergist)	Dust	111 µg/g	9
Propoxur	Air	0.04 µg/m^3	1
	Air	0.32 µg/m^3	3
	Air	10 µg/m^3	7
	Dust	0.6 µg/g	1
	Dust	1.6 µg/g	8
Tetramethrin	Air	10 µg/m^3	8
Transfluthrin (thermal vaporiser)	Air	20 µg/m^3	7
In cupboard vaporiser	Air	71 µg/m^3	7

References:

1 Schenk et al., Indoor Air 7:135-142, 1997
2 Berger-Preiss et al., Indoor Air 7:35-142, 1997
3 Whitmore et al., Arch. Env. Cont. Tox. 26:47-59, 1994
4 Lewis et al., Arch. Env. Cont. Tox. 26:37-46, 1994
5 Gordon et al., J. Exp. Anal. Env. Epidemiol. 9:456-470, 1999
6 Currie et al., Am. Ind. Hyg. Ass. J. 57(1):23-27, 1990 (*all high values*)
7 Pauluhn, personal communications, also Appl. Occ. Env. Hyg. 13(6):469-478, 1998
8 IEH review, 1999
9 HSL report (in press) Coldwell et al., 2001

It has been stated (Ref. 7) that for pyrethroids, there is no correlation between airborne concentrations and concentrations in house dust

Ref 9 found none of the following in 28 samples of house dust taken from non-professional users' houses:

Chlorpyrifos, dichlorvos, dimethoate, fenitrothion, bioallethrin, tetramethrin, phenothrin, deltamethrin, bioresmethrin, bifenthrin, 2.4-D, 2,4-DB, 2,4,5-T, 2,4,5-TP, dichlorprop, mecoprop, MPCA, dicamba, dinoseb.

BSG Indicative exposures meta-model

The DG XI Biocides Steering Group developed a conceptual model for potential dermal exposure in 1998. This has become a founding concept for the "HSL MODEL" cross-reference. The matrix appears below

Using indicative exposures according to task

Median deposit, mg.min^{-1}		**Percentile**	**"Low" 4 mg.min^{-1}**	**"Medium" 20 mg.min^{-1}**	**"High" 100 mg.min^{-1}**	**"Top" 500 mg.min^{-1}**
Profile 1	Narrow (GSD 2.45)	50% 75% 95%	4 7 18	20 37 87	100 180 440	500 920 2200
Profile 2	Intermediate (GSD 3.36)	50% 75% 95%	4 8 29	20 45 150	100 230 730	500 1100 3700
Profile 3	Wide (GSD 6.04)	50% 75% 95%	4 14 77	20 67 390	100 340 1900	500 1700 9700

(Percentile values at 50%, 75%, and 95% are commonly used in the regulation of pesticide products.)

It is possible to map tasks onto the matrix as set out below:

	"Low" 4 mg.min^{-1}	**"Medium" 20 mg.min^{-1}**	**"High" 100 mg.min^{-1}**	**"Top" 500 mg.min^{-1}**
Profile 1	* Timber pre-treatment (solvent) * Cda spraying *Trigger spray	* Anti-foul mix and load * Flea dusting * Brushing overhead	* Spraying overhead * Aerosol space spray	
Profile 2		* Low pressure spray * Timber pre-treatment (aqueous) * Anti-fouling brushing	* Anti-fouling spray	
Profile 3	* Fence brushing		* Medium pressure spray * Dipping	* Sheep dipping

The model can be used in two ways:

- to identify an application which is similar to that for which there are no data and use the corresponding indicative data, or for precautionary estimates, the data set one cell below or one cell to the right
- to conduct a few studies to establish a mean value, and select an indicative data cell based on the emerging pattern.

It is clear that the indicative distribution matrix provides a useful tool for assessing exposure where little is currently known about the application in mind. The matrix is used only to predict rates of contamination related to potential dermal exposure, but does not include contamination to the hands (or feet). Separate models exist to help predict hand exposure and empirical models have been derived for exposures inside gloves, (Garrod et al., Ann. Occ. Hyg., 45(1):55-60, 2001).

The rates of contamination are often most usefully converted into mg/hour to give a clearer representation of the level of exposure that is occurring. For instance at the 95^{th} percentile the 100 mg/min wide profile cell equates to a deposition of almost 120 ml per hour.

The assessor should attempt to place the expected level of contamination in this context. On many occasions it will be possible to make an assessment on the basis of a cell to the right (five times higher) or below (up to three times higher) the cell within which the assessor believes the contamination rate to reside. With this added level of confidence it may prove possible to complete a screening tier risk assessment using calculations based on these very worst case predictions.

Bayesian logic techniques may provide a method to further refine the assessment and provide the necessary level of reassurance required by the assessor, whilst at the same time reducing to a minimum the quantity of new data that is required to be generated.

Exposure to hands when wearing gloves

HSE data (Garrod et al., Ann. Occ. Hyg., 45(1):55-60, 2001) show that protective gloves do have the capacity to reduce exposure to the hands but are nonetheless fallible. The distribution of in-glove exposure to hands is independent of substance or task and relates more to the age of the glove and the number of times the glove is removed and replaced during a work operation. In this sense, quality procedures which require operators to remove gloves frequently to record information may play a significant role in increasing the potential for exposure.

A median value for all non-zero data was indicated at 1.36 mg of in-use product per minute, a 75^{th} percentile at 4.21 mg per minute and a 95^{th} percentile at 71.9 mg per minute, assuming product densities of 1.0 g ml^{-1}.

Full details are to be found in the original paper.

Computer based data models

Bayesian **E**xposure **A**ssessment **T**oolkit (BEAT model)
(under development)

BEAT is a probabilistic task based model built around an evolving database that currently contains approximately 450 exposure assessments grouped into 20 different exposure scenarios or 'jobs'. For a proposed exposure scenario the user provides information on the constituent tasks performed, the product and technique. A comparison is then made between this information and comparable data extracted from the database on each stored exposure scenario. An algorithm acting upon a rule base formed from occupational hygienists' expert knowledge then decides how similar the proposed exposure scenario is to those stored in the database and assign a quantitative measure of their similarity.

From these measures of similarity BEAT constructs a Bayesian joint prior belief for their exposure parameters. The greater the similarity between scenarios the more alike their exposure distributions are supposed to be. That is, the closer their geometric mean and standard deviations ought to be in value. The database is then searched for exposure data on these existing scenarios and these data are used to update the prior beliefs, using Baye's Theorem, into a posterior belief function for the parameters of the exposure distribution of the proposed scenario.

The raw model output – a posterior density for the geometric mean and standard deviation of the exposures for the proposed scenario - can be used in several ways:

1) The geometric mean and standard deviation for which the posterior density attains its maximum provide the *most plausible estimates* of the GM and GSD for the proposed scenario.

2) Evaluating the posterior density at values for the GM and GSD that correspond to the distributions in the indicative distributions matrix allows a prediction of the *most plausible* matrix cell to be made.

3) Integration of the hypothesised exposure distribution (log normal) with the posterior density for its GM and GSD yields the *predictive distribution.* This exposure distribution incorporates the inherent variability of exposures with the uncertainty associated with the model's predictions.

The current computer-based version of BEAT only offers the second option. For the user, the effective model output is a matrix of twelve 'probabilities' each describing the likelihood that the exposure scenario belongs in a particular cell of the indicative distributions matrix. For risk assessment purposes, relevant percentiles should be taken from the most plausible of the twelve distributions.

In circumstances where actual exposure data on the proposed scenario is available then the sequential nature of Bayesian statistics allows the posterior density (as described above) to be used as a prior for a second Bayesian analysis using the actual exposure data. The current version of BEAT has no provision for this second stage of analysis.

Description of the **BEAT** algorithm for assessing the similarity of exposure scenarios (*under development*)

The algorithm for determining a similarity score between an existing and proposed job (or exposure scenario) has a hierarchical structure based upon three levels. At the topmost level the physical state of the in-use products are compared. Where they are different the existing job and all associated exposure data are discarded as having no likeness the proposed scenario.

The second tier compares the tasks that make up each job. Tasks are grouped generically into Dermal Exposure Operation units (DEO units) (borrowed from RISKOFDERM EU project). There are six such generic groups:

- Handling of objects
- Manual dispersion
- Hand tool dispersion
- Spray dispersion
- Immersion
- Mechanical treatment

To these six generic tasks a seventh category is added - incidental exposure. This final category has been added to allow for periods of work where no direct involvement with the product takes place. Whilst exposure may occur during this time through (for example) contact with contaminated surfaces, the main reason for the inclusion of this category is to allow improved comparisons of tasks between jobs.

Two jobs are compared in the following way. The percentage of time spent on each category of task is supplied by the user for the proposed job and extracted from the database for an existing one. These percentages are then 'normalised' to correspond to the percentage of active time spent on each DEO unit. For example, during timber pre-treatment (currently the only existing job with 'incidental exposure' included) 30% of the time is spent handling objects whilst 70% of time is categorised as incidental exposure. After normalisation, timber pre-treatment becomes 100% handling of objects and thus (on the basis of tasks only) the same as antifoulant net deployment - also 100% handling of objects. (A reverse adjustment must be made to the antifoulant exposure data at the Bayesian statistics stage to account for the 70% of time classified as incidental exposure under timber pre-treatment.)

After normalisation, the percentages of time that *both* jobs perform each DEO unit are found. Additionally, the system finds the total percentage of time spent in each job performing DEO units not performed at all during the other job. For example,

Proposed job: 80% spray dispersion, 20% handling of objects.
Existing job: 60% spray dispersion, 20% handling of objects, 20% hand tool dispersion.

Time (jointly) spent on spray dispersion 60%
Time (jointly) spent on handling of objects 20%
20% of existing job spent on DEO units not performed in the proposed job.

Contrast this example with:

Proposed job: 80% spray dispersion, 20% handling of objects.
Existing job: 60% spray dispersion, 40% handling of objects.

Time (jointly) spent on spray dispersion 60%
Time (jointly) spent on handling of objects 20%
No mutually exclusive DEO units.

In both instances the total time spent on the same DEO units is 80%, but the exposures are more likely to be the same in the second instance because there are no DEO units performed exclusively during one job.

The third tier of the algorithm considers similarity at the level of each DEO. Here, 'modifiers' of exposure that are considered influential in determining dermal exposure are compared to assess whether the tasks are really alike or not. This comparison is done for every DEO that features in both the existing and proposed jobs. Modifiers are assigned to DEO units according to their supposed influence, some modifiers being assigned to more than one DEO unit. Comparison of these modifiers between the existing and proposed job yield 'similarity scores' for each shared DEO unit. These scores are then used to weight the results of the second tier of the algorithm, the comparison of DEO units. The assignment of modifiers to DEO units is as follows:

Handling of objects: extent of contact, frequency of contact, contamination of objects.
Manual dispersion: application rate, orientation.
Hand tool dispersion: application rate, orientation, distance from source.
Spray dispersion: application rate, pressure, orientation, distance from source, segregation.
Immersing: segregation.
Mechanical treatment: segregation, distance to source.

Comparing their values for an existing and proposed job, each modifier is assigned a 'similarity score'. Within each DEO unit these scores are multiplied together to provide a similarity score for that DEO unit.

$$Score(DEO_i) = \prod_{modifers DEO_i} score(modifer)$$

The total similarity score for the proposed and existing job is computed as follows.

$$Total\ similarity\ score = \sum_{i=1}^{6} time(DEO_i) \times score(DEO_i) - 0.5 \sum time\ \ different\ DEO$$

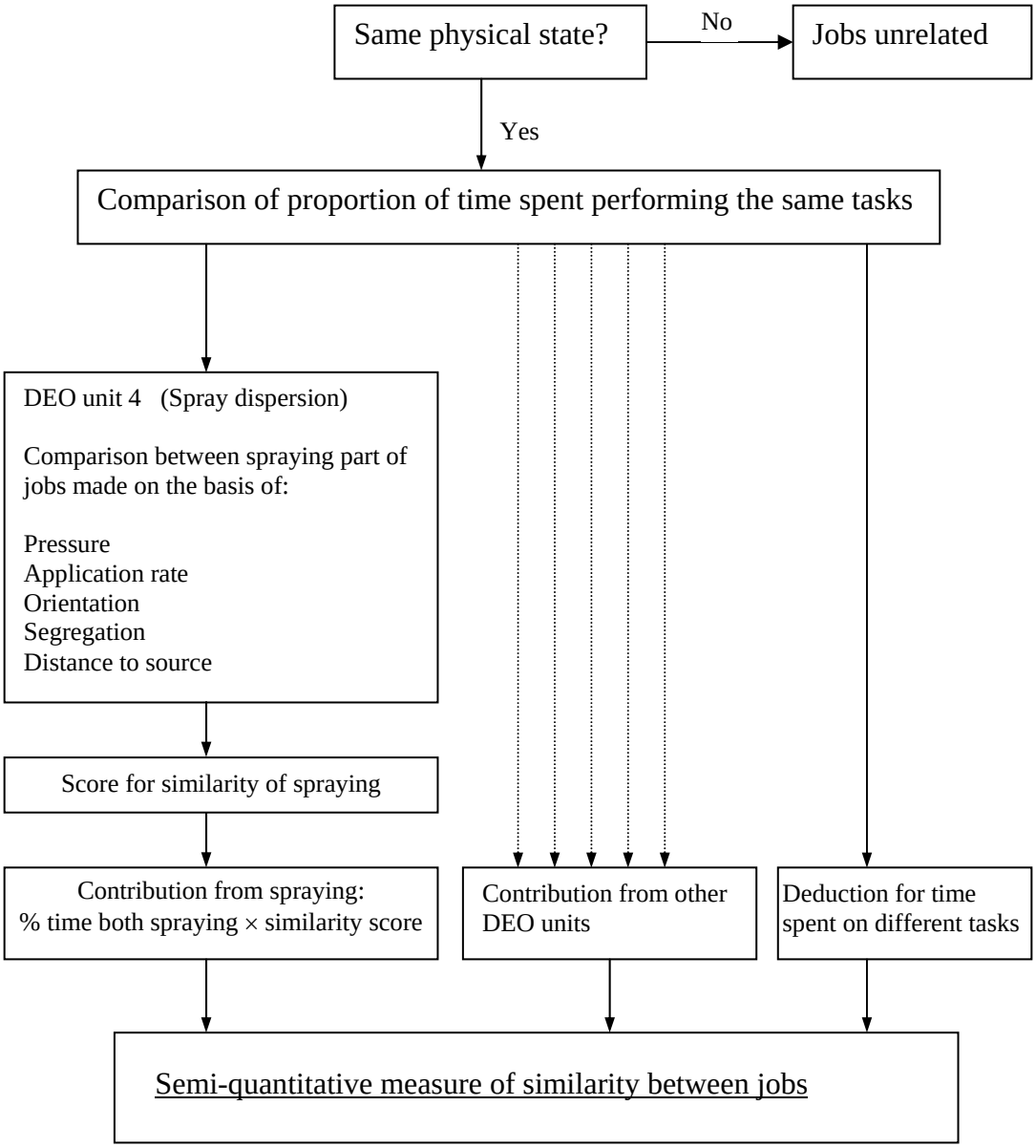
Distance from source has slightly different interpretations depending upon the context. For hand tool dispersion it will be determined by the 'tool' e.g. a paint brush is classified as hand held whilst a long handled mop is 'arms length'. For spray dispersion it refers to the distance between the spray nozzle and the operator e.g. an aerosol spray can is handheld whilst a tractor mounted spray would be classified as greater than arms length.

Segregation also includes instances of containment. Segregation has not been included as a modifier for handling, manual dispersion and hand tool dispersion - by definition these categories exclude the possibility of segregation.

Notable absentees from the list of modifiers include ventilation and more detailed physical properties of the substance, in particular particle size for solids and the viscosity and volatility for liquids. Future refinements to the algorithm ought to include these. (Some care needs to be exercised in the inclusion of physical properties as their influence has already been partly considered for handling of objects under ‘contamination of objects’).

By weighting the percentage of time spent on the same DEO unit by a score derived from the modifiers in this way ensures that each modifier is given appropriate consideration when assessing composite exposure scenarios involving more than one DEO unit. Where a modifier has an important influence on exposures for a particular DEO unit, but little time is spent jointly performing such tasks, then the determinant has only a modest overall influence.

This approach is quite modular in nature. Refinements can be made to the way in which the modifiers for each DEO unit are compared and new modifiers added without having to alter any other parts of the algorithm.



Schema of the **BEAT** algorithm for determining similarities between jobs.

Determining the similarity between individual modifiers

Pressure

The geometric mean pressure for an existing job is calculated from the known pressures for exposure records. The ratio of this average pressure for an existing job and the pressure for the 'proposed job' (supplied by the user) provides a measure of the similarity in pressures.

$$r = \frac{pressure_{new}}{pressure_{existing}} \qquad \text{pressure}_{\text{new}} \geq \text{pressure}_{\text{existing}}$$

$$r = \frac{pressure_{existing}}{pressure_{new}} \qquad \text{pressure}_{\text{existing}} > \text{pressure}_{\text{new}}$$

Pressure score = 1 $\quad r \leq 1.25$ or $pressure_{new}$ not given

$= 1 - \frac{r - 1.25}{2.5} \quad 1.25 < r \leq 2.5$

$= 0.5 \quad r > 2.5$

Application rate

The geometric mean application rate for an existing job is calculated from the available known quantities applied and duration of application from exposure records. The ratio of this average rate of application for an existing job, and the application rate for the 'proposed job' (supplied by the user), provides a measure of the similarity in application rates.

$$r = \frac{rate_{new}}{rate_{existing}} \qquad \text{rate}_{\text{new}} \geq \text{rate}_{\text{existing}}$$

$$r = \frac{rate_{existing}}{rate_{new}} \qquad \text{rate}_{\text{existing}} > \text{rate}_{\text{new}}$$

Application rate score = 1 $\quad r \leq 2$ or $rate_{new}$ not given

$= 1 - \frac{r - 2}{6} \quad 2 < r \leq 5$

$= 0.5 \quad r > 5$

Orientation

For each existing job the exposure records are searched and the % of records where orientation was classified as downwards, level and overhead respectively are calculated. These triplets are compared with a corresponding triplet describing the orientation of the 'proposed job' (supplied by the user) according to the following algorithm:

Define

$Orientation_{existing}$*=(% downwards +2*% level +3*% overhead)/100*

$Orientation_{new}$ *=(% downwards +2*% level +3*% overhead)/100*

These overall measures of orientation take advantage of the inherent ordering in the classification scheme for distance to source.

Then

$$Similarity\ score = 1 - abs(Orientation_{existing} - Orientation_{new})/4$$

$$= 1 \text{ either orientation unspecified}$$

The minimum similarity score (of 0.5) occurs when one job is exclusively downwards and the other exclusively overhead.

Distance to source
This is a qualitative measure of the distance between the source of emission (of the product) and the user. As such, it only pertains to hand tool dispersion, spray dispersion and mechanical treatment. Three classifications are used:

Hand held
Arms length
Greater than arms length

All exposure records relating to a particular existing job are searched and the percentage of records in each category calculated (usually this would overwhelmingly be one category). This triplet is then compared to the classification accorded to the proposed exposure scenario according to the following algorithm.

Similarity score = 1- (0.4 * % arms length) – (0.6* % > arms length) *if new job handheld*

= 1-(0.4* % handheld) – (0.4* % > arms length) *if new job is arms length*

= 1-(0.6* % handheld) – (0.4* % arms length) *if new job is > arms length*

=1 *if distance to source is unavailable for either job*

This complexity arises through accommodating existing jobs with associated exposure records with different classifications for ‘distance to source’. More usually, where all the exposure records have the same classification, the similarity score simplifies to:

		Existing job		
		Hand held	Arms length	> arms length
New job	Hand held	1	0.6	0.3
	Arms length	0.3	1	0.3
	> arms length	0.3	0.6	1

Segregation/Containment
This covers two different but related concepts. Both describe situations where a physical barrier affords operators some protection from exposure to the product. Containment mechanisms tend to be associated with the product e.g. some sort of holding vessel, whilst segregation is not e.g. a tractor cab surrounding the operator. Only two qualitative levels of this modifier are used:

No segregation/containment

Partial or complete segregation/containment.

The similarity score for this modifier is then defined as:

1	classifications of modifier unknown for one or more jobs
1	classifications the same
0.4	classifications different

Extent of contact, Frequency of contact, Contamination of objects

This information has not been collected individually for each exposure record. Instead, this information is recorded for each existing job, their values having been decided through consultation with occupational hygienists who are familiar with these exposure scenarios. The following classifications have been adopted:

- Extent of contact: fingertips; hands and forearms; half-front body; whole front body.
- Frequency of contact: rare; intermittent; frequent; continuous.
- Contamination of objects: touch dry; damp; wet; saturated [*].

[*] Some comparable descriptors are required for objects contaminated with solids.

These descriptors have a ranking and so are converted to an ordinal score by assigning integer values from 1 to 4 to each descriptor, one corresponding to the 'lowest' descriptor. The difference between the ordinal scores for the existing and proposed job is used to measure their similarity.

Difference in ordinal score	Similarity score
0	1
1	0.8
2	0.5
3	0.2

Where the user does not supply a value for a modifier a default similarity score of one is assigned to that modifier. Thus, if the user supplies little information, high overall similarity scores are obtained for comparisons with all existing jobs which have a similar composition in DEO units. For example, a proposed exposure scenario of 90% spray dispersion, 10% handling of objects and with no other information supplied will be considered very similar to all the spraying scenarios in the database. In such an instance the final BEAT estimates will be almost identical to those obtained using classical statistical techniques, when the whole of the spraying exposure data set is considered as observations from the same 'spraying' distribution. Thus BEAT will predict (with almost no uncertainty) a modest rate of exposure (20mg/min) but with a wide profile. Note, this is different from a more precautionary approach where the worst case distribution is chosen from the distinct exposure distributions for each spray scenario.

Example: Remedial and antifoulant spraying

Remedial biocides: 90% spray dispersion, 10% handling of objects. Extent of contact: hands + forearms. Frequency of contact: frequent. Contamination of objects: damp. Application rate: 1.0 litre/min. Pressure: 4.6 bar. Orientation: 19% downwards, 75% level, 6% overhead. Segregation: none. Distance to source: arms length.

Antifoulant spraying: 100% spray dispersion. Application rate: 1.3 litre/min. Pressure: 119 bar. Orientation: 100% level. Segregation none. Distance to source: arms length.

Time spent on same DEO units: spray dispersion 90%
Time spent on mutually exclusive DEO units: handling of objects 10%

Similarity scores for modifiers of spray dispersion.

Distance to source	1.0
Segregation	1.0
Application rate – ratio = 1.3	score = 1.0
Pressure – ratio = 29	score = 0.5
Orientation – ‘distance’ = 0.1	score = 0.97

Similarity for remedial and antifoulant spraying =

$[0.9\times(1.0\times1.0\times1.0\times0.5\times0.97)] - 0.1 = 0.34$

Specification of joint prior from similarity measures

Within a Bayesian framework prior beliefs about parameters are represented by a distribution for the parameters themselves. Without going into the mathematical details the table below indicates how the measure of similarity between two jobs translates into beliefs about their geometric means. The table gives 75 and 95 percent 'confidence intervals' for the ratio of the two geometric means for varying similarities.

Similarity	75 % 'confidence interval'	95 % 'confidence interval'
0.2	0.03 – 30.40	0.0002 - 4135
0.3	0.10 – 9.74	0.004 - 258
0.4	0.22 – 4.56	0.025 - 40.5
0.5	0.36 – 2.75	0.085 -11.8
0.6	0.51 – 1.96	0.19 -5.18
0.7	0.64 – 1.57	0.33 - 3.00
0.8	0.74 - 1.35	0.48 - 2.08
0.9	0.82 - 1.22	0.61 - 1.63
1.0	0.87 - 1.14	0.72 - 1.38

For example, a similarity between jobs of 0.6 corresponds to a belief that there is a 75% probability that the geometric means (of their exposure distributions) will be within a factor of 2 and a 95% probability that their GMs will be within a factor of 5.

This table suggests a method for determining the similarity scores for individual modifiers of exposure. Consider two jobs that are entirely alike except for differences in one modifier. Their similarity measure will be determined totally by the similarity score for that one modifier (adjusted for the time spent on the appropriate DEO units). For example, consider two spray applications with no mixing and loading or post application phases (i.e. 100% spray dispersion) alike in every respect except pressure where one is performed at 4 bar, the other at 10 bar. (In many instances this would lead to differing application rates as well but suppose that here they are the same.) These two jobs would be assigned a similarity of 0.5 and this corresponds to believing there is a 75% chance that their GMs would be within a factor of 2.75. If, amongst experts, there was a consensus that the exposures would be more alike then the similarity scores for pressure could be adjusted upwards.

It might be beneficial for an alternative algorithm to be developed by other experts to investigate how robust the model predictions are to changes in the 'expert knowledge'. If the overall structure is maintained but with changes to the similarity scores for individual modifiers then it would be straightforward to alter the software to allow either rule base to be chosen. This would only be a development stage, the final version ought to have a single agreed algorithm. BEAT's predictions ought to be relatively robust to these sort of changes because the rule base only determines how much 'weight' is assigned to particular data sets and does not determine the exposures directly.

EASE (model implemented in EUSES) (inhalation)

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

In 1999, the Institute of Occupational Medicine in Edinburgh (IOM) conducted a series of validation studies. These studies involved over 4,000 inhalation exposure measurements covering fifty-three EASE end-points. The data included measurements of solvent vapours, non-fibrous dusts and fibres, both asbestos and synthetic fibres. In 56% of the end-points the EASE prediction was mostly greater than the exposure measurements and in one third of the end-points the EASE estimates were comparable with the measurements. The predictions were generally more reliable for solid aerosols compared with gases and vapours. Similar studies involving dermal exposure assessment suggest that EASE also tends to overestimate the dermal exposure by about one order of magnitude, although the average measured exposure levels appear to increase in line with the predictions from EASE.

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

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

Fugitive emission (secondary exposure) model

There are many different approaches to modelling heavy vapour or buoyant aerosol dispersions in the atmosphere, each with a range of applicability. Such models have complex inputs and require operation by experts.

The recommended model is D*R*I*F*T (Webber, AEA Technology 1992; report AEAT/HSE SRD/HSE/R586). This models a dispersing vapour cloud taking into account transitions from concentrated vapours to passive, diluted clouds, including turbulent characteristics and down-wing obstacles.

The DRIFT model is available for interrogation at HSL Buxton.

3.4 Mathematical models

Mathematical models are calculation routines that are based on the physical properties of a substance and the environment into which these substances are released. This section reports those models that are considered adequate for human exposure assessment. It is notable that:

- many mathematical models relate to residential situations and few to the workplace;
- some are valid for restricted scenarios only; and
- the majority of models relate to exposure by inhalation.

There are also models that predict uptake via the skin, once skin deposition has taken place. There is no attempt to review the scientific background to these models - wherever possible, references are quoted. The collection includes a routine for default-value based calculations.

Mathematical models - advantages and drawbacks

The advantages include:

- the basis for the calculation algorithm is scientific;
- the assumptions made, the inputs and outputs can be simply documented;
- they are capable of validation with real data.

But the disadvantages include:

- models can be gross approximations of the real world
- assumptions may be invalid, e.g. instantaneous mixing of air and vapour;
- the full range of real variables cannot be accounted-for;
- single-value outputs may lead to uncritical use of that output.

Model reference

The models in this section are allocated a reference name - the index is on the next page. The reference name is the same as quoted in Chapter 2.3.2.

In general, few of the models have been validated against real situations. However, as state-of-the-art at the end of 2001, the following models are recommended for use in the following tiers of exposure assessment.

The first items presented have the status of default-value calculations, while the models that follow are true mathematical models.

Introduction

Exposure is a consequence of contact with a substance. The biocide type 18 (insecticides) has excited the greatest interest for risk assessors, and this is reflected in the number of models relating to insecticides. The next most interest has been for paint solvents, and few (if any) of these models are applicable to biocidal active substances.

Furthermore, the inhalation route has been most intensively studied. Models for dermal and ingestion uptake are relatively sparse, possibly due to the greater importance of human factors and behavioural inputs.

Most models produce single values from deterministic routines. The input values should be selected from real data distributions, as recommended in Chapter 2, Section 1. Great care needs to be taken in modelling reasonable worst cases where there are a number of scenarios undertaken per day - in such situations, probabilistic routines are preferred.

None of the models address aggregated exposure (that is, exposure resulting from the full range of sources where an active substance might be used), nor exposure through dietary intake.

As noted above, this is not an extensive review of all the models that are available. Reviews such as (Matoba and Van Veen, in Occupational and Residential Exposure Assessment (Franklin and Worgan, eds.) J. Wiley and Sons (in press); Van Veen et al., Ann. Occ. Hyg. 45 suppl 1, S107-S118) are available for reference. The models described below are recommended for use in estimating human exposure to biocidal products.

Droplet Simulation Model (Fraunhofer)

The Fraunhofer Institute for Toxicology and Aerosol Research has produced a report (Koch et al., 2002 in press) on inhalation and dermal exposure during spray application of biocidal products. In the context of this project, a deterministic model for predicting the aerosol exposure was developed.

The model calculates the airborne concentration of the respirable, the thoracic and the inhalable, or any other meaningful size fraction of **aerosols** containing biocidal substances in indoor environments originating from the release of liquid biocidal sprays. The model is a short term exposure model covering time scales typical for the release process. Long term emissions of vapors from walls and other surfaces are not included.
However, the model can easily be extended to dermal exposure due to deposition of droplets during the spraying process.

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

The main input parameters are: the released droplet spectrum, the release rate, the concentration of the active substance, the release pattern (surface spraying against floor, ceiling, wall; room spraying, ...), the vapor 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.

In the actual state of the model the concentration is calculated at the position of the operator in the breathing height. It is assumed that in the horizontal plane the position of the source and the receptor are identical. In the vertical direction however, release height and receptor height need not necessarily to be of the same value.

The model delivers the temporal concentration patterns at the receptor position and also integral values such as the inhaled dose.

Initial validation with regard to the airborne concentration in a model room under different conditions has been undertaken. Here, typical spray processes have been carried out and the resulting exposure concentrations of health related size fractions were measure online. Concentration levels and temporal patterns were predicted with reasonable accuracy by the model.

Since the model is based on implementation of *MATHEMATICA ™*, a not very widespread tool for performing symbolic and numerical mathematical calculations, a more user friendly version of the model based on generally implemented platforms will be developed in the near future.

HSL 2000

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

It is appropriate for:

- secondary exposure
- exposure by inhalation
- Tier 1 of assessment.

It is inappropriate for:

- primary use
- dermal and ingestion exposure routes.

Input values are the room dimension, ventilation rate, a mixing factor, temperature, pressure, air density and viscosity (values entered), and the contaminant data (vapour pressure, molecular weight, quantity applied and the surface area). The output is an airborne concentration profile.

Some validation has been done. The model's output is precautionary, over-predicting airborne concentrations by a factor of two. The model does not reproduce the effect for materials having very low volatility, of taking longer than calculations predict to reach an equilibrium concentration in real life.

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

SKINPERM

This is a simple arithmetical calculation routine in an EXCEL spreadsheet. The input formulae are presented on the W ten Berge homepage (http://home.wxs.nl/~wtberge/) for diffusion through the skin from aqueous solutions or neat liquid. Uptake via the skin from gases and vapours is not implemented.

It is appropriate for:

- professional and non-professional primary and secondary exposure
- exposure by skin contact / deposition
- Tier 1 of assessment.

The input values use exposure data or exposure estimates for deposits on the skin. The input data require the substance molecular weight, its partition coefficient ($log_{10}K_{ow}$), its concentration (mg / cm^3), the area of skin contaminated and the duration of contact. The output is expressed as uptake via the skin.

The routine is fully implemented in CONSEXPO, and available as "skinperm".

DEPOSITION

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

The model is believed to be appropriate for:

- professional users (e.g. oil mist) and non-professionals (e.g. vaporised insecticide)
- exposure by skin deposition
- Tier 1 of assessment.

The input values are the area available for potential dermal exposure, the deposition velocity, the airborne concentration and the exposure duration. The output is expressed as mg deposit.

AIRCHANGE CONCN

This is a simple arithmetical calculation routine in an EXCEL spreadsheet. Given an initial airborne concentration, it calculates the concentration after a period of time through passive ventilation.

The model is believed to be appropriate for:

- secondary exposure by inhalation (re-entry)
- Tier 1 of assessment.

The input values are the initial concentration, the number of air changes per hour, and the elapsed number of hours. The output is expressed as mg/m^3.

The routine is available as "airchange concn" from HSE.

CONSEXPO 3.0

Features. The CONSEXPO (CONSumer EXPOsure models) program is being developed at the RIVM (The Dutch National Institute of Public Health and the Environment) to provide estimation routines for exposure to consumer products, including biocides (Van Veen, 2001). CONSEXPO contains the simple screening models that are proposed in the European Union Technical Guidance Document for new and existing substances legislation. It extends these models with dedicated models for specific exposure scenarios. An example is the painting model, that predicts exposure to substances evaporating from paint. Other examples include a spray model.

- Total exposure is defined from the combination of contact, exposure and uptake scenarios for each route of entry and dose measures are calculated. These dose measures contain concentration estimates, and short and long term average doses in terms of milligram chemical per day per kilogram bodyweight.
- The program allows for stochastic parameters and each parameter can attain a normal, lognormal or uniform distribution, or an empirical distribution defined by data. Exposure and dose distributions reflect stochastic parameters and these distributions can be depicted and percentiles can be quantified.
- The program provides sensitivity analyses for each stochastic parameter, where mean exposures or doses as function of the value of a selected stochastic parameter are depicted and analysed. Sensitive parameters will cause big differences in model outcome, while other will cause hardly any differences.

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

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

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

Validation Van Veen et al. (1999) report two experiments to test the CONSEXPO painting model with evaporation as source term. The model predicts upper room concentrations well. Model predictions for paint and paint stripper were within 80% of the measured

concentrations. Weegels and Van Veen (2001) quantify exposure relevant consumer behaviour and study interdependence of exposure factors.

Van Veen, M.P., Fortezza F., Bloemen H.J.Th., and Kliest J.J. (1999) Indoor Air Exposure to Volatile Compounds emitted by Paints: Model and Experiment *Journal of Exposure Analysis and Environmental Epidemiology* **9,** 569-574.

Van Veen M.P., Fortezza F., Spaans E. and T.T. Mensinga. In press. Non-professional paint stripping, model prediction and experimental validation of indoor dichloromethane levels. Indoor Air.

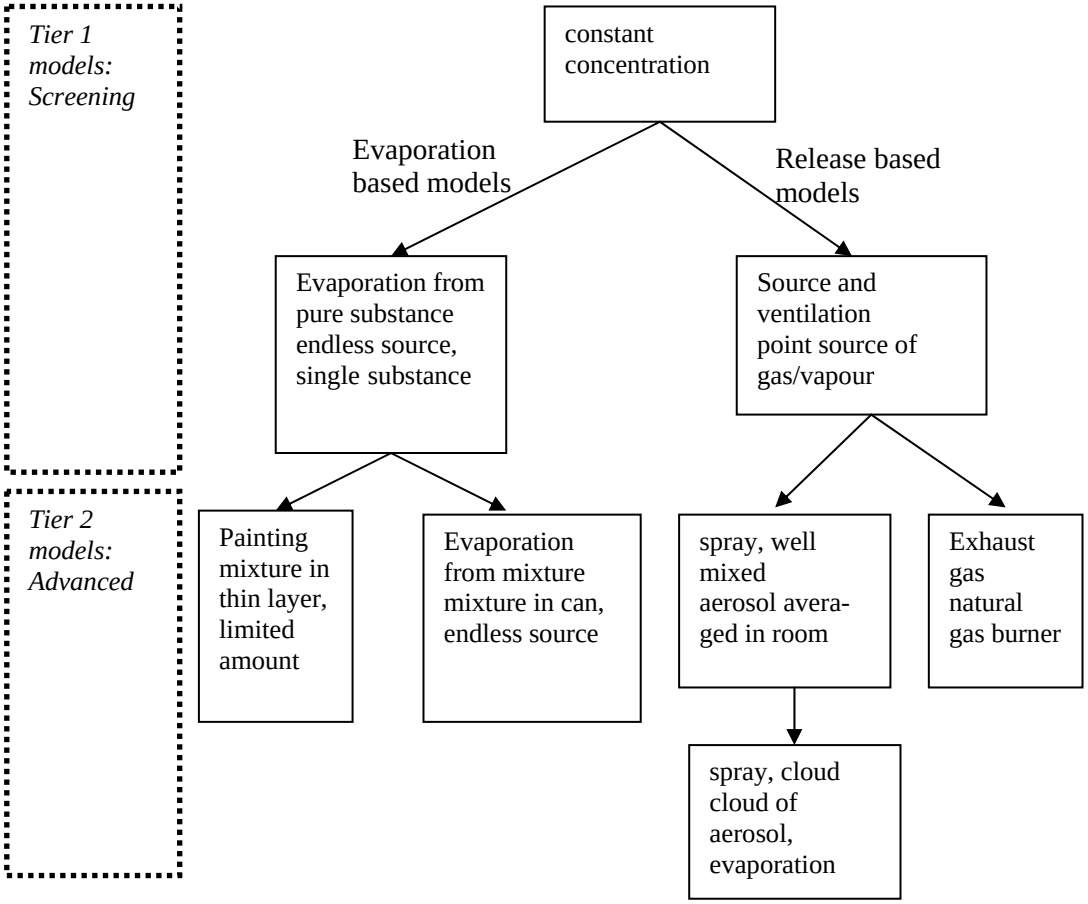
Van Veen M.P. 2001. CONSEXPO 3.0, Consumer exposure and uptake models. Report 612810 011, RIVM, Bilthoven (with CD-ROM).

Weegels M.F. and Van Veen M.P. 2001 Variation of Consumer Contact with Household Products: a Preliminary Investigation. Risk Analysis 21: 499-511.

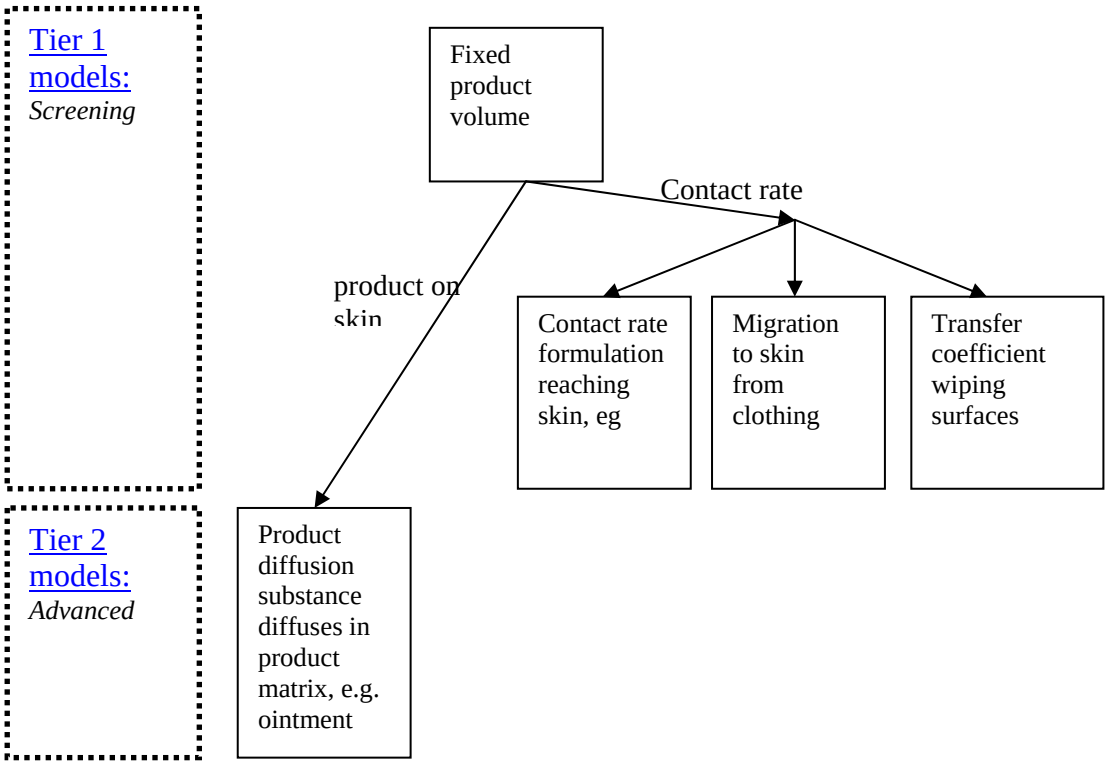
Models in the CONSEXPO 3 program

The models in the CONSEXPO 3 program range from simple screening models to complicated models. The upper model is the most simple, omitting even the time course of exposure. The ones below it incorporate time and a better description of exposure scenarios. The flow diagrams below shortly overview the models and their position within the tiered system of exposure assessment.

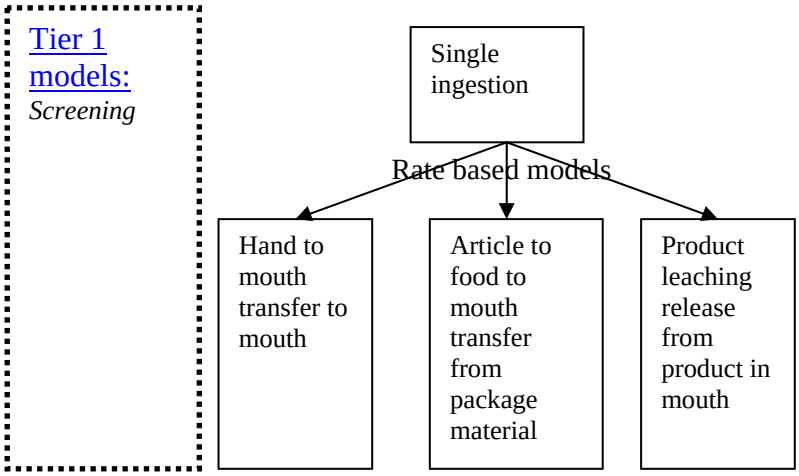
<u>Inhalation</u>



Dermal


Tier 1 models:
Screening
Tier 2 models:
Advanced
Fixed product volume
Contact rate
product on skin
Contact rate formulation reaching skin, eg
Migration to skin from clothing
Transfer coefficient wiping surfaces
Product diffusion substance diffuses in product matrix, e.g. ointment

Oral


Tier 1 models:
Screening
Single ingestion
Rate based models
Hand to mouth transfer to mouth
Article to food to mouth transfer from package material
Product leaching release from product in mouth

B. 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. Prime use of these models are 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.

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/

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. The feature of the generic houses is as shown in.

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, the such many database might cause a confuse to risk assessors who aims 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-story residence will be chosen by defaults, and that US EPA(1997) recommends a fixed story 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/

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 (foots and gallons) instead of SI-units. User input and interpretation of results is hampered for those not used to these units.

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/

C. 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 $PDR = C \times CR$, 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 a an in use concentration or an 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.

D. 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 tapwater 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.

Price P.S., Young J.S. and Chaisson C.F. 2001. Assessing Aggregate and Cumulative Pesticide Risks Using a Probabilistic Model. Annals of Occupational Hygiene 45: 131-142.

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.
US EPA (U.S. Environmental Protection Agency). 1997. Exposure Factors Handbook. EPA/600/P-95/002F(a-c), Washington, DC.
US EPA. 1997. Standard Operating Procedures (SOPs) for Residential Exposure Assessments. US-EPA, Draft.

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.

3.5 Defaults for non-professional use and residential exposure to biocides

1 General Introduction

In contrast to the professional user, hardly any (public) data are available for the estimation of the exposure of the non-professional user to biocides. Therefore, in most cases an exposure estimation should be obtained using a model. For the risk assessment of the non-professional user to biocides there is a significant need for characterization/standardization of the exposure. However, as a group of products, biocides vary enormously with regard to exposure and uptake. The decision was therefore taken to define the different main categories within the biocides, and to put together a fact sheet per main category. This chapter deals with non-professional use of ‘pest control products’. A fact sheet about ‘disinfectant products’ is being prepared.

Within the pest control products main category, as few product categories as possible are defined, which together describe the whole main category. The “pest control products” main category includes the following product categories: sprays, electrical evaporators and baits. The composition and the use of the type of products within the category is examined for every product category. To estimate the exposure and uptake of substances from pest control products, default models with default parameter values are determined for every product category in this fact sheet. The default-models and default-parameter values are available in the form of a database. Using this data, it is possible to standardize the exposure calculations for consumers due to the use of pest control products.

This fact sheet is principally aimed at exposure to the formulation (i.e., the whole product) and is, as such, independent of the active ingredient. This means that the information about the active ingredient must be added later. This mainly concerns information about the concentration and the physical-chemical properties of the active ingredient.

Non-professional use only
The default values in the fact sheets have been put together for consumers (private or non-professional users). They are not applicable for people who work with pest control products in a professional capacity, such as in the agricultural sector, for example. This fact sheet therefore only describes pest control products which are available to the consumer for private use.

Using the models in CONSEXPO and the default values for consumers presented here as

background data, it is nonetheless possible to calculate the exposure and uptake of pest control products by professional users. Of course, the differences in products and product use between the consumer and those using pest control products professionally must be taken into account.

Exposure during application and post-application
Two groups can be distinguished in the risk assessment for consumers: the person who applies the product and those who experience the highest exposure after application; this is usually children. The person who applies the product (the user) is the one who actually uses the formulation and, if necessary, dilutes it to the required concentration (‘mixing and loading’). We expect the user to be confronted with a high exposure during ‘mixing and loading’ and during use.

In the post-application phase, children are regarded as the risk group with a high exposure, based on the following exposure arguments: crawling children can have intensive contact with treated surfaces, they have extensive hand-mouth contact, play relatively close to the ground and, furthermore, have a relatively low body weight.

The exposure calculations are based on children of between 10 and 11 months, since this group demonstrates the most crawling and hand-mouth contact, combined with a relatively low body weight.

‘Reasonable worst case’ estimate
The basis for the calculation and/or estimation of the default parameter values are consumers who frequently use a certain pest control product under relatively less favorable circumstances. For example, when using an aerosol can, basic assumptions are: relatively frequent use, application of a relatively large amount in a small room with a low ventilation rate, and a relatively long stay in that room. Every scenario is based on a realistic situation, in which exposure and uptake are substantial.

For all calculations of exposure and/or uptake the 75^{th} or 25^{th} percentile is used.
Multiplication of two 75^{th} –percentile parameter values will result in a 93.75th percentile, whereas multiplication of three 75^{th} –percentile parameter values will result in a 98.5th percentile.
For the calculations using CONSEXPO (Van Veen, 2001) not all parameter values are multiplied, on the other hand, parameter values may influence each other.
Since for all parameter values a $75/25^{th}$-percentile is calculated or estimated, the resulting outcome in the calculation is a higher exposure and/or uptake. Given the number of parameters and the relationship between the parameters, it is expected that the calculated values for exposure and uptake will result in a 99-percentile.

The end result is a 'reasonable worst-case' estimate for consumers who use relatively large amounts of pest control products under less favorable circumstances. In the “General fact sheet” (Bremmer and van Veen, 2000), the boundary conditions under which the defaults are arrived at are dealt with in more depth.

Reliability of the data
A number of parameters are difficult to estimate based on the literature sources and unpublished research. A value must still be chosen for these parameters, otherwise it is not possible to carry out any quantitative exposure estimates. This is why a quality factor (Q-

factor) is introduced, which is in fact a grading system for the value of the estimate of the exposure parameter. Low Q-factors indicate that the default value is based on insufficient (or no) data. If such a default is used in an exposure analysis, it should be looked at and, if possible, adapted. If representative data is supplied by applicants or producers, it can replace the default values. High Q-factors indicate that the defaults are based on sufficient (or more..) data. These defaults generally require less attention. It is possible that they will need to be adapted if the exposure scenarios require it. For example, an exposure estimate might be carried out for a room of a particular size; the well-founded default room size would then need to be replaced by the required value. A Q-factor is given to all parameter values in the fact sheets, indicating the reliability of the estimate of the default value. The quality factor can have a value of between 1 and 9. Table 1 shows a summary of the meaning of the values of the quality factor. In the "General fact sheet" (Bremmer and van Veen, 2000), the value of the quality factor is dealt with in more depth.

Table1 Value of quality factor Q

Q	**Value**
9	Ample and good quality data
8	good quality data
7	quality and number of studies satisfactory
6	useable, but open to improvement
5	little data, parameter value is usable as default value
4	single data source supplemented with expert judgment, parameter value doubtful as default value
3	single data source supplemented with expert judgment, parameter value not reliable as default value
2	educated guess from similarities with other products
1	educated guess, no data

2 Spray applications

2.1 Introduction

Pest control products to be sprayed are available on the Dutch market in many shapes and sizes. During a small shopping trip to make an inventory of the products, it was found that garden centers and Do It Yourself stores have ample choice in brands and product types, such as ready-to-use aerosol cans, liquids and powders. The two supermarkets visited had both set up a separate stand with anti-insect products during the summer months. The target organisms for these pest control products are invertebrates, mainly insects such as aphids, mosquitoes or fleas.

Straetmans (2000) has put together a detailed literature overview about the exposure of the consumer to biocides during and after a spray application. Straetmans' data is used as a starting point for this chapter.

During use, sprays produce an aerosol cloud of very small to small droplets. The speed with which the droplets fall depends on the size of the droplet. Smaller droplets stay in the air for longer. The aerosol generation also means that few volatile ingredients remain in the air for any time. Llewellyn et al. (1996) show that a much higher exposure occurs in a situation where spraying is carried out above the head than when it is aimed at the floor (surface sprays). This can be attributed to the contact with the settling of large aerosol particulates.

There are two main aspects when characterizing the exposure of spray applications, that is, whether the formulation still needs to be processed before application (mixing and loading) and the target of the application. With regard to mixing and loading, there is a distinction between:

- **Liquid concentrate,** that is diluted and sprayed in a plant sprayer and whereby, during the dilution, evaporation can occur,
- **Powders and granules,** which are dissolved in water and are sprayed in a plant sprayer; the powder can disperse during dissolving.

With regard to the target, one can distinguish between the following four types of application.

- **Targeted spot** application refers to the spraying of hiding places of crawling insects and ant tunnels: it often concerns a relatively small surface to be sprayed, which is sometimes difficult to reach both for the user and for the non-user, for example, behind the refrigerator or a radiator, or in/under kitchen cabinets. When considering the method and extent of exposure, the spraying of plants against red spider mite and such like can be compared with the 'spot' application.
- **Crack and crevice** application concerns the spraying of cracks and crevices to control silver fish, cockroaches and so forth, for example, on baseboards in living and accommodation areas, and in cracks and holes in wooden floors.
- **General surface** application is the spraying of large surfaces such as a carpet or couch to control dust mites or fleas, for example.
- **Air space** application is the spraying of living, working or accommodation areas against flying insects, whereby the user stands in the middle of the room and sprays all four of its upper corners.

These spray applications differ from each other in the manner and extent to which the user and the by-standers are exposed. For example, a difference is expected in exposure during crack and crevice application and during a general surface spray, due to the longer application time of the latter treatment. A difference in the exposure during application can also occur due to the height at which the spraying takes place; above the head, as is usual during an air space application, or aimed at the floor, such as during a general surface spray. After application of these sprays, there is a difference in the size of the wipeable surface, amongst other things. Worst case, it is assumed that the entire sprayed surface of all types of spray are within the reach of crawling children. The default-scenarios for exposure after application are drawn up for this target group.

In the remainder of this chapter, we first concentrate on a number of parameters that are important for several spray applications, such as the frequency of use, the droplet size and the respirable fraction. We then describe the exposure during mixing and loading of a plant

sprayer, for both liquid concentrates and powders/granules. The exposure during and after application is then described for the four spray applications mentioned above.

2.2 General parameters for the spraying process

Table 2 shows all of the models used in this chapter to describe the mixing and loading and to describe the different types of spray applications.

Table 2 Overview of the models used for spray applications

Situation		**Route of exposure**			
		contact	inhalation	dermal	oral
before application	Dilution of liquid	contact	evaporation from mixture	contact rate	
	Dissolving a powder or granules	contact	constant concentration	contact rate	
During application	Targeted spot	contact	spray cloud	contact rate	spray cloud
	Crack and crevice	contact	spray cloud	contact rate	spray cloud
	General surface	contact	spray cloud	contact rate	spray cloud
	Air space	contact	spray cloud	contact rate	spray cloud
After application (aimed at children)	Targeted spot	contact		transfer coefficient	hand-mouth
	Crack and crevice	contact		transfer coefficient	hand-mouth
	General surface	contact		transfer coefficient	hand-mouth
	Air space	contact		transfer coefficient	hand-mouth

The models that describe the spray applications are the same for the four different methods of spraying (targeted spot, crack and crevice, general surface and air space). In this section, we concentrate on parameters that are important for several spraying methods. These parameters are grouped together into the models in which they are applied. The models themselves and the meaning of the parameters are not considered here; these are described in detail in "CONSEXPO 3.0, consumer exposure and uptake models" (Van Veen, 2001).

2.2.1 Parameters for the contact scenario

- *Frequency of Use*

Up to now, there has been little insight into the extent to which consumers use pest control products. The only references that were found were: Weegels (1997) and Baas and Van Veen (2002, in preparation). Weegels carried out a survey using a questionnaire and by asking a limited number of users (out of a total of 30 people on the panel) to keep a diary about the extent and the method of their use of consumer products, including biocides. Baas and Van Veen report on observational research and interviews with users of biocide sprays.

In general, the use of pest control products will be limited to the actual control of any plague, that is, the product will not be used if there are no pests. Therefore it is expected that the use of pest control products mainly to take place in the summer, since it is usually in this period that invertebrates (insects, arachnids, slugs, snails and such like) appear. In the 3 weeks during which Weegels carried out her diary survey, 11 people (from the panel of 30) actually used biocides. These 11 people were selected on the grounds that they had used biocides in the month prior to the research. During a period of 3 weeks, these 11 people used a spray a total of 11 times, whereby repeated sprayings during one course of treatment, as is often recommended on the packaging, were each counted separately. These values can be used to calculate a yearly frequency if one assumes that over a six month period, mainly in the summertime, biocides are used with a frequency equal to that in the 3 weeks during which the diary survey was carried out, and that no biocides were used in the other six months of the

year. It should be remembered that people are considered who actually use biocides, and therefore do not represent the general public. This is consistent with the goal of the study: to find out about the exposure and risk of those who use sprays.

Based on these assumptions, the frequency of spray applications is calculated to be 9 times per person per year. Of the 11 times that a spray was used in van Weegels' survey, it was used 8 times after mixing and loading of a liquid, but there not one single case of spraying after mixing and loading of a powder or granules. The frequency of mixing and loading, related to the frequency of spraying (9 times/person/year), is calculated at 6 times per person per year.

Baas and Van Veen (2002, in preparation) report the results of interviews coupled with the observations of spraying behavior. Just as with Weegels' survey, they used people who had indicated that they use pest control products; organic products were also included. Table 3 shows the frequencies of use found. The air space application concerns ready-to-use products, where no mixing and loading is required.

Table 3 Frequency of use (Baas and Van Veen, 2002, in preparation)

Application	**Number of people**	**Frequency per year [mean ± SD]**
Targeted spot	14	3.7 ± 2.9
Air space	2	84 ± 8.5
Crack and crevice	1	12
General surface	3	2.3 ± 0.6

The limited data given above is used to derive default values and quality factors for the frequency of use of sprays; these are shown in table 4.

Default values

Table 4 Frequency of use default values

Application	**Frequency [times per year]**	**Q**
Mixing and loading, liquid	6	5
Mixing and loading, powder or granules	3	5
Spraying, targeted spot	9	5
Spraying, air space	90 [1)]	5
Spraying, crack and crevice	9	5
Spraying, general surface	9	5

1) daily use over a period of 3 months

It should be remembered that for the default values, it is endeavored to estimate the 75th percentile and not averages. For the relatively high value of the air space application, it should be remembered that the product is used at locations where there is a continual problem due to mosquitoes or flies during the 'fly season'. This is confirmed by the Dutch Animal Plague Knowledge and Advice Center, which states that in areas with many mosquitoes (near moorland, for example) such products are used several times a week (KAD, 2001). A daily use over a 3-month period is assumed, based on a 'heavy' user.

2.2.2 Density

In various models and scenarios that describe the spraying process, the density of the product is an important parameter. We assume that the active ingredient in liquid concentrates is normally dissolved in volatile organic solvents. The density of these solvents is around 0.7 g/cm^3; this value is used as the default value for the density of liquid concentrates. If it turns out that water is the main constituent of a liquid concentrate, a density of 1 g/cm^3 is used. In ready-to-use aerosols, the active ingredient is diluted in an organic solvent; the default value for the density is here also taken to be 0.7 g/cm^3. Products that are sprayed using a plant sprayer are dissolved in water. The density of the ready-to-use formulation is set at 1 g/cm^3.

Default values

Density of the solvents:
- main ingredient volatile organic solvents; 0.7 g/cm^3 (quality factor Q: 7)
- main ingredient water; 1 g/cm^3 (quality factor Q: 7)

2.2.3 Parameters for the 'spray cloud model'

To calculate the inhalation exposure for the user, the 'spray cloud model' from CONSEXPO is used for all spray applications.

- *Droplet size*

Pest control products can be sprayed using a ready-to-use aerosol can or a plant sprayer. The droplet size is an important parameter when estimating the exposure. Smaller drops fall at a lower speed and stay in the air for longer. The large droplets will quickly disappear from the air after being formed. As an indication: the falling time of droplets with a diameter of 100 µm from a height of 3 meters is calculated at 11 sec, and for droplets of 10 µm it is calculated at 17 min (Biocides Steering Group, 1998). If a larger droplet is sprayed, part of the aerosol cloud will consist of finer droplets which stay in the air for longer, as a result of edge effects around the nozzle and the 'bounce back' effect due to spraying onto a surface. There is hardly any measurement data available for the droplet size.

"Assessment of human exposure to biocides" from the Biocides Steering Group (1998) gives a WHO classification with regard to the droplet size of sprays (table 5).

Table 5 Classification of aerosol droplets

Droplet diameter [µm] a)	**Classification**
< 15	mist
< 25	aerosol, fine
25-50	aerosol, coarse
51-100	mist
101-200	spray, fine
210-400	spray, medium
>400	spray, coarse

a): the median diameter; half of the particles are larger, half are smaller

In the same study, a classification is also given for the droplet size for various types of agricultural use (table 6).

Table 6 Droplet size for different types of agricultural use

Aim of use	**Droplet diameter [µm]**
flying insects	10-50

insects on plants	30-50
precipitation on surface	40-100
application on the ground	250-500

The Dutch Aerosol Association (NAV,1995)distinguishes between aerosol sprays in aerosol cans with very fine atomized dry sprays (such as asthma sprays and insecticides) and fine atomized wet sprays (such as hair sprays and paint sprays).
Matoba et al. (1993) measured the droplet size of an aerosol can with a spray for air space applications. The average droplet size was 30 µm with a range of 1-120 µm. Based on the measurements, Matoba et al. classified the droplets into three groups: 10 % of the particles have a droplet size of 60 µm, 80 % have a droplet size of 20 µm, and 10 % of the particles have a droplet size of 5 µm. A spray for air space applications generally has a smaller droplet diameter than a spray for surface applications.

Based on the data above, an average droplet size for aerosol cans for air space spraying is taken to be 5 µm, and for aerosol cans for surface applications it is taken to be 15 µm. The default value for the droplet size for a plant sprayer is given as 30 µm (table 7).
The default values for the droplet size in CONSEXPO concern the average diameter of the aerosol particles. Given the small amount of data a relatively small average droplet size is used, resulting in a (possible too) high exposure. Given this uncertainty, the quality factor is set at 5.

For the risk assessment of new pest control products, applied using an aerosol can, the applicant or producer is obliged to supply data regarding the droplet size to the Dutch Board for the Authorization of Pesticides (CTB).

- *Respirable fraction*

In the ‘droplet size’ section above, an average particle size for various spray applications is assumed of 5, 15 and 30 µm, respectively. In the Biocides Steering Group's report (1998), it was indicated that for an aerosol cloud with particles having an average aerodynamic diameter of 5, 10 and 10 µm, respectively, the respirable part of the inhaled particles is 34.4, 1.7 and 0.1 %, respectively.

The droplet size is obviously a distribution. Mainly based on the measurements by Matoba et el.(1993), it is assumed that, worst case, 10 % of the particles with an average particle size of 15 µm will be smaller than 5 µm. Based on the data from the Biocides Steering Group, it is assumed that, of the droplets smaller than 5 µm, half are respirable.

Based on these assumptions (“of particles with an average particle size of 15 µm, 10 % is smaller than 5 µm” and “of the particles smaller that 5 µm, half are respirable”) it is calculated that, of the particles with an average particle size of 15 µm, 5 % of the particles are respirable. In CONSEXPO it is assumed that the other 95 % precipitate in the upper airways and are then taken in orally. Using the same reasoning, one would expect 4 % of the particles with an average particle size of 30 µm to be smaller than 5 µm and, therefore, 2 % of the particles is expected to be respirable.

Table 7 Default values for particle size and respirable fraction

Spray application	Particle diameter [µm]	Respirable fraction [a] [%]	Q
Aerosol can			
air space	5	34.4	5
targeted spot; crack and crevice; general surface	15	5	5
Plant sprayer			
targeted spot; crack and crevice; general surface	30	2	5

a) CONSEXPO assumes that the other part is taken in via the oral route

- *Airborne fraction*

Sprays for a surface application (such as targeted spot, crack and crevice and general surface sprays) produce a coarser droplet, designed to end up on the sprayed surface. Part of the aerosol cloud will actually consist of finer droplets which stay in the air for longer and can be inhaled. No references were found with relation to the percentage of the aerosol cloud that become airborne. The default value will initially be set at 15%.

Sprays for air space spraying applications are meant to produce a very fine mist which stays in the air for a longer period of time. The value of this parameter can therefore be set at 100% for air space spray applications: all of the active ingredient is present in the air after spraying.

- *Radius aerosol cloud*

To get an idea of the diameter of the aerosol cloud, Straetmans (2000) sprayed various types of sprays, from a distance of 50 cm, onto kitchen towel, after which the diameter of the wet patch was measured. The different equipment (ready-to use sprays and a plant sprayer) appeared to consistently produce aerosol clouds of ± 20 cm in diameter (variation of ± 18 to 21 cm). The default value for this parameter has therefore been set at 20 cm for all spray applications.

2.2.4 Parameters for the 'contact rate' model

The 'contact rate' model from CONSEXPO is used to calculate the dermal exposure of the user during application, for all spray applications.

- *Contact rate formulation*

During professional use of surface sprays, at a pressure of 1-3 bar, a value of 53.7 mg formulation/min was found as the 75th percentile for the dermal exposure (Biocides Steering Group (1998)). Thompson & Roff (1996) report a total amount of 0.006 – 0.35 ml formulation ending up on the skin when using a spray. The application time was 8 min and 23 sec, that is, a contact rate of 42 µl/min for 0.35 ml. Since Thompson & Roff's data is based on consumer use, it is taken as the default value. For a density of 0.7 g/cm^3 , 42 µl/min is equivalent to a value of 29 mg/min This value is used for targeted spot, crack and crevice and general surface applications.

For targeted spot, crack and crevice and general surface applications, the emission speed, during actual spraying, is 1.3 g/sec. For air space applications, an emission speed of 0.7 g/sec is assumed. The contact rate is related to the emission speed, the amount of formulation that

leaves the aerosol can per minute. For air space sprays, a contact rate formulation is calculated that is proportionally lower then the emission speed, that is, a 0.7/1.3 part of the contact rate formulation of the other three spray applications. The contact rate formulation is calculated to be 23 µl/min (0.7 / 1.3 * 42 µl/min), which is equal to 16 mg/min.

2.2.5 Parameters for the 'transfer coefficient' model
The 'transfer coefficient' model from CONSEXPO is used for the exposure of children after application of the product, for all four of the spray applications. The parameter values for the four applications are similar, and are therefore discussed here.

- *Dislodgeable fraction formulation*

In an HSL Pilot study on aerosols (cited in the Biocides Steering Group's report, 1998) 10 % is given as the value for the 'dislodgeable residue from treated carpet' parameter. The concept SOP's of the US-EPA (1997) assume that 50 % of the amount of the active ingredient gets on to the surface and can be brushed off. Based on this data, the default value for the dislodgeable fraction is set at 30% .

- *Transfer coefficient*

The 'transfer coefficient' is the surface that is wiped per unit time due to skin contact. The concept-SOP's from the EPA (1997) give a value of 2.3 m^2 /day, whereby it is assumed that there is activity for 4 hours a day, which means a transfer coefficient of 0.6 m^2 /hr.

2.2.6 Parameters for hand-mouth contact
If dermal exposure of children occurs after the application of a pest control product, those children can also be exposed orally due to hand–mouth contact. The parameter that describes hand- mouth contact is the 'intake rate formulation' parameter.

- *Intake rate formulation*

Dermal exposure of children can take place on any uncovered skin, that is, on the head, the arms and hands, and on the legs and feet. It is assumed that all of the product that ends up on the hands is taken in orally due to hand-mouth contact. The hands form about 10 % of the total uncovered skin (see Bremmer and van Veen, 2001). It is therefore assumed that 10 % of the amount of the product that ends up on the skin of a child is taken in orally by hand-mouth contact. The intake rate formulation can be calculated based on this assumption.

2.3 Exposure to liquid concentrate during mixing and loading

The exposure to the active ingredient, which the user experiences during the dilution or dissolving of the active substance with/in water and during the loading in a plant sprayer, depends on the factors listed below, but will be independent of the final method of application of the spray. This is why the exposure during mixing and loading for the four different application areas is bundled together and is handled as 'exposure before application'.

When determining the defaults, a distinction is made between 'diluting a liquid' and 'dissolving a powder'. These product forms influence the dermal and inhalation exposure of the user during mixing and loading. In all literature references, the powder or liquid was dissolved in water (including Roff & Baldwin, 1997; Weegels, 1997; Leidy et al, 1996; Fenske et al., 1990).

- *Use duration and total duration*

Smith (1984) gives the length of time measured for mixing and loading pesticides, which were used outside for the spraying of crops. Considering the amounts used, this data cannot be compared with the mixing and loading of biocides for use in a plant sprayer indoors. Weegels (1997) gives an average total time (for two people) of 80 sec, for mixing and loading a liquid in a plant sprayer.

Dermal exposure: contact rate

Dermal exposure during mixing and loading of biocides for indoor use will almost always be restricted to the hands (Van Hemmen, 1992). Smith (1984) gives an indication of the amount of formulation that ends up on the skin during mixing and loading per unit time, measured using so-called 'wrist pads'. Van Hemmen does not include any data collected using such pads in his inventory of measurement data during professional exposure, since a considerable amount of formulation will get onto the palm of the hand and the fingers without being detected by the pads.

- *Contact rate formulation*

The results of Van Hemmen's inventory (1992) give an indicative value for dermal exposure (in mg/hr) during mixing and loading. This value is the 90th-percentile of the measured exposure: 0.3 ml formulation (liquid concentrate)/hr by the dilution of 25 kg of the formulation. Van Hemmen indicates that there is a strong correlation between the level of the exposure and the amount of pesticide that is used. For consumer exposure, the values mentioned will have to be extrapolated to predict the amounts that are used by the consumer. In Weegels (1997) and Roff & Baldwin (1997) a final concentration of 0.1% active ingredient in the diluted formulation is given for mixing and loading by consumers. Roff & Baldwin mixed 200 ml of concentrate in 2.3 liters of water. For a plant sprayer with a capacity of 2 liters, this is equivalent to 174 ml. 25 kg of liquid concentrate is equivalent to is 35.7 liters (density: ±0.7 g/ml for organic solvents). This data is used to calculate a *contact rate* of 0.025 µl/min for the consumer. Roff & Baldwin's own data for 'spilling' (<10 µl total concentrate on the skin), cannot be used to calculate a *contact rate,* as no duration is given for mixing and loading. Van Hemmen's indicative value for professional application is extrapolated to the consumer application. A quality factor of 3 is therefore assigned.

Inhalation exposure: evaporation from mixture

During mixing and loading, inhalation exposure to volatile chemical substances which evaporate from the concentrate can occur. This exposure can be described using the evaporation model 'evaporation from mixture'.

- *Release area*

No data was found for this parameter. It is assumed that evaporation takes place from a bottle with a not-too-small circular opening with a 5 cm diameter.

- *Room volume*

'Room volume' is interpreted here as 'personal volume': a small area around the user of 1 m^3. For the short time in which the treatment takes place, a small area around the user is relevant for the inhalation exposure of the user, to be able to describe the evaporation of the active ingredient from the concentrate. Since no data were found with regard to the size of the room, a quality factor of Q = 4 is assigned.

- *Ventilation*

The ventilation rate that Bremmer & van Veen (2000) give for a non-specified room is taken as a default value; namely 0.6 hr^{-1}

Default values

Default values for mixing and loading: dilution of a liquid

Model	.Parameter	Default value	Q	References, comments
Contact	frequency	6 $year^{-1}$	5	see 2.2.1
	use duration	80 sec	6	see above
	total duration	80 sec	6	see above
	start exposure	0	9	direct exposure
Dermal exposure				
Contact rate	contact rate formulation	0.025 µl/min	3	see above
	density formulation	0.7 g/cm^3	7	see 2.2.2
Inhalation exposure				
Evaporation from mixture	release area	20 cm^2	4	see above
	room volume	1 m^3	4	see above
	temperature	20 °C	8	room temperature
	ventilation	0.6 hr^{-1}	8	see above

2.4 Exposure to powder and granules during mixing and loading

There are several differences with regard to the exposure to powder and granules during mixing and loading compared to the dilution of a liquid concentrate:
- powders can disperse (as can the dust around granules, to a lesser extent),
- with regard to the dermal exposure, specific measurement data about the worker's exposure is known.

A number of parameters (use duration, total duration, room volume) have the same value as for the dilution of a liquid. Only the parameters with a different value are mentioned below.

Dermal exposure: contact rate

- *Contact rate formulation*

Van Hemmen (1992) gives 2 g formulation/hr as the indicative value for dermal exposure to solids during the mixing and loading of 25 kg of formulation. Converting this for consumer exposure, and assuming the use of 0.4 g in 2 liters (based on the directions for use on the packaging), this gives a *contact rate* of 0.53 µg formulation/min. Van Hemmen's indicative value for professional application is extrapolated to the consumer application. A quality factor of 3 is therefore assigned.

Inhalation exposure: constant concentration

- *Room volume*

'Room volume' is interpreted here as 'personal volume': a small area of 1 m^3 around the user. A small area around the user is relevant for the inhalation exposure of the user, for the short time in which the treatment takes place, as it enables the evaporation of the active ingredient from the concentrate to be described. Since no data with regard to the size of the room were found, a quality factor of Q = 4 is assigned.

- *Amount released*

Van Hemmen (1992) gives an indicative value of 15 mg formulation/hr for the inhalation exposure during the professional use of solid substances during mixing and loading, based on the use of 25 kg of formulation. For consumer exposure when using 0.4 g of solid substance, this is equivalent to an inhalation exposure of $4*10^{-3}$ µg formulation per min.

Van Hemmen's indicative value for professional application is extrapolated to the consumer application. A quality factor of 3 is therefore assigned.
The quality of granules, particularly the degree of powder forming, determines how much lower the exposure will be for granules. For the time being, it is assumed that for granules a maximum of 10% is present in the form of powder. The inhalation exposure is therefore expected to be 10-fold lower than with powders, and is set at $4*10^{-4}$ µg formulation per min.

Default values
Default values for mixing and loading, dissolving a powder/granules

Model	Parameter	Default value	Q	References, comments
Contact	frequency	3 $year^{-1}$	5	see 2.2.1
	use duration	80 sec	6	see 2.3
	total duration	80 sec	6	see 2.3
	start exposure	0	9	direct exposure
Dermal exposure				
Contact rate	contact rate formulation	0.53 µg/min	3	see above
Inhalation exposure				
Constant concentration	room volume	1 m^3	4	see 2.3
	amount released: powder granules	 $4*10^{-3}$ µg/min $4*10^{-4}$ µg/min	 3 3	 see above see above

2.5 Targeted spot application

Scenario
This scenario is based on a private user who sprays an object from close by. It is also assumed that the spraying is carried out indoors. Targeted spot treatment can take place anywhere in the house, per target. This will often involve plants on the window sill in the living room, but treating the cat in the kitchen or spraying an ant trail along a window or behind the refrigerator also falls into this category. Using the 'realistic worst case'-scenario setting, a relatively small room is assumed, which will result in a higher exposure. The inhalation exposure 'spray: cloud' model and the dermal exposure model 'contact rate' from CONSEXPO 3.0 are used to describe this scenario. The oral exposure is handled in the inhalation exposure model. CONSEXPO assumes that the non-respirable fraction is taken in orally.

The largest part of the formulation will end up on the object being sprayed, but some will also end up on the surface around it. The exposure after application concentrates on the exposure of crawling children, if they come into contact with these surfaces. It is assumed that a child (default 10.5 months) crawls over this surface for 1 hour a day during a 14-day period. Exposure after application is described using the dermal exposure model 'transfer coefficient' and the oral exposure model 'hand-mouth contact'.

Exposure during application
Contact
- *Use duration*

Baas and Van Veen (2002, in preparation) report a use duration of between 8 and 185 seconds (average of 76± 58 sec) based on observations of aerosol can use. Weegels (1997) reports a spraying period of between 30 and 56 seconds, again based on observations. In diaries kept by volunteers, a period of between 4 and 40 minutes was recorded. This latter

time period is more likely to represent the total duration of the job than the active spraying time. Based on this data, a default value of 90 sec was assumed as the period of time during which spraying actually occurs, and a use duration, the time during which the spraying takes place, of 6 minutes.

- *Total duration*

Using the 'spray cloud' model from CONSEXPO, the average exposure during the duration of exposure was calculated (mean event concentration) as the parameter for the inhalation exposure. The inhalation exposure during the spraying process will be at a maximum some time after spraying, and with then decrease. A total time of 4 hours is taken as the default value for the inhalation exposure during the application. It is assumed that the user leaves the treated room 4 hours after the application.

Inhalation exposure 'spray cloud model'

- *Emission rate formulation*

To determine the amount of formulation that leaves the sprayer per unit of time, the using up of an 'aerosol type sprayer' was calculated (mostly in older literature such as Wright & Jackson, 1975 and Wright & Jackson, 1976; Wright & Leidy 1978). If the data from the various types of sprayers is compared, 'aerosol type sprayers' seem to be at the bottom of the range of use per time unit (± 0.35 g/sec). The 'compressed air sprayers' are somewhat higher (± 1 g/sec; Wright & Jackson, 1975; Wright & Leidy, 1978), while the commercially available 'aerosol spray cans' generate the most formulation per second (1.6 g/sec, on average; Thompson & Roff, 1996). For the plant sprayer in Weegels (1997), a *generation rate* of 1.4 g/sec was calculated.

Based on the literature, no distinction could be made between the use of ready-to-use aerosol cans and plant sprayers. For the default value, the use of the different spray equipment is assumed to be the same, and is estimated at 1.3 g formulation/sec. As it is assumed that spraying actually occurred for a period of 90 sec during a time span of 6 minutes, the default value for the emission rate formulation is 0.33 g formulation/sec.

- *Release height*

The places to be sprayed will mainly be in the area from ground level up to window sill height, but the directions for use also indicate that lamp shades can be treated. As the products are usually plant sprays, and the plants will be treated at window sill or work top height, unless a specific value is given in the WG/GA, a default value for the spraying height is set at 100 cm.

- *Room volume* and *ventilation rate*

Treatment can take place anywhere in the house. Using the 'realistic worst case'-scenario setting, a relatively small room with no extra ventilation is assumed. Standard values from the "General Fact sheet" (Bremmer and van Veen, 2000) were used, where the room, which is not further specified, has a volume of 20 m^3 and a ventilation rate of 0.6 h^{-1}.

- *Surface*

No data is available for this parameter. The scenario assumes that individual house plants are treated. A default value of 2 m^2 was chosen for the treated surface.

Exposure after application
Contact

- *Use duration, total duration*

When estimating the total duration of exposure, it is important to know whether the application takes place inside or outside. During their observational research, Baas and Van Veen (2002, in preparation) only came across use of these products outside. House plants and pets are treated outside. We would expect the residues to disappear quickly outside, but no specific research has been found.

Products can also be used indoors. From the literature it is known that measurable residues are still present in the treated room long after the treatment with a pesticide (Leidy et al., 1987; Wright et al., 1994; Koehler & Moye, 1995; Leidy et al., 1996). The total duration of the contact with the active ingredient can, in principle, be stretched out over a period of months. As the user and the by-stander are usually occupants of the house in which the formulation is used, this entire period should be included. Simulations of the exposure show that the tail end of the exposure contributes little to the exposure as a whole. When defining the total contact time of the user, only the start of the period after use is looked at, which is quantified as 14 days after the treatment. This value is used for children who are exposed orally and dermally after application.

Dermal exposure: transfer coefficient

- *Dislodgeable fraction formulation*

By multiplying the emission rate formulation and the use duration, the total amount of sprayed formulation can be calculated (0.33 g/sec x 360 sec = 118.8 g). The scenario assumes that some of the formulation ends up on the object being sprayed, and some ends up on the surfaces around it. Section § 2.2.3 shows that the airborne fraction is taken to be 15 %. It is assumed that this amount (15 % of the total amount sprayed 118.8 g = 17.8 g) ends up on the floor next to the object that is being sprayed. Section § 2.2.5 shows that of the amount on the floor surface, 30 % is dislodgeable/wipeable (i.e., 5.3g). The floor surface is 2 m^2 (see *surface* below). The dislodgeable fraction formulation is therefore calculated as 2.7 g/m^2.

- *Surface*

The scenario assumes that some of the formulation ends up on the object being sprayed, and some ends up on the surfaces around it. A default value of $2m^2$ was chosen for the surface on which the formulation lands around the treated object.

Default values

Default values for exposure during targeted spot application with an aerosol can

Model	Parameter	Default value	Q	References, comments
Contact	frequency	9 $year^{-1}$	5	see 2.2.1
	use duration	6 min	6	see above
	total duration	4 hr	6	see above
	start exposure	0	9	direct exposure
Inhalation exposure				
Spray: cloud model	emission rate formulation[a)]	0.33 g/sec	6	see above
	density formulation	0.7 g/cm^3	7	see 2.2.2
	airborne fraction	15 %	4	see 2.2.3
	droplet size	15 µm	5	see 2.2.3
	release height	100 cm	6	see above
	radius aerosol cloud	20 cm	6	see 2.2.3
	room volume	20 m^3	8	see above
	ventilation rate	0.6 hr^{-1}	8	see above
	surface	2 m^2	4	see above
	respirable fraction	5 %	5	see 2.2.3
Dermal exposure				
Contact rate	contact rate formulation	42 µl/min	5	see 2.2.4

a) calculated parameter, see text

Default values of exposure after targeted spot application

Model	Parameter	Default value	Q	References, comments
Contact	frequency	9 $year^{-1}$	5	see 2.2.1
	use duration	14 x 1 hr	6	see above
	total duration	14 days	6	see above
	start exposure	0	9	direct exposure
Dermal exposure				
Transfer coefficient	dislodgeable fraction formulation [a)]	2.7 g/m^2	6	see above
	transfer coefficient	0.6 m^2/hr	6	see 2.2.5
	surface	2 m^2	4	see above
Oral exposure				
Hand-mouth contact	intake rate formulation		5	see 2.2.6

a) calculated parameter, see text

In the scenario it is indicated that the default values are for spraying with an aerosol can. If the spraying is carried out using a plant sprayer, water is the main ingredient of the sprayed liquid instead of an organic solvent. As a consequence, the density becomes 1 g/cm^3 (see § 2.2.2). One must also take into account a different droplet size (30 µm instead of 15 µm) and therefore also a different respirable fraction (2 % instead of 5 %) (see § 2.2.3).

2.6 Crack and crevice application

Scenario

This scenario is based on a private user who is controlling crawling insects on the ceiling. It is assumed that the application is to be carried out on individual target areas, whereby one quarter of the ceiling is treated using an aerosol can. The user is assumed to stay in the treated room for 4 hours after the application.

To calculate the exposure of the user during the crack and crevice application, the 'spray cloud model' is used for the inhalation exposure and the 'contact rate' model is used for the dermal exposure.

The exposure after application is described for crawling children who are present in the room after a crack and crevice treatment has been carried out. It is assumed that a child (default 10.5 months) crawls over the treated surface for 1 hour a day during a 14 day period. Exposure after application is described using the dermal exposure model 'transfer factor' and the oral exposure model 'hand-mouth contact'.

Exposure during application
Contact

- *Use duration*

In the literature, the following times are reported for the use duration: Leidy et al., 1982 : 8 – 11 min.; Wright & Jackson, 1975: 6.1 – 8.1 min.; Wright & Jackson, 1976: 10.3 – 11.9 min. Observational research by Baas and Van Veen (2002, in preparation) shows that the actual spraying time is much shorter. For a duration of use of the aerosol can of between 40 and 160 seconds, the period of active spraying was between 10 and 26 seconds. This might be explained by assuming that the previously mentioned references include the entire job, while Baas and Van Veen (2002, in preparation) only measure the duration of spraying. On this basis, the default value for the time during which spraying actually takes place is set at 60 sec (this duration is important when calculating the emission rate, among other things; see below). It is assumed that the time during which the spraying takes place, the use duration, is 4 minutes.

- *Total duration*

In Leidy et al.(1996), the concentration of the used active ingredient (chlorpyrifos) in the air 1 week after a crack and crevice treatment is 50% of the concentration straight after spraying. Over an 84 day period, the measured concentrations are in some cases equal and in all cases are measurable, even in adjacent untreated rooms. Leidy et al. (1984) show that during crack and crevice treatment (of diazinon), where spraying was carried out under increased (air) pressure, more than 10% of the original concentration, measured straight after the treatment, was still evident at various heights above the sprayed surface 5 weeks after spraying. Davis & Ahmed (1998) report a few instances of surface treatment using chlorpyrifos where, two weeks after application, the product still formed a gas with the resulting deposits. Eight to nine days after a crack and crevice treatment (chlorpyrifos) with a 4.5 liter pressure sprayer, Byrne et al. (1998) still measured concentrations at different heights from 20 up to >50% of the concentrations immediately after spraying. The concentrations of the active ingredients in the air or as a residue on a surface, are of course related to factors such as the type of treatment, the type of equipment, the amounts used for the treatment, the treatment time, etc. This is why the above-mentioned data cannot simply be used to compare a treatment with a ready-to-use spray or a plant sprayer.

For the inhalation exposure, the *average* exposure per application is calculated using the spray cloud model from CONSEXPO. A total time of 4 hours is taken as the default value for the inhalation exposure. It is assumed that the user stays in the treated room for 4 hours after the application.

Inhalation exposure: 'spray cloud model'

- *Emission rate formulation*

The use of the spray per unit time will depend, among other things, on the type of equipment and not on the application. Considering the fact that commercially available aerosol cans often propose a combined 'targeted spot' and 'crack and crevice' treatment in their directions for use (often using the same equipment), the same value for the emission rate of 1.3 g/sec is kept to for the actual spraying using these sprays.

The use duration indicates that in the duration of use of 4 minutes, the period of active spraying was 60 sec. The average emission rate of the formulation during the 4 minutes is 0.33 g/sec.

- *Release height*

'Crack and crevice' sprays are designed to spray baseboards, cracks and crevices, i.e., long splits on the floor with a minimal spray width. The directions for use for this type of spray sometimes state that it is not meant to be used as an air space spray. Baas and Van Veen (2002, in preparation) and Llewellyn et al. (1996) show that there are also applications on the ceiling. Following the " worst case" principle, the spraying height is adjusted for these ceiling applications, and is set at 220 cm.

- *Room volume and ventilation rate*

If no room is specified, the default value for the treated area is derived from Bremmer & van Veen (2000): a room with a surface area of 8 m^2, a volume of 20 m^3 and a ventilation rate of 0.6 hr^{-1}.

- *Surface treated area*

From two articles of Wright & Jackson (1975;1976), it can be deduced that if the crack and crevice treatment is carried out using a small tube on the spray nozzle, the size of the treated surface is 3.4 % and 14.2 % of the total floor surface respectively. It is assumed that the 'width' of the sprayed surface is 5 cm.

Byrne et al. (1998) indicate that when treating without the tube, the treatment area is 30 cm 'wide', that is, a factor 6 larger than with the tube. Based on this factor, and using the data from Wright & Jackson, it is calculated that the treated surface during treatment without the small tube on the spray nozzle is between 21% and 85% of the total floor surface (6x3.4=21 and 6x14.2=85). For the default, 25% of the surface is taken to be the treated surface; for the room mentioned above (surface 8 m^2), this is equivalent to 2 m^2.

Exposure after application

Contact

- *Use duration; total duration*

Based on the data in 'total duration' for exposure during application, and the considerations in section 2.5 under 'total duration', it is expected that with regard to the exposure after application, a playing child will crawl over the treated area for 1 hour a day during a 14 day period.

Dermal exposure: transfer coefficient

- *Dislodgeable fraction formulation*

By multiplying the emission rate formulation and the use duration, the total amount of sprayed formulation can be calculated (240 sec x 0.33 g/sec = 79.2 g). The scenario assumes

that this amount is sprayed on the ceiling. The airborne fraction is 15 %. It is assumed that this amount (15 % of the total amount sprayed, or 11.88g) ends up on the floor surface. Section 2.2.5 shows that, of this amount, 30 % is dislodgeable, i.e., it can be brushed away (0.3 x11.88=3.56g). The surface is 2 m^2 (see *surface* below). The dislodgeable fraction formulation is calculated at 3.56/2 =1.8 g/m^2 .

- *Surface*

In the above calculation, 2 m^2 of ceiling is treated. It is assumed that some of this ends up on the floor, on 2 m^2 of the floor surface.

Default values

Default values for exposure during crack and crevice application with an aerosol can

Model	Parameter	Default value	Q	References, comments
Contact	frequency	9 $year^{-1}$	5	see 2.2.1
	use duration	4 min	6	see above
	total duration	4 hr	6	see above
	start exposure	0	9	direct exposure
Inhalation exposure				
Spray cloud model	emission rate formulation[a)]	0.33 g/sec	6	see above
	density formulation	0.7 g/ml	7	see 2.2.2
	airborne fraction	15 %	4	see 2.2.3
	droplet size	15 µm	5	see 2.2.3
	release height	220 cm	6	see above
	radius aerosol cloud	20 cm	6	see 2.2.3
	room volume	20 m^3	8	see above
	ventilation rate	0.6 hr^{-1}	8	see above
	surface	2 m^2	6	see above
	respirable fraction	5 %	5	see 2.2.3
Dermal exposure				
Contact rate	contact rate formulation	42 µl/min	5	see 2.2.4

a) calculated parameter, see text

Default values exposure after application of crack and crevice spray

Model	Parameter	Default value	Q	References, comments
Contact	frequency	9 $year^{-1}$	5	see 2.2.1
	use duration	14 x 1 hr	6	see above
	total duration	14 days	6	see above
	start exposure	0	9	direct exposure
Dermal exposure				
Transfer coefficient	dislodgeable fraction formulation[a)]	1.8 g/m^2	6	see above
	transfer coefficient	0.6 m^2/hr	6	see 2.2.5
	surface	2 m^2	6	see above
oral exposure				
Hand-mouth contact	intake rate formulation		5	see 2.2.6

a) calculated parameter, see text

The scenario indicates that the default values are given for spraying with an aerosol can. If spraying is carried out using a plant sprayer, water is the main ingredient of the sprayed liquid instead of an organic solvent. The consequences for the density is that it becomes 1 g/cm^3 (see 2.2.2). One should also take into account a different droplet size (30 µm instead of 15 µm) and therefore also a different respirable fraction (2 % instead of 5 %) (see 2.2.3).

2.7 General surface application

Scenario

This scenario is based on a private user spraying the floor surface of a living room with an aerosol can. To calculate the exposure of the user during the application, the 'spray cloud model' is used for the inhalation exposure and the 'contact rate' model is used for the dermal exposure. The oral exposure is handled in the inhalation exposure model. CONSEXPO assumes that the non-respirable fraction is taken in orally.

The exposure after application is described for crawling children present in the room after the treatment has been carried out. It is assumed that a child (default 10.5 months) crawls over the treated surface for 1 hour a day during a 14-day period. Exposure after application is described using the dermal exposure model 'transfer factor' and the oral exposure model 'hand-mouth contact'.

Exposure during application

Use duration

Baas and Van Veen (2002, in preparation) describe a number of general surface applications, where the use duration varies between 44 and 350 seconds. The period of active spraying was shorter: between 31 and 278 seconds. Five minutes (300 sec) is used as the default value for the active spraying time. Ten minutes is used as the value for the use duration, the time during which the spraying takes place.

- *Total duration*

For the total duration, the same values are used as for the crack and crevice application (see section 2.6). For the exposure during application, a total duration of 4 hours is assigned, assuming that the user stays in the treated room for 4 hours after application. With regard to the exposure after application, it is assumed that a playing child crawls over the treated area for 1 hour a day during a 14-day period.

Inhalation exposure: 'spray cloud model'

- *Emission rate formulation*

There are aerosol cans for sale that, according to the directions for use, can be used to treat large surface areas. It is not obvious whether these are other types of sprays than those sold for 'targeted spot' and 'crack and crevice' applications. Although it is expected that the spraying nozzle, in particular, is different on these sprays (and therefore their use), there is no specific data available. For this reason, the value used for the other sprays, calculated as 1.3 g/sec during active spraying, will be used as the default. The use duration indicates that during a time span of 10 minutes, the period of active spraying was 5 minutes. Consequently, 0.65 g formulation/sec is used as the default value for the emission rate formulation.

- *Release height*

'General surface' sprays will mainly be used on floor coverings, although it is also possible to use such a spray to treat a couch for fleas. Baas and Van Veen (2002, in preparation) indicate that during a general surface application the spray is directed towards the floor or the ground. The default spraying height is set at 25 cm.

- *Room volume* and *ventilation rate*

A larger room means a larger floor surface. Spraying is therefore carried out for longer in a larger room, and more of the product is applied. A relatively large room has been chosen as the default value, as it is expected that the exposure, particularly the exposure after application, will yield the highest value in such a room. The values for a living room from the "General fact sheet" (Bremmer and van Veen, 2000) are used as the default values for the room and the ventilation rate. The volume of the living room is 58 m^3, the ventilation rate is 0.5 hr^{-1}.

- *Surface of treated area*

The surface area of the living room, the treated surface in the scenario, is 22 m^2.

Exposure after application

Dermal exposure: transfer coefficient

- *Dislodgeable fraction formulation*

By multiplying the emission rate formulation and the use duration, the total amount of sprayed formulation can be calculated (0.65 g/sec x 600 sec = 390 g). It is assumed that this amount ends up on the floor surface of the living room, so that the amount of formulation per surface unit can be calculated (390 g on 22 m^2, or 17.7 g/m^2). Section 2.2.5 shows that, of this amount, 30 % is dislodgeable. The dislodgeable fraction formulation is calculated at 5.3 g/m^2.

Default values

Default values for exposure during general surface application with an aerosol can

Model	Parameter	Default value	Q	References, comments
Contact	frequency	9 $year^{-1}$	5	see 2.2.1
	use duration	10 min	6	see above
	total duration	4 hr	6	see above
	start exposure	0	9	direct exposure
Inhalation exposure				
Spray cloud model	emission rate formulation [a)]	0.65 g/sec	6	see above
	density formulation	0.7 g/ml	7	see 2.2.2
	airborne fraction	15 %	4	see 2.2.3
	droplet size	15 µm	5	see 2.2.3
	release height	25 cm	6	see above
	radius aerosol cloud	20 cm	6	see 2.2.3
	room volume	58 m^3	9	see above
	ventilation rate	0.5 hr^{-1}	8	see above
	surface	22 m^2	9	see above
	respirable fraction	5 %	5	see 2.2.3
Dermal exposure				
Contact rate	contact rate formulation	42 µl/min	5	see 2.2.4

a) calculated parameter, see text

Default values for exposure after application of general surface spray

Model	Parameter	Default value	Q	References, comments
Contact	frequency	9 $year^{-1}$	5	see 2.2.1
	use duration	14 x 1 hr	6	see above
	total duration	14 days	6	see above
	start exposure	0	9	direct exposure
Dermal exposure				
Transfer coefficient	dislodgeable fraction formulation[a)]	5.3 g/m^2	6	see above
	transfer coefficient	0.6 m^2/hr	6	see 2.2.5
	surface	22 m^2	9	see above
Oral exposure				
Hand-mouth contact	intake rate formulation		5	see 2.2.6

a) calculated parameter, see text

The scenario indicates that the default values are drawn up for spraying with an aerosol can. If the spraying is carried out using a plant sprayer, water is the main ingredient of the sprayed liquid instead of an organic solvent. The consequences for the density is that it becomes 1 g/cm^3 (see 2.2.2). A different droplet size (30 µm instead of 15 µm) should also be taken into account, and therefore also a different respirable fraction (2 % instead of 5 %) (see 2.2.3).

2.8 Air space application

Scenario

This scenario is based on a private user who sprays an aerosol can in the living room to control flies or mosquitoes. Spraying is carried out from the middle of the room in the direction of the four upper corners. A daily use during a 3-month period is assumed. To calculate the exposure of the user during the application, the 'spray cloud model' is used for the inhalation exposure and the 'contact rate' model is used for the dermal exposure. The oral exposure is handled in the inhalation exposure model; in CONSEXPO it is assumed that the non-respirable fraction is taken in orally.

The exposure after application is described for crawling children present in the room after the treatment has been carried out. It is assumed that a child (default 10.5 months) crawls over the floor of the treated room for 1 hour a day during a 7 day period. Exposure after application is described using the dermal exposure model 'transfer factor' and the oral exposure model 'hand-mouth contact'.

Exposure during application

Contact

- *Use duration*

According to the directions for use on an air space spray, you should spray for 1 sec per 10 m^3. For a living room, chosen as the default room (see below), with a volume of 58 m^3, this means spraying for 5.8 sec. The manufacturer of a different air space spray indicates 10 sec spraying per 20 m^2 floor surface. The above-mentioned room has a floor surface of 22m^2, which means spraying for 11 sec. Observations by Baas and Van Veen (2002, in preparation) indicate that the two volunteers who used the air space applications only used them for 1 second.

The default value for the active spraying time with an air space spray is set at 10 seconds; this higher value is mainly based on the directions for use. The use duration, the time during

which the spraying takes place, is assumed to be twice as long and is therefore set at 20 seconds.

- *Total duration*

For the total duration, the same values are used as for the crack and crevice application (see section 2.6). A total time of 4 hours is taken as the exposure during the application. It is assumed that the user stays in the treated room for 4 hours after the application.

Inhalation exposure: 'spray cloud model'

- *Emission rate formulation*

Using data from Matoba et al. (1993) the use of an air space spray is calculated at 0.7 g/sec. This is half the value used for other application areas. An explanation may lie in the fact that an air space spray has a spraying nozzle which atomizes the product extremely finely, whereby the use per time unit is smaller that for other types of sprays.

Roff & Baldwin (1997) also found a much lower use for air space sprays than for 'general surface sprays' (1- 4 to 5 ml/m^3 versus 10 - 50 ml/m^2, respectively). For this reason, 0.7 g/sec is used as the default value when using air space sprays. The use duration, the time during which the spraying takes place, is twice as long as the actual spraying time. The emission rate formulation is therefore 0.35g/sec.

- *Release height*

Based on the directions for use, the spraying height of an air space spray will be the default height of a Dutch man/woman, plus a small part of the hand/arm length, when the spray is aimed upwards into the four corners of the room. The default for the spraying height is set at 180 cm.

- *Room volume, surface area, ventilation rate*

The control of flying insects takes place in various rooms of the house, such as in the living room and in bedrooms. As there is a direct relationship between the size of the room and the duration of the spraying, a higher exposure is expected when treating a larger room. As a "worst case", therefore the living room is chosen as the default room. The default values for a living room are given in the "General fact sheet" (Bremmer and van Veen, 2000): volume of the living room 58 m^3, surface area 22 m^2 and ventilation rate 0.5 hr^{-1}.

Exposure after application

The exposure after application is described for crawling children present in the room after application. It is assumed that the spray is distributed evenly over the floor surface after spraying. Since air space sprays are used daily, residues can accumulate on the floor (see Matoba et al. (1998)). It is assumed that a child (default 10.5 months) crawls over the floor of the treated room for 1 hour a day, and that the residues are cleaned off the floor once a week (as a result of walking, crawling, brushing, vacuuming, mopping etc). This means implicitly that the potential exposure to residues on the floor after 7 days is considered to be zero again. It is assumed that the accumulation of the residues during these 7 days is linear. In other words, on the day of application the amount of residue is R, on day two it is 2R…… and on day seven the amount of residue is 7 R. The average exposure during these 7 days is 4 times as high as the exposure on the day of application.

Dermal exposure*: *transfer coefficient

- *Dislodgeable fraction formulation*

By multiplying the emission rate formulation and the use duration, the total amount of sprayed formulation can be calculated (0.35 g/sec x 20 sec = 7.8 g). It is assumed that this amount ends up on the floor surface of the living room ($22m^2$), so that the amount of formulation per unit surface can be calculated (318 mg/m^2). Section 2.2.5 shows that, of this amount, 30 % is dislodgeable. The dislodgeable fraction formulation is therefore 30 % of the amount of formulation per unit surface. The dislodgeable fraction formulation, on the day of application, is calculated as 95 mg/m^2. By accumulation (see above) the average exposure during the application time is 4 times as high as the exposure on the day of application. The average dislodgeable fraction formulation during the entire application is calculated as 380 mg/m^2.

Default values

Default values for exposure during air space spray application

Model	Parameter	Default value	Q	References, comments
Contact	frequency	90 $year^{-1}$ a)	5	see 2.2.1
	use duration	20 sec	6	see above
	total duration	4 hr	6	see above
	start exposure	0	9	direct exposure
Inhalation exposure				
Spray cloud model	emission rate formulation b)	0.35 g/sec	6	see above
	density formulation	0.7 g/cm^3	7	see 2.2.2
	airborne fraction	100 %	6	see 2.2.3
	droplet size	5 µm	5	see 2.2.3
	release height	180 cm	6	estimation
	radius aerosol cloud	20 cm	6	see 2.2.3
	room volume	58 m^3	9	see above
	ventilation rate	0.5 hr^{-1}	8	see above
	surface	22 m^2	9	see above
	respirable fraction	34.4 %	5	see 2.2.3
Dermal exposure				
Contact rate	contact rate formulation	23 µl/min	5	see 2.2.4

a) daily use over a 3 month period
b) calculated parameter, see text

Default values for exposure after application of air space spray

Model	Parameter	Default value	Q	References, comments
Contact	frequency	90 $year^{-1}$ a)	5	see 2.2.1
	use duration	7 x1hr	6	see above
	total duration	7 days	6	see above
	start exposure	0	9	direct exposure
Dermal exposure				
Transfer coefficient	dislodgeable fraction formulation b)	380 mg/m^2	6	see above
	transfer coefficient	0.6 m^2/hr	6	see 2.2.5
	surface	22 m^2	9	see above
Oral exposure				
Hand-mouth contact	intake rate formulation		5	see 2.2.6

a) daily use over a 3 month period
b) calculated parameter, see text

3. Evaporation from strips and cassettes

Pest control products which evaporate from strips and cassettes are mainly used in the Netherlands to control moths, carpet beetle larvae and flying insects. The active substances are trapped in a solid matrix, paper or plastic strips, or are present in cassettes. In all cases, the evaporation of the active substances takes place during the application.

3.1 Use and composition

Pest control products which evaporate from strips and cassettes are split into two groups, depending on the exposure.

- Products for use in a small 'sealed' area (closet/trunk/suitcase)
  This mainly concerns products to control moths and carpet beetle larvae (fur beetles). The products are hung or spread out in closets, blanket boxes, suitcases with clothes etc. The insecticide evaporates slowly and spreads throughout the small area.
- Products for use in a room.
  This mainly concerns products to control flying insects, used in a room. In all cases, the products are sealed until the moment of use; evaporation of the product only starts when the product is opened.

In the first application group, the two subcategories listed below can be distinguished with regard to the exposure.

- Moth paper supplied in the form of individual sheets. In general, these sheets are sufficient for an area of approximately 1 m^3, and must be cut into pieces for smaller areas such as a closet or suitcase.
- Strips, pieces of paper or plastic strips that are ready-to-use and supplied in an (aluminum) cassette from which you can take as much as you need. There are also cassettes which should be hung in the closet after opening, in their entirety.

The exposure takes place during mixing and loading and otherwise only incidentally during the application. The duration of the dermal contact is different for the two subcategories.

The second application is in the form of strips or cassettes, both of which are used in a room to control flying insects. When used against flying insects, the product is hung in a room and the insecticide is supposed to get into the air in the whole room. In this way, all people present in the room are continuously exposed. The contact duration then depends on what the room in question is used for (kitchen or bedroom).
Oral exposure can also be expected. From the literature, it seems that when PVC strips with dichlorvos are used, the air concentration is equivalent to the concentration in food during the normal preparation of a meal (Elgar et al. 1972), (Collins & DeVries 1973).

From the CTB-Pesticide database (CTB, 1998) it seems that organophosphates and pyrethroids are used as active ingredients (a.i.). These substances seem to be applied mainly in a solid plastic matrix, in cassettes or in impregnated paper.

The use of dichlorvos in PVC strips is mainly described in the older literature (Leary, 1974; Elgar et al., 1972; Elgar and Steer, 1972; Weiss et al., 1998).

Table 8 shows the above-mentioned methods of exposure by evaporation from strips and cassettes.

Table 8 Ways of exposure due to evaporation from strips and cassettes

Exposure	Small area (closet/trunk/suitcase)		Room
	paper strips	strips/cassette	cassettes
Mixing and loading			
Dermal	contact duration = time of folding, cutting, positioning	short (hanging up the strip)	not applicable
Inhalation	evaporation in preparatory stage	evaporation in preparatory stage	
Application			
Dermal	not applicable		not applicable
Inhalation	- the saturated air in small sealed areas results in a brief high concentration. - leakage from the sealed area		for use in rooms there is long term contact, depending on the use of the room
Oral	not applicable		food
After application			
	not applicable		not applicable

3.2 Exposure to products in sealed areas

Mixing and loading
Contact

- *Frequency*

The frequency is determined by the number of times that a consumer cuts up strips of paper to put in closets. When determining this frequency, a consumer is assumed who chooses this type of pest control, and not the average consumer. No literature references were found. From the directions for use, the average period of effectiveness is set at 4 months; a frequency of 3 times a year is assigned on this basis.

- *Use duration, total duration*

It is assumed that the consumer prepares several strips at a time when cutting up the paper. No literature references are known about these times. For the time being, it is assumed that 10 minutes is needed to cut and/or fold a piece of anti-moth paper and then to distribute it among the clothes.

Inhalation exposure: evaporation from pure substance

The exposure during mixing and loading is determined by the concentration that occurs during cutting. An inhalation exposure due to evaporation and a dermal exposure due to handling the strip is anticipated. The “evaporation from pure substance” model is used for the inhalation exposure, whereby the surface is corrected for the weight fraction of the active ingredient. The “evaporation from mixture” model is not applicable, since, based on Raoult's law, it assumes an ideal liquid. A plastic or paper matrix is not an ideal liquid. In the “evaporation from pure substance” model, it is assumed that only the pure substance, i.e., the active ingredient, is present. The model does not take into account the fact that the active ingredient is caught in a solid matrix. The evaporating surface is adapted to the percentage of active ingredient in the matrix. Using the “evaporation from pure substance” model, an overestimate of the exposure will be calculated. There is currently no model which better describes the exposure.

- *Release area*

It is assumed that a strip is cut with a surface area of 120 cm^2. The effective surface is the surface as if the active ingredient were present in its pure form. The effective surface is calculated by multiplying the surface by the fraction of active ingredient. If the weight fraction of the active ingredient in the above-mentioned strip of 120 cm^2 is 0.25, for example, the effective surface is 120 x 0.25 = 30 cm^2.

- *Room volume*

The initial area in which the substance evaporates is presumed to be 1 m^3 around the user.

- *Ventilation rate*

The ventilation rate is taken to be the same as a standard ventilated room: 0.6 hr^{-1} from the "General fact sheet" (Bremmer and van Veen, 2000).

Application

Contact

- *Frequency .*

A more general effect on the exposure is the consumer use of anti-moth products: does the consumer always hang them up in the closet, or are they only used for long-term storage, since the storage place will then rarely be opened. When used to control moths, it is possible that the product is used all year round, and that exposure only actually takes place a few times a year. As a "worst case", it is assumed that the anti-moth products are used in the every-day closet, and that there is therefore the potential for daily contact. The frequency is set at 365 times per year.

- *Duration of use and total duration*

Inhalation exposure will mainly occur briefly when opening the closet/trunk/ suitcase. There are no observations on this matter. It is not known how much leakage there is from the sealed area into the room, whereby inhalation exposure at a low concentration is expected.

In the model to calculate the inhalation exposure, it is assumed 'worst case' that the user has his/her nose in the closet throughout the period of application. This is a 'worst case' assumption, since, when opening the closet/trunk/suitcase, the active ingredient will spread around the area, whereby the concentration will decrease. There is currently no model which better describes the inhalation exposure.
For the default values for the use duration and the total duration, an estimate is made of the time during which exposure to the concentration of the active ingredient in the closet takes place; this time is estimated to be 5 minutes.

Inhalation exposure: evaporation from pure substance

The application phase actually covers the entire lifetime of the product. This definition means that the phase after application becomes unimportant. Exposure takes place by the evaporation of the active ingredient. The 'evaporation from pure substance' model is used here, whereby the surface is corrected for the weight fraction of the active ingredient (see mixing and loading). Just as for 'mixing and loading' an overestimate of the exposure will be calculated.

- *Room volume*

The area is taken to be a closet with a volume of 1.5 m^3.

- *Ventilation rate*

Based on the background data from the "General fact sheet"(Bremmer and van Veen, 2000), the ventilation rate in a closet that is opened once a day is estimated to be 0.3 hr^{-1}

Default values: products in a sealed room, mixing and loading

Model	Parameter	Default value	Q	References, comments
Contact	frequency	3 $year^{-1}$	5	see above
	use duration	10 min	3	see above
	total duration	10 min	3	see above
	start	0		direct exposure
Inhalation exposure				
Evaporation from pure substance	release area[a)]			see above
	temperature	20 ^oC	9	room temperature
	room volume	1 m^3	5	see above
	ventilation rate	0.6 hr^{-1}	8	see above
Dermal exposure				
Contact rate	contact rate	1 mg/min	2	estimation
	density	1 g/cm^3	5	estimation

a) calculated parameter, see text

Default values: products in sealed area, during application

Model	Parameter	Default value	Q	References, comments
Contact	frequency	1 day^{-1}	3	see above
	use duration	5 min	3	see above
	total duration	5 min	3	see above
	start	0		direct exposure
Inhalation exposure				
Evaporation from pure substance	release area[a)]			see above
	temperature	20 ^oC	9	room temperature
	room volume	1.5 m^3	5	see above
	ventilation rate	0.3 hr^{-1}	4	see above

a) calculated parameter, see text

3.3 Exposure to products in living areas

Application
Contact

- *Frequency, duration of use and total duration*

It is assumed that the products are used in the summertime, from mid-May to mid-September. The total duration is 5 months. During these 5 months, exposure can occur daily. The frequency is therefore daily for 5 months per year. It is assumed that the products are used in a living area in which people are present for 8 hours a day.

Inhalation exposure: evaporation from pure substance

The "evaporation from pure substance" model is used. The reasoning given for the application of products in sealed areas (3.2) is also applicable here.

- *Release area*

The surface area of PVC strips is between 200 and 220 cm^2 . The effective surface is the surface as if the active ingredient were present in its pure form. The effective surface is calculated by multiplying the surface area (220 cm^2) by the fraction of the active ingredient.

- *Room volume* and v*entilation rate*

This is based on the standard values from the "General Fact sheet" (Bremmer and van Veen 2000): a room of 58m^3 and a ventilation rate of 0.5 hr^{-1}.

Default values: products in living areas during application

Model	**Parameter**	**Default value**	**Q**	**References, comments**
Contact	frequency	1 day^{-1} a)	6	see above
	use duration	8 hr/day	6	see above
	total duration	8 hr/day	6	see above
	start	0	8	direct exposure
Inhalation exposure				
Evaporation from pure substance	release area b)			see above
	temperature	20 ^oC	9	room temperature
	room volume	58 m^3	8	see above
	ventilation rate	0.5 hr^{-1}	8	see above

a) daily use over a period of 3 months, or 150 times a year
b) calculated parameter, see text

4 Electrical evaporators

4.1 Introduction

Electrical evaporators are used to kill insects, in particular flies and mosquitoes. An electrical evaporator is plugged into an electrical socket; the solvent and active ingredient are heated, resulting in evaporation. Once in the colder air of the room, the solvent condenses and the active ingredient almost immediately and completely turns into droplets, which rise to the ceiling due to the warmer air.

Use and composition

The exposure to active ingredients from electrical evaporators is modeled in detail by Matoba et al. (1994). This model seems to adequately predict both the behavior of the active ingredient and the aerosol in a room as a concentration of the active ingredient, although only one validation experiment was carried out. However, the model is too complex to implement in scope of these fact sheets. From a model point of view, the working mechanism of the electrical evaporator is comparable to that of an air space spray. With an electrical evaporator, just as with an air space spray, small droplets are generated which float in the air. The question is whether the generated droplets give rise to exposure by staying in the air for a certain period of time, or whether it is only the exposure due to evaporation that is important. Matoba et al. (1994) indicate that 98% of a synthetic pyrethroid (mol. weight: 302.41; vapor pressure: 1.68 $x10^{-2}$ Pa) condenses and that the droplet with the active ingredient formed in this way is in the air for 49.3 seconds.

For this fact sheet, the well mixed spray model will be used as a simplified approach of the Matoba-model. The assumption here is that active ingredients used in an electrical evaporator at room temperature are negligibly volatile. This will normally be the case as the used active ingredients will only be evaporated slowly due to heating.

The insects against which the evaporator is used, in particular flies and mosquitoes, mainly come out at dusk. This means that the equipment is mainly used in the evening in living areas and bedrooms. In bedrooms, exposure can take place all night long.

Electrical mosquito evaporators have a cartridge of 45 to 50 ml containing a solvent and the active ingredient. Matoba et al. (1994) mention n-paraffins (especially a mixture of n-tetradecane: 70%; n-pentadecane: 24%) as solvents.

4.2 Exposure

Scenario
This scenario is based on the application of an electrical evaporator in a bedroom, for 8 hours a day for 5 months a year. With regard to the exposure after application, a child (default 10.5 months) is assumed who crawls over the floor for 1 hour a day during the 5 month application period.

Exposure during application
Contact
- *Use duration, total duration*

There are two types of evaporators with regard to the working time. There are evaporators with an on/off switch that operate continuously once switched on. There are also evaporators with a built-in time switch that have their own on/off rhythm. It is assumed that electrical evaporators are use in the evening in living areas and bedrooms, and that those in the living room are turned off at bed time. If the apparatus is used in the bedroom, the exposure takes place during the entire period that the people are asleep. A default value for the use duration when used in a bedroom is set at 8 hours. This value is also used for a child's bedroom, assuming that the electrical evaporator is functioning there for 8 hours a day.

There is no data known about the frequency of use. It will be used most intensively in areas with lots of mosquitoes. Mosquitoes can appear from April to November, with a peak in the late summer and fall. The Dutch Animal Plague Knowledge and Advice Center states that in areas with many mosquitoes (near moorland, for example) aerosol sprays are used to control those mosquitoes several times a week (KAD, 2001). Based on this data, the default value assumes a use of 5 months per year.

Inhalation exposure: spray-well mixed model
- *Generation rate formulation*

The emission rate of the active ingredient was measured by Matoba et al. (1994), who found a rate of 7.36×10^{-7} g/sec. The value is converted to the emission rate of the formulation, which is 1.3 mg formulation/min.

- *Airborne fraction*

All evaporated substances enter the air and form small droplets. The airborne fraction is therefore 100 %.

- *Density*

The density will depend on the solvent. When organic solvents with a relatively high boiling point are used (including n-tetradecane and n-pentadecane), the density will normally be in the region of 0.8 g/cm^3.

- *Droplet size, respirable fraction.*

Matoba et al.(1994) indicate that the droplets are initially 3.5 µm. Due to condensation and evaporation, the droplet sizes vary between 3.5 and 15 µm. The default value for the average droplet size of the particles is taken to be 5 µm. Section § 2.2.3 shows that a respirable fraction of 34.4 % for the particles with a diameter of 5 µm is expected.

- *Room volume, ventilation rate*

We assume the room to be the smallest bedroom from the "General fact sheet" (Bremmer and van Veen, 2000) of 7 m^2 with a volume of 16 m^3. In this report, the default value for the ventilation rate of a bedroom is given as 1 hr^{-1}.

Exposure after application

The active ingredient is expected to not only rise to the ceiling, but also to spread around the room. The first reason is that extensive monitoring of a sprayed chlorpyrifos application shows that the chlorpyrifos spreads itself around a room (Gurunathan et al., 1998). Some of the chlorpyrifos was also found on toys on which it had not landed initially. The second reason is that when using an electrical evaporator, the active ingredient has also been found on the walls and floor (Matoba, 1994). Based on measurements whereby an electrical evaporator with the above-mentioned synthetic pyrethroid (mol. weight: 302.41; vapor pressure $1.68x10^{-2}$ Pa) was used for 6 hours in a room of 23.3 m^3 with a ventilation rate of 0.58 hr^{-1},Matoba et al. (1994) calculated that the amount of the pyrethroid on the floor and on the walls was comparable. They calculated that 12 hours after the start of the application, the amount of pyrethroid on the floor and on the walls was approximately 0.01 % of the amount that was present on the ceiling, and was approximately 1 % of the amount in the air.

Based on the above, it is assumed that some of the active ingredient will end up on the floor and some will become attached to other materials such as toys and bed linen. Children crawling over the floor can be exposed dermally; oral exposure can also occur due to hand-mouth contact. Oral exposure can also take place when young children mouth toys and/or bed linen.

The scenario assumes that the electrical evaporator is used daily during a 5 month period. The extent of the exposure will depend on the properties of the applied active ingredient, the vapor pressure, and the speed of degradation of the substance, but also on the absorption and re-absorption properties of the substance and the sort of materials present in the room. External factors such as the ventilation rate will also have an influence.

Based of the available data, it is not possible to make a reliable estimate of the amounts of the product that may be present on bed linen, toys and on the floor. To make a sound estimate of the exposure after application, a good possibility is to empirically determine the amount of product on the floor. Based on these measurements, the transfer coefficient model can be used to calculate the dermal exposure, and the hand-mouth contact scenario to calculate the oral exposure. The calculation of the dermal and oral exposure is comparable to the calculation of the exposure after application of a spray, as shown in chapter 2.

Dermal exposure: transfer coefficient

- *Dislodgeable fraction formulation*

It was previously stated that no reliable estimate can be made of the amount of product present on the floor. If this amount is known from measurements, the dislodgeable fraction formulation can be calculated. Section § 2.2.5 shows that of the amount on the floor surface, 30 % is dislodgeable.

4.3 Default values

Default values after application of electrical evaporator

Model	**Parameter**	**Default value**	**Q**	**References, comments**
Contact	frequency	1 day^{-1} a)	5	see above
	use duration	8 hr	5	see above
	total duration	8 hr	5	see above
	start	0	9	direct exposure
Inhalation exposure				
Spray-well mixed model	generation rate formulation	1.3 mg/min	6	see above
	airborne fraction	100 %	6	see above
	density	0.8 g/cm^3	6	see above
	droplet size	5 µm	5	see above
	release height	110 cm	7	height socket
	room volume	16 m^3	9	see above
	ventilation rate	1 hr^{-1}	7	see above
	respirable fraction	34.4 %	5	see above

a) daily use over a period of 3 months, or 150 times a year

Default values after application of electrical evaporator

Model	**Parameter**	**Default value**	**Q**	**References, comments**
Contact	frequency	1 day^{-1} a)	5	see above
	use duration	150 x 1 hr	6	see above
	total duration	150 days	6	see above
	start exposure	0	9	direct exposure
Dermal exposure				
Transfer coefficient	dislodgeable fraction formulation	30 %	6	see above
	transfer coefficient	0.6 m^2/hr	6	see 2.2.5
	surface	7 m^2	9	floor surface
Oral exposure				
Hand-mouth contact	intake rate formulation		5	see 2.2.6

a) daily use over a period of 3 months, or 150 times a year

5 Insect repellents

5.1 Use and composition

Insect repellents aim to repel bloodsucking insects, fleas or ticks. In moderate climates these are mosquitoes (Culicidae), sand flies (Phlebotomidae), biting midges or black flies (Ceratopogonidae, Simuliidae) and horse flies (Tabanidae), which are not only troublesome but also act as carriers of disease (Haupt and Haupt, 1998). In the tropics the tsetse fly (*Glossina*) should be added as the carrier of sleeping sickness. The mechanism of action the active ingredients in insect repellents is not revealed yet, (see Fradin, 1998), their effectiveness is determined experimentally.

The products are supplied as a liquid (milk, gel, lotion) in a plastic bottle, as impregnated cloths, as sticks or as a spray. All of these products are ready to use. They must be applied to the skin and should prevent insects from landing on the skin. They are normally applied to the uncovered parts of the skin. Users sometimes apply the products to their clothes to prevent insects such as ticks from getting into the clothes, or to prevent mosquitoes from biting through the clothes. Exposure occurs when these products are applied to the skin. This obviously results in dermal exposure. Oral exposure can also occur as a result of hand-mouth contact, since the product is applied using the hands and the product is also applied to the hands. With the sprays, inhalation contact with aerosols is possible.

The active ingredients in insect repellents are described below.

- DEET (N,N-diethyl-3-methylbenzamide) is the most important active ingredient in insect repellents. There is a broad spectrum of repellents that are effective against mosquitoes, black flies, fleas and ticks. DEET is the most effective and the best studied repellent. It is used worldwide, whereby human poisoning occurs now and then due to misuse and specific over-sensitivity. Various sources summarize these cases of poisoning (Fradin, 1998;Osimitz and Murphy, 1997; Veltri et al., 1994). These references mainly concern children, where cases with the highest doses occur. For adults, poisoning occurs as a result of too high a dosage or due to increased skin penetration.
- Citronella oil. Citronella is the active ingredient in most 'natural' or 'vegetable-based' insect repellents. It is registered by the US-EPA as an insect repellent. Citronella oil smells like lemon and used to be extracted from the grass *Cymbopogon nardus*. There is little data comparing the efficiency of products based on citronella and products based on DEET. In a study by Wright (1975, cited in Fradin, 1998) 0.01 µmol DEET per liter of air was enough to prevent 90% of the mosquitoes from landing on the skin; a concentration of citronellol (one of the active ingredients in citronella oil) of one thousand times higher was required to achieve the same effect.
- Bite Blocker is a vegetable-based repellent that has been available for a long time in Europe and since 1997 in the US. Bite Blocker seems to use soya oil, geranium oil and coconut oil as active ingredients in its formulation. Studies at the University of Guelph, Ontario, Canada (Lindsay et al., 1996, cited in Fradin, 1998) show that 97 % protection against *Aedes*-mosquito bites was achieved under field conditions, even up to 3.5 hours after application. At the same time, a spray of 6.65% DEET gave 86% protection, and a citronella-repellent only gave 40% protection.

5.2 Exposure

Scenario

Repellents are applied on the uncovered skin: on the head, hands, arms, legs and feet. Exposure takes place dermally and orally. The inhalation route is excluded due to the use outdoors, and because use indoors only takes place in the summer in situations where there is a high ventilation rate. On these grounds, the inhalation exposure to aerosol sprays in also considered to be negligible.

Insect repellents are also applied on the hands. If the product is supplied in the form of a liquid or cream, it is applied using the hands. Hand-mouth contact can occur, leading to the ingestion of some of the repellent. Exposure due to hand-mouth contact will mainly be important for children. The exposure is described for adults and children of 10.5 months.

Contact

- *Frequency*

The US-EPA (1998) reports an average frequency of 15 applications per year of DEET for the entire population of the US, and 19 applications per year for the male population. An average frequency of 12 applications per year is given for children. The US-EPA report does not indicate standard deviations of these figures. Research by Weegels and Van Veen (2001) indicates that for a product used by consumers, the coefficient of variation quickly approaches the region of 1. If this coefficient of variation is taken as being applicable, a reasonably high frequency of use for men is 27 days per year (when assuming a log normal distribution, the 75th percentile of the frequency). For children, a reasonably high use is 21 days per year (when assuming a log normal distribution, the 75th percentile of the frequency). The default value for the frequency of use is set at 27 days per year, where a use of twice a day is assumed (see use duration).

The frequencies are calculated based on the frequency of use from the American DEET data and the variation in Dutch consumer products. Data from the US is not necessarily applicable to the Dutch situation (different climate, different habits). The calculation is also carried out using parameters between which there is little or no relationship. The quality factor Q for the frequency of use is therefore set at 4.

- *Use duration, total duration*

The duration of protection and the related number of applications per day varies according to the active ingredient and the parasite that has to be repelled. The duration of protection was investigated for the active ingredient DEET, and proved to depend on the concentration of DEET and the sort of parasite (see Fradin, 1998). In general, products which have no special matrix have a duration of protection of between 2 and 4 hours for a concentration of the active ingredient of 10-12.5%, and 6 to 8 hours for a concentration of 20-50% a.i. A duration of protection of 1.9 hours is given for a 5 % solution of citronella oil (Spero, 1993, cited in Fradin, 1998). Another product based on citronella gave a protection duration of 2 hours, whereby the best protection occurred within 40 minutes. A duration of protection of around 3.3 hours is given for Bite-Blocker (Lindsay et al., 1996, cited in Fradin, 1998).

The duration of protection indicates that exposure for less effective products (citronella, bite blocker, DEET<10%) will be maximally 3 hours, while the exposure for effective products (DEET>20%) will be 6 hours. It can also be assumed that less effective products are used more frequently. For two applications, there is a total duration of exposure of 6 hours, equal to the duration of a single application of the effective substance. As the default two applications per day with a duration of exposure of 3 hours per application are assumed.

Dermal exposure: fixed volume model

- *Amount of product on the skin*

Data is available about the repellents themselves and comparable data about suntan creams and body lotions, allowing the amount applied to the skin per application to be estimated.

- The US-EPA assessment of DEET (US-EPA, 1998) assumes an average of between 1.0 and 1.3 grams of active ingredient per application. Children and adults fall within this range. Unfortunately, the concentration of DEET contained in the formulation is not stated. If we assume concentrations of 60 and 20% DEET in the formulation, the amount of product applied on the skin is approximately 1.9 and 5.8 grams, respectively.
- The default values for amounts of suntan creams and body lotion applied, given in the ‘Cosmetics fact sheet ’ are 10 g and 8 g per application (Bremmer et al., 2002, in

preparation). For both products, almost all of the skin is treated. Insect repellents are applied on the uncovered skin: on the head, hands, arms, legs and feet. The surface of these body parts is 64 % of the total body surface (Bremmer and van Veen, 2000). If the use of repellents is comparable to that of suntan creams and body lotions, 5 to 6 g is used per application. Based on the above, the default value and the amount of repellent per application is set at 6 g.

- The default value for the total body surface of children of 10.5 months is 0.437 m^2. The total body surface of an adult is 1.75 m^2(Bremmer and van Veen, 2000). If it is assumed that there is a linear relationship between the body surface and the amount of repellent used, the amount of repellent used for a child of 10.5 months would be 1.5 grams per application.

Oral exposure: hand-mouth contact

- *Intake rate*

Children exhibit a great deal of hand-mouth contact; for adults the contact is mainly between the fingers and the mouth. As the applied products are expected to be rubbed over the skin by adults using their bare hands, the oral route will also be important for adults. It is expected that children will take in the amount that is rubbed into the hands orally, and that adults will take in the amount on the fingers.

For children of 10.5 months, the fraction of the surface formed by the hands is approximately 10 % of the total treated body surface (head, hands, arms, legs and feet) (Bremmer and van Veen, 2002, in preparation). For adults, the fraction of the surface formed by the fingers is approximately 4 % of the total treated body surface (Bremmer and van Veen, 2000). For adults, this means that 4 % of 6 g (240 mg) is taken in by hand-mouth contact in 3 hours. The intake rate is calculated at 80 mg/hr. For a child of 10.5 months, it is calculated that 10 % of 1.5 g (150 mg) is ingested in 3 hours, or 50 mg/hr.

5.3 Default values

Default values for the application of insect repellents

Model	**Parameter**	**Default value**	**Q**	**References, comments**
Contact	frequency	54 $year^{-1}$ a)	4	see above
	use duration	3 hr	6	see above
	total duration	3 hr	6	see above
	start	0	9	direct exposure
Dermal exposure				
Fixed volume model	dilution	1	8	instructions for use
	weight of product adult child (10.5 months)	 6 g 1.5 g	 5 5	see above
	density formulation	0.9 g/cm^3	7	estimation
oral exposure				
Hand-mouth contact	intake rate formulation adult child (10.5 months)	 80 mg / hr b) 50 mg / hr b)	 4 4	see above

a) 27 days, application 2 times per day
b) calculated parameter, see text

6 Baits

Baits are used to kill mice, rats, ants and cockroaches. The products are placed at the appropriate places, the animals eat some of the products and die. The products against rats and mice are mainly grains to which the active ingredient has been added. It is always compulsory to dye the product in such cases.

In addition to the above-mentioned products, there are also baits to control flies in cattle and poultry sheds. These products are exclusively for professional use, and are not discussed in the present scope.

For the baits to control rats and mice, there is a definite division between products for professional use and for consumer use. For consumer use, the net contents of a single packet may not be higher than 200g, and bait stations must be included. For professional use, the net contents of a single package is minimally 800g. For use in rooms, the bait must be put out in feeding boxes that are closed on the top; for outdoor use, it must be put out in specially designed feeding stations, in such a way that the bait is not within the reach of children, cattle, pets or birds. The data above was obtained from the Pesticide Database from the Dutch Board for the Authorization of Pesticides (CTB, 2000a).

Ant and cockroach bait stations
Ant and cockroach bait stations are all entirely closed boxes (made of metal or plastic) in which the user only has to make a small hole to be able to use it. The bait stations are positioned in places where the ant or cockroaches walk.

The ants take the product out of the box and back to their nest, so that they die in the nest. It takes several days before the whole nest is wiped out. This is why the bait stations should remain in the same place for at least one week. One bait station is enough for a small room. The bait will cease to be effective after about 1 month, due to the contents being removed by the ants and by it drying out. One type of ant bait station contains approximately 12 g of product.

To control German cockroaches, depending on the numbers, between 1 and 5 bait stations (with 1.2 to 1.5 g per station) are advised per 10 m^2 . The bait in the bait stations will work well for approximately 3 months. To control the larger types of cockroach, such as the Oriental, the Australian and American cockroaches, the use of between 1 and 3 bait stations (of 7.5 g) per 10 m^2 is advised (CTB, 2000a). Cockroach bait stations are intended for indoor use. Ant bait stations can be used both indoors (e.g. in kitchens) and outdoors (e.g. on balconies and patios). The active ingredient in ant bait stations are trichlorfon and foxim; in cockroach bait stations: fenitrothion and hydramethylnon (CTB, 2000a).

Mouse and rat baits
The baits for mice consist of grain to which the active substances has been added. These products must be dyed. For consumer use, the net contents of a single packet may not be higher than 200g of product. The packaging includes specially designed feeding stations, closed on top. The mouse pellets are sometimes pre-packed in a sealed bag which has to be put into the bait station. In a number of cases, the pellets themselves need to be placed in the bait station. This bait can only be used indoors. The dosage is 25 to 50 g (usually 40 g) per 10 to 15 m^2 surface. A good quantity of the product should be present for several days. This should be checked daily or every other day. If necessary, the bait should be topped up until

no more is eaten. Products that are moldy or contaminated must be replaced. When the activity is stopped, the remains of the product must be collected and packed in plastic. This should be disposed of as small chemical waste or as household garbage (CTB, 2000a).

Only a few baits were found for consumers to control brown rats. These were ready-to-use rings that should be placed somewhere that is frequented by the rats, such as in or near an entrance to a burrow or hiding place, on paths, or places where they collect or eat food. Sewers, under the floors of buildings where it is very damp, and waterfronts are explicitly mentioned. The active ingredient in mouse poison is bromadiolon, difethialon, or difenacum; in rat poison it is warfarin (CTB, 2000a).

6.1 Exposure

The vapor pressure of the above mentioned active substances is very low. Evaporation of these substances will be so small that the inhalation exposure is considered to be negligible.

Ant and cockroach bait stations
Some dermal exposure could occur when making the hole in the bait station. In addition, an extremely small, mainly dermal exposure could occur by ants or cockroaches taking the substance out of the bait station, after which people come into contact with it. For the time being, the exposure due to the use of ant and cockroach bait stations is considered to be negligible. Accidents (swallowing, children who open bait stations) do not form a part of a standard assessment.

Mice and rat baits
This mainly concerns ready-to-use products, which are often pre-packed and then only have to be placed into a bait station. It must take into account that some of the users will anyhow open the packets. In such a case, a small amount of dermal exposure will occur.

Dermal exposure can once again occur when topping up and tidying up the baits. It should be remembered that the bait stations can be made of thin cardboard. The exposure when topping up and tidying up the bait stations could be higher than that when setting up the bait stations.

Scenario
The use of baits against mice is described as the default. It is assumed that two bait stations are positioned, 4 times a year, with 40g bait per bait station. In the scenario, the topping up of a bait station is regarded as positioning a new bait station. Exposure can occur during ‘mixing and loading’ and when tidying up the bait station, which falls into the ‘after application’ category. The exposure during application is considered to be negligible. The exposure concerned is dermal exposure of a part of the hands. No data about the dermal exposure have been found.

The method of exposure during ‘mixing and loading’ and ‘after application’ is the same . As no data was found, the exposure is not split into ‘mixing and loading’ and ‘after application’, but an estimate of the total exposure is made. For the time being, it is assumed that the total dermal exposure per bait station with 40 g of bait will be maximally 0.5 % of the applied amount of product (0.5 % of 40 g = 0.2 g). For mathematical reasons, the model assumes that the entire exposure takes place during mixing and loading.

6.2 Default values for bait stations to control mice

Model	Parameter	Default value	Q	References, comments
Contact	frequency	8 x/ year	4	see above
	use duration	5 min	5	estimation
	total duration	5 min	5	estimation
	start exposure	0	5	direct exposure
Dermal exposure fixed volume model				
	weight of product	0.2 g	2	estimation
	density	1.5 g/cm^3	5	estimation

7 Dusting powders

This chapter deals with fine dusting powders. Dusting powders are used to control ants, wasps, flees and crawling insects. In addition, but mainly for professional use, there are also powders that have to be dissolved or suspended in water prior to spraying. This type of product is covered in chapter 2 “Spray applications”.

7.1 Use and composition

Ant dusting powder
Powders to control ants are exclusively permitted for application outdoors. The dusting of a small amount of powder at the entrance to the ant nest, i.e., in crevices and between tiles and the like, is preferred. If the user cannot find the nest entrance, a small amount of powder should be dusted on paths and/or along doorsteps and window frames and other places where the ants enter the house. The following is stated in one set of instructions for dusting a product : “Cut a corner off the inner packet using scissors, so that the contents can easily be scattered”. The active substances for ant dusting powders are deltamethrin, foxim and permethrin.

Wasp powder
Wasp powders for non-professional use are only permitted for the control of wasps outdoors. To control wasps, a small amount of powder should be put at the opening of the nest, preferably in the evening when the wasps are already in the nest. Active substances are deltamethrin and permethrin

Cat and dog fleas
To control fleas and their larvae around dogs and cats, the places where the dog and/or cat sleeps or lies down should be treated with powder. ‘Cracks, crevices and surfaces’ can be treated with the insect powder. Up until April 1995 a flea powder was permitted which was sprinkled over the animals fur and rubbed into the skin. The current thinking is: “For the effective control of fleas it is necessary to treat both the area around your cat or dog and the animal itself with a registered product designed for this purpose”. Active substances in dusting powders to control fleas and their larvae are deltamethrin, permethrin and propoxur.

Crawling insects
To control crawling insects (house cricket, firebrats, carpet beetles, lice, fleas, wood lice and earwigs) in living and accommodation areas, dusting powders are permitted with permethrin and propoxur as the active substances. The directions for use indicate: “Use in cracks and

crevices, treat the places where insects can hide; lightly dust the areas to be treated; do not use on people or pets!"

Dust mite
The directions for use indicate: "Sprinkle the powder over the carpet, distribute it equally over the carpet and brush the carpet with a broom, vacuum it up when it is completely dry". The drying time is 1-3 hours; the carpet must not be walked on while it is drying. The recommendation is to check regularly, for example every 3 months in the first year and then once a year, to see whether a repeat treatment is necessary. The dosage given is: 1 packet of 750 g for 12 m^2 low pile, 10 m^2 middle pile and 7.5 m^2 deep pile carpet. The active substance is benzylbenzoate.

Germination inhibiting products on potatoes
Germination inhibitors can be used to discourage potatoes from germinating. Germination inhibitors in powder form are permitted for non-professional users. To discourage germination, stored potatoes are dusted with the powder in the fall, before they have produced shoots. Chloroprofam is usually used as the germination inhibitor. The dosage is 500 grams per 250 kg of potatoes. It is used exclusively for potatoes for the retail market, with the understanding that the treated batches may not be consumed within 2 months after treatment.

The above-mentioned products are mainly H-products. A few powders to control fleas in the area around cats and dogs are listed under the H-products, in addition to a powder for this use listed under the V-products. The powders to control fleas in the area around cats and dogs, which fall under the H-products category, are all permitted for another application, for example the control of ants. The products that inhibit the germination of potatoes fall into the L-products category. Several of the above-mentioned products are permitted for more than one of the mentioned applications. The information about the use and composition was obtained from the Pesticide Database of the CTB (CTB, 2000a).

7.2 Exposure

Dusting powders can be split up into four categories:
- powders that are scattered outdoors (to control ants and wasps);
- powders used indoors to lightly dust the area to be treated. The area to be treated is the floor and/or the area where a dog or cat sleeps or lies down (to combat dog and cat fleas and against crawling insects);
- substances that have to be brushed into the carpet (against dust mite);
- germination inhibitors for potatoes.

Inhalation exposure due to evaporation
The active substances in dusting powders are all substances with an extremely low vapor pressure, and are therefore not very volatile. The inhalation exposure due to evaporation is therefore considered to be negligible. All products are fine powders that need to be scattered (for the control of ants and wasps), or with which the surface to be treated must be dusted (such as for fleas and crawling insects).

Mixing and loading
A large number of the dusting powders are supplied in a shaker, similar to an icing sugar shaker. The preparation usually involves pricking through the holes in the shaker to be able to

sprinkle the contents. There are also powders that are supplied in a plastic bag, where the corner has to be cut off before the powder can be sprinkled. For the time being, it is assumed that there are no products for which the powder has to be taken out of the bag and put into a shaker. On these grounds, the exposure during mixing and loading is considered to be negligible.

Dusted surfaces and amounts used

The amount of powder that is used when controlling dust mite, according to the directions for use, is 60 to 100 g per m^2 (see § 7.1). Based on this data, 2200 g is taken as the default value for the amount of powder dusted in a living room of 22 m^2 (Bremmer and van Veen, 2000).

The calculation of the amount of germination inhibitor on potatoes is based on the winter storage of 125 kg of potatoes. According to the directions for use, 250 g of germination inhibitor should be used. It is assumed that the storage of 125 kg of potatoes covers an area of 3 m^2.

No data were found on the size of the dusted surface and the amount of dusted powder for the other applications. The dusted surfaces given in the table are estimates. It is assumed that 60 g per m^2 is the amount of powder dusted per unit surface for these applications. This value is estimated based on the powder used when controlling dust mites.

Default values for dusted surfaces and amounts used

Type of powder	**Use**	**Dusted surface [m^2]**	**Q**	**Amount of powder dusted [g]**	**Q**
Wasp powder	outside	0.25	4	15	4
Ant powder	outside	1	4	60	4
Flea powder	inside	1	4	60	4
Crawling insects	inside	1	4	60	4
Dust mite	inside	22	8	2200	8
Germination inhibitor	inside	3	6	250	7

Scenario

This scenario is based on a non-professional user who is controlling crawling insects indoors with the help of a dusting powder. For the room in which the treatment takes place, we assume the default room given in the “General fact sheet”(Bremmer and van Veen, 2000) of 20 m^3, 8 m^2, and a ventilation rate of 0.6 hr^{-1}. It is assumed that 60 g of powder is dusted onto 1 m^2.

After application, dermal exposure can take place by a child crawling over the treated area. Oral exposure can then take place by hand-mouth contact. As the default, a child of 10.5 months who crawls over the treated area is assumed. For application indoors, it is assumed that a child is in contact with the treated area for 1 hour a day during the 14 days after application.

Exposure outdoors

A number of models have been developed in CONSEXPO to describe the inhalation exposure in a room. The ‘spray cloud model’ describes the inhalation exposure due to spraying aerosols indoors, for example, and the ‘evaporation from mixture' model describes the exposure due to the evaporation of a substance in a room. These models can all be applied to calculate the inhalation exposure in a room. These models cannot be applied to calculate the inhalation exposure outdoors.

The dermal and the oral exposure after application outdoors can be described with the help of CONSEXPO (using the 'transfer coefficient' and the 'hand-mouth contact' model, respectively). For application outdoors, where there is influence of sunlight, wind and rain, it is assumed that exposure occurs over a 7 day period. For outdoor application it still is assumed that the child is in contact with the treated area, for 1 hour a day.

Exposure during application
Inhalation/oral exposure: 'spray cloud model'
During the dusting of the surface under treatment, the dusted particles can be breathed in and oral and/or inhalation exposure can occur. In the section above it is assumed that the evaporation of the active substance is negligible; here is mainly referred to the inhalation/oral exposure to dusted particles. When using dusting powders, the surface being treated is almost always on the ground (outdoors; ant control on the patio), the floor (indoors; fleas and crawling insects), or objects on the floor (cat or dog baskets, potatoes). An exception is the control of wasps (nests).

The parameter which has the most influence with regard to the dispersion of particles, and therefore the exposure, is the particle size of the powder particles. In addition to the amount dusted and the duration, the sprinkling height is also of importance. The force of the wind also has to be taken into account when outdoors. Extremely fine particles can disperse with the slightest wind, and will not immediately reach the ground.

No special model, developed for the application, is available for the use of dusting powders. The use of dusting powders can be described with the help of the "spray cloud model", which was developed for the spraying of aerosols. The definitions for a number of parameters do have to be somewhat altered. The spray cloud model describes the behavior of a cloud of aerosol particles, but it can also describe a cloud of solid particles, that is, a dusted powder. The model shows the situation whereby the user's head ends up in the cloud of dispersed powder. This is not always the case. A situation is therefore described whereby an overestimate of the exposure is calculated.

- *Emission rate formulation*

The emission rate formulation is calculated by dividing the amount of powder dusted by the duration of use. If 60 g of dusting powder is dusted in 5 minutes, the emission rate formulation is 60/5 = 12g/min.

- *Radius aerosol cloud*

The "radius aerosol cloud" from the spray cloud model concerns the initial radius of the aerosol cloud, before deposition occurs. For the use of a dusting powder, the default value for "radius aerosol cloud" is first calculated as the radius of a circle with, as its surface, half of the surface over which the powder is scattered. For a dusted surface of 1 m^2, the default value for the "radius aerosol cloud" is taken to be the radius of a circle with a surface of 0.5 m^2 ; this is calculated as 40 cm.

- *Release height*

A sprinkling or dusting height of 50 cm is taken as the default .

- *Droplet size, airborne fraction.*

The average diameter of the dusted particles should be filled in as the droplet size. The diameter of the particles is important for the time that the particles remain in the air. Smaller

droplets fall more slowly. With regard to the number of particles in the air, in addition to the "particle size", the "airborne fraction" is also important. The airborne fraction is defined as the fraction of the particles that is dispersed in the air.

As a guideline for the size of the particles, the particle size distribution of agricultural lime is assumed. For lime marl the legal requirement is that 99 % of the lime particles are smaller than 1000 µm and 90 % are smaller than 150 µm. Based on this data, it is provisionally defined that most of the particles will have a diameter of between 50 and 150 µm. For the smallest 5% of the particles, the average particle size is set at 25 µm. It is assumed that this 5 % disperses itself in the air, that is, the "airborne fraction" is set at 5 %.

- *Respirable fraction*

The Biocides Steering Group(1998) indicates that 0.1 % of particles with a diameter of 15 µm are respirable, and that particles of 18 µm and larger are not respirable. CONSEXPO assumes that inhaled particles which are not respirable are taken in orally. For the time being, all particles that are dusted are assumed to be larger than 18 µm. This means that the respirable fraction is 0; no inhalation exposure occurs. It is assumed that all of the inhaled particles are taken in orally.

Dermal exposure: contact rate

- *Contact rate formulation*

When sprinkling/dusting the surface to be treated, dermal exposure can occur, particularly of the hands. This is definitely the case for products to control dust mites, which have to be brushed into the carpet. The dermal exposure is described using the contact rate model.

No data on the amount of the product that ends up on the hands have been found.
Van Hemmen (1992) gives 2 g formulation /hr as the indicative value for dermal exposure to solids during the mixing and loading of 25 kg of formulation (see §2.4). This can be converted into a contact rate formulation of 1.3 µg/min per gram of dusted powder.

If 60 g of dusting powder is dusted, the contact rate formulation is 60 x 1.3 = 78 µg/min. This value is used as the default value for the contact rate formulation. Van Hemmen's indicative value for professional application during mixing and loading is extrapolated to a consumer application for the scattering of powder. A quality factor of 3 is therefore assigned.

Exposure after application
Dermal exposure: "transfer coefficient" model

- *Transfer-coefficient*

Data about the transfer coefficient (the factor that indicates what surface is rubbed off by the skin per unit time, and is therefore transferred from the floor to the skin) is given by the EPA (1997). For children from 6 to 18 months who crawl over the treated carpet, a factor of 0.6 m^2/hr is given, where the EPA assumes a maximum of 4 hours of activity per day.

- *Dislodgeable fraction formulation*

In an HSL Pilot study on aerosols (cited in the Biocides Steering Group's report, 1998) 10 % is given as the value for the parameter 'dislodgeable residue from treated carpet'. The concept-SOP's of the US-EPA assume that 50 % of the amount of the active ingredient gets on to the surface. Based on this data, the default value for the dislodgeable fraction is set at 30%. If 60g of flea powder is sprinkled onto 1 m^2, the dislodgeable fraction formulation is therefore 60 x 0.3 =18 g/m^2.

Oral exposure: hand-mouth contact

- *Intake rate formulation*

For the oral exposure due to hand-mouth contact, it is assumed that 10 % of the amount of a product that gets onto a child's skin is taken in orally by hand-mouth contact (see § 2.2.6). The intake rate formulation can be calculated based on this assumption.

Default values for the application of dusting powder against crawling insects, indoors

Model	Parameter	Default value	Q	References, comments
Contact	frequency	5 year $^{-1}$	5	in summer, once a month
	use duration	5 min	4	estimation
	total duration	5 min	4	estimation
	start	0	9	direct exposure
Inhalation exposure spray – cloud model				
	emission rate formulation	12 µg/min [a)]	4	see above
	density formulation	1.5 g /cm^3	5	estimation
	airborne fraction	0.05 g/g	3	see above
	droplet size	25 µm	3	see above
	release height	50 cm	5	see above
	radius aerosol cloud	40 cm [a)]	3	see above
	room volume	20 m^3	8	see above
	ventilation rate	0.6 h^{-1}	8	see above
	surface	1 m^2	5	see above
	respirable fraction	0	5	see above
Dermal exposure contact rate				
	contact rate formulation	4.8 mg/min [a)]	3	see above

a) calculated parameter, see text

Default values after the application of dusting powder against crawling insects, indoors

Model	Parameter	Default value	Q	References, comments
Contact	frequency	5 year^{-1}	5	in summer once a month
	use duration	14 x 1 hr	6	see above
	total duration	14 days	6	see above
	start	0	9	direct exposure
Dermal exposure transfer factor				
	dislodgeable fraction formulation	18 g/m^2 [a)]	3	see above
	transfer coefficient	0.6 m^2/hr	6	see above
	surface	1 m^2	5	see above
Inhalation exposure hand-mouth contact				
	intake rate formulation	-- mg/min[a)]	3	see above

a) calculated parameter, see text

8 Textile biocides, gasses and foggers

8.1 Textile biocides

This concerns moth, decay and fungus-resistant products in textiles. One could think here of products such as carpets, awnings and tents. One could also think of mosquito nets which are impregnated with insecticide.
In the H-products category (1.4.1), only two products were found that are permitted in wool-processing factories to control insects that damage wool and silk. These products are added to

wool, silk, wool mixtures, and textile threads made up from them (CTB, 2000a). The active substance in both cases was permethrin. In “Textile finishing companies and carpet factories” (VROM, 1992) chlorophenyl and ammonia fluorosilicates are also named as moth, decay and fungus-resistant products. In the Netherlands, there are currently no permitted products with which to impregnate cotton (tents, awnings) with moth, decay and fungus resistant products (CTB, 2000b).

Textile biocides are applied to the textile during the production process. They are not used by consumers and are therefore not elaborated on in this study. Exposure by consumers to textile biocides can therefore only occur by using the treated products. The estimate of the exposure can be carried out in a similar way as the risk assessment for AZO-dyes in clothes (Zeilmaker et al., 1999).

8.2 Gasses and foggers

A number of pest control products is applied as gasses or a gas is formed during use. There are also pest control products which are applied in an atomized form.

The gas methylbromide is used as a pest control product for professional use in “storage, business and accommodation areas”. Examples of gas forming products are aluminum phosphide (AlP) and magnesium phosphide (Mg_2P_2). If these phosphides come into contact with moisture, the extremely poisonous gas phosphine (PH_3) is produced. The products mentioned above are permitted as supply protection products, to control animal organisms (mites and insects). The products or goods that can be gassed with phosphine include grains, grain products, seeds, nuts, spices, tea, tobacco, cotton and wool, in addition to furniture and empty buildings. The products may not be applied in living and accommodation areas or to control wood-attacking insects in buildings. Methylbromide is also allowed to control rats on board ships, since they cannot be controlled with anything else. The products may only be used by experts, under stringent conditions.

The soil in green houses used to be disinfected by gassing with methylbromide. This application has not been permitted for some time. In the past, to control wood-attacking insects in buildings, the building in question was packed in and gassed; prussic acid (hydrocyanic acid) was used as the active substance. The data above was obtained from the Pesticide Database of the Dutch Board for the Authorization of Pesticides (CTB, 2000a).

To prevent potatoes from germinating, they are “gassed” with a germination inhibitor (usually chlorprofam). Germination inhibitors are introduced into the internal air stream of the stored potatoes using a jet engine spray (“fog”). This type of product may only be used by professional users. The products fall into the “crop protection products” category.

All the above-mentioned applications for the use of gasses, gas-forming products and foggers are only permitted for professionals, and not for non-professional users. Exposure of consumers due to the use of these products will therefore not occur.

9 Uncertainties and limitations

This report records a number of default parameters which can be used in the exposure assessment of the non-professional user of pest control products, with the help of

CONSEXPO. The model approach for estimating the exposure has huge advantages. There is little quantitative data about consumer exposure to pest control products. The model approach makes it possible to extrapolate the relatively sparse data for certain products to other products and other scenarios, for which no there is no specific data. The determination of default values for the various model parameters also ensures that a high degree of consistency can be achieved in the assessments.

One should realize that the exposure estimates from a model depend on the quality and the reliability of the input-data. It is therefore recommend that one is alert in the choice of parameter values and the determination and improvement of default values. This last point is mainly true for scenarios and the related parameters which can have a major influence on the final exposure estimate.

The scenario of the dermal exposure of crawling children is based on a number of assumptions which must be substantiated further in the future. The quantitative estimate of the so-called hand-to-mouth route should also be further investigated.

It should also be noted that the model-modules used in CONSEXPO are developed for particular purposes (e.g., the spray-cloud model was developed for an aerosol can or trigger spray). When there are no adequate alternatives, one is forced to use some modules for derived scenarios. Until better models are available, the models suggested in the text are the best alternative. When drawing up an exposure calculation, the limitations of the used model must be stated.

Some examples are given below (already mentioned previously in the text):
For dusting powders the calculations are carried out using the ‘spray-cloud model’. This model assumes that the user has his/her nose in the aerosol cloud, which is a realistic assumption for a number of spray-applications. When scattering an ant powder, however, it can be assumed that there is some exposure to the powder, but not that the user has his/her nose in the powder cloud.
Another example of a (too) worst case assumption concerns the inhalation exposure due to evaporation of the active ingredient from strips and cassettes. For the inhalation exposure the “evaporation from pure substance” model is used.
In the “evaporation from pure substance” model, it is assumed that only the pure substance, i.e., the active ingredient, is present. The model does not take into account the fact that the active ingredient is caught in a solid matrix. The evaporating surface is adapted to the percentage of active ingredient in the matrix, however. Using the “evaporation from pure substance” model, an overestimate of the exposure will be calculated. There is currently no model which better describes the exposure.

In the next versions of CONSEXPO and/or in the update of this report (if more data is available) these aspects will be further elaborated on. Depending on what is needed, further adapting exposure modules of certain scenarios can be considered or developing new modules, for example.

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PART 3

SUMMARY OF CONTENTS

This guidance includes the concepts developed in report 97/505/3040/DEB/E2 and relates also to guidance on exposure assessment being developed for New and Existing Substances. The guidance is in three parts:

Part 1	Background information; concepts; models used for exposure estimation
Part 2	Specific guidance on estimating exposure, with flow diagrams
Part 3	Worked examples

Part 3 contains a series of examples for human exposure assessment in a range of biocide product types.

Recommendation

These examples, taken together with a compendium of decisions from human risk assessment, should provide the reference base for a future knowledge management project to simplify the assessment process.

This compilation is intended solely as examples. These should not be quoted, except as a procedure in support of authorisation. The examples illustrate only the principles and practice of exposure estimation.

The data and numbers used are for exemplifying only. They should not be considered as reference data.

INTRODUCTION

This compilation is intended solely as examples. These should not be quoted, except as a procedure in support of authorisation. The examples illustrate the principles and practice of exposure estimation. The examples are organised into sections as follows:

1 Reasonable worst case and foreseeable misuse

The following examples are set out by product type (in brief). Part 2.3.2 sets out the pattern of use statements for each of the product types in some detail. These examples present an indication of what is reasonable to include in an exposure estimate (reasonable worst case, foreseeable misuse) and what to exclude.

The "foreseeable non-proper (or incorrect) use" in this context is defined as an incorrect behaviour occurring with a distinct probability during use of biocidal products by professionals and non-professionals. Non-professional users do not necessarily have the knowledge and skills to handle biocidal products in compliance with the prescribed instructions and/or control measures. This is also true for part of the professional users. If the use of biocidal products is not routinely required in the workplace or is not a consistent part of the business, the qualification of these professionals to apply biocidal products is no better than within the general public.

Exposure situations, which result from accidents, malfunction or deliberate misuse, should not be addressed in this context.

Product type 2 Private area and public health area disinfectant, etc.

Products in this group are used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals. The product-type also includes products used as algicides in these areas.

The product-type is organised into the following sub-types:

- Disinfectants for private areas
- Disinfectants for professional cleaning and industrial areas
- Disinfectants for medical equipment
- Disinfectants for laundries
- Disinfectants for air-conditioning system
- Disinfectants for chemical toilets
- Disinfectants for swimming pools
- Disinfectants for waste water and hospital waste

Reasonable worst case use:	Splash or spillage of liquids
Foreseeable misuse:	Over-dosing, use of products not recommended for that application, bad rinse

Product type 4 Food and feed area disinfectants

Food and feed area disinfectants are used for disinfection of equipment, containers, consumption utensils, surfaces or pipe work associated with production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.

The product-type can be organised into the following application areas:

- Food and feed area disinfectants used in agriculture

- Disinfectants used in the food-processing industry
- Disinfectants used for food handling in retail shops or other food handling areas

Reasonable worst case use:	Spray application at over pressure
Foreseeable misuse:	Spray application at over concentration, over-dosing, bad rinse

Product type 6 In-can preservatives

In-can preservatives are biocidal-products used for the preservation of manufactured products, other than foodstuff or feedingstuff, in containers by the control of microbial deterioration to ensure their shelf life.

In-can preservatives are used in virtually all water-based non-food products.

The product-type can based on application areas be organised into four application areas:
- In-can preservatives for paints
- In-can preservatives for inks, fountain water, adhesives and sealants
- In-can preservatives for cleaning materials
- In-can preservatives for and other products

Reasonable worst case use:	Use of household detergent at high-end concentration in water. Splash and spillage of concentrates
Foreseeable misuse:	Use neat with abrasive for grease removal from hands. Use of concentrates

Product type 7 Film preservatives

Film preservatives are used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paint, plastic, sealants, adhesives, paper and art works.

The product-type can be organised into three subtypes:
- Film preservatives for paints
- Film preservatives for plastics
- Film preservatives for sealants, fillers and other products

Reasonable worst case use:	Painting at top end of duration range and exposure range, application in non-ventilated area, repeated contact with hands
Foreseeable misuse:	Painting indoors, product intended for use outdoors. Contact with surface before product is dry.

Product type 8 Wood preservatives

The product-type includes products used for the preservation of wood or wood products by the control of wood-destroying or wood-disfiguring organisms. The product-type includes both preventive and curative products.

The product-type can be organised into two subtypes:

- Vacuum preservatives and pressure preservatives
- Preservatives for surface treatment

Reasonable worst case use:	Application at top end of duration and exposure range. Use without protective equipment
Foreseeable misuse:	Error in diluting concentrate (up to 300% of intended strength)

Product type 11 Preservatives for liquid-cooling and processing systems

Products of this product-type are used for the preservation of water or other liquids used in cooling, heating or processing systems by the control of harmful organisms such as microbes, algae and mussels.

Reasonable worst case use:	Application at top end of intended concentration range.. Uncontrolled windage and blowdown.
Foreseeable misuse:	Bathing in decorative fountain. Over-dosing because of bad control of water balance in a cooling tower.

Product type 12 Slimicides for wood and paper pulp

Slimicides are added to paper pulp to prevent the formation of slime during the pulping process by biocidal control of bacteria in the pulp.

Reasonable worst case use:	Bad monitoring and control
Foreseeable misuse:	Over-dosing because of bad water balance control

.

Product type 13 Metalworking-fluid preservatives

Metalworking-fluid preservatives are used for control of microbial deterioration of metalworking fluids.

Reasonable worst case use:	Higher concentration than Maximum recommended
Foreseeable misuse:	Bad personal protective equipment

Product type 14 Rodenticides

The product-type includes products used in the combat of mice, rats and other rodents.

Reasonable worst case use: Mixing baits at top end of exposure range and concentration

Foreseeable misuse: Error in diluting concentrate (up to 300% of intended strength)

Product type 18 Insecticides, acaricides, etc

Insecticides, acaricides and products to control other arthropods are used in the combating of arthropods (e.g. insects, arachnids and crustaceans).

Reasonable worst case use: Application at top end of duration and exposure range

Foreseeable misuse: Spillage of concentrate

Product type 21 Antifouling products

Antifouling products are used to control the settlement and growth of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

Reasonable worst case use: Bad personal protective equipment during spraying

Foreseeable misuse: Non-professional application, wearing minimal clothing

2 Primary and secondary exposure routes and scenarios

The examples below (cross-refer Part 2.1.5) give the likely exposure routes:
I - inhalation (lung), D - dermal (via the skin), G - ingestion (gastric)

Primary exposure to biocidal product - task list		**Route ***
1.1	**Handling objects**	
1.1.1	Transfer - filling and emptying / dusts and weighing	I, D / I*****
1.1.2	Transfer - filling and emptying solids (non dust) or liquids and weighing	D/ I*****
1.1.3	Handling wet objects (se also 1.4)	D/ I*****
1.1.4	Handling dry / dusty objects	I, D/ I*****
1.2	**Dispersion of product with hand-held tool**	
1.2.1	Mixing and diluting	D/ I*****
1.2.2	Wiping surface (includes polishing)	D/ I*****
1.2.3	Scrubbing, scouring and abrading surface	I, D/ I*****
1.2.4	Spreading onto surface with comb, trowel or float	D/ I*****
1.2.5	Pouring onto surface	D/ I*****
1.2.6	Coating surfaces with brush or roller	D/ I*****
1.2.7	Application using a placement device (e.g. caulk gun, nozzle)	D/ I*****
1.2.8	Sweeping using broom	D/ I*****
1.2.9	Mopping	D/ I*****
1.3	**Dispersion of product with hand-held pressurised equipment**	
1.3.1	Spraying liquids for surface treatment	I, D/ I*****
1.3.2	Spraying dusts for surface treatment	I, D/ I*****
1.3.3	Foaming for surface treatment	I, D/ I*****
1.3.4	Spraying for surface coating	I, D/ I*****
1.3.5	Spraying air spaces (e.g. knock-down treatments)	I, D/ I*****
1.3.6	Injection of liquid or dust into soil or surface layers	I, D/ I*****
1.4	**Immersion**	
1.4.1	Bathing, showering	D, G/ I*****
1.4.2	Washing articles	D/ I*****
1.4.3	Manual dipping articles	D/ I*****
1.4.4	Automated / mechanical dipping, coating and impregnating articles	I, D/ I*****
1.5	**Interface with machinery and industrial systems**	
1.5.1	Systems dispersing vapours, gases, liquid aerosols or dusts	I, D/ I*****
1.5.2	Systems with liquid streams or sumps	D/ I*****
1.6	**Ancillary activities**	
1.6.1	Maintenance, servicing, cleaning, assembly and fitting	D, (I) / I*****
1.6.2	Sampling and in-situ testing	D, (I) / I*****
1.6.3	Other (define)	define/ I*****

*Note - if the biocide is volatile, the route will always include "inhaled" (**I***)

Secondary exposure sources and routes

Secondary exposure routes - biocidal products	
1	**Exposure by inhalation**
1.1	*Application phase*
1.1.1	Vapour during application
1.1.2	Liquid or dust aerosol during application
1.2	*Post-application phase*
1.2.1	Volatilised product
1.2.2	Generated dust aerosols in reworking treated objects
1.2.3	Re-suspended solid aerosols (e.g. through vacuum cleaning) or product removal
2	**Exposure by skin contact**
2.1	*Application phase*
2.1.1	Deposition of aerosol, dust on exposed skin
2.2	*Post-application phase*
2.2.1	Contact with treated surfaces or articles
2.2.2	Contact with dusts
2.2.3	Contact with contaminated areas, clothing or tools
3	**Exposure by ingestion**
3.1	*Post-application phase*
3.1.1	Ingestion of dislodged dust and deposits (children)
3.1.2	Mouthing treated articles (children)
3.1.3	Ingestion of food / water contaminated with direct deposits
3.1.4	Ingestion of food contaminated with dislodged deposits

Scenarios - examples

Product type 2	Private area and public health area disinfectant, etc.
Primary exposure:	Teacher disinfecting area in kindergarten after child sickness
Secondary exposure:	Child inhaling airborne disinfectant residues / vapours

Product type 4	Food and feed area disinfectants
Primary exposure:	Professional disinfecting surface by wiping and leave-to-dry
Secondary exposure:	Customer ingestion of food in contact with surface

Product type 6	In-can preservatives
Primary exposure:	Householder applying preserved emulsion paint
Secondary exposure:	Child contact with surface before it has dried

Product type 7	Film preservatives
Primary exposure:	Tradesman applying mould resistant mastic in bathroom
Secondary exposure:	Householder contact with mastic surface after curing (very low probability, secondary exposure does not apply)

Product type 8	Wood preservatives
Primary exposure:	Industrial impregnation of wood products
Secondary exposure:	Professional sanding a preserved product

Product type 11	Preservatives for liquid-cooling and processing systems
Primary exposure:	Addition of concentrate to recirculating system
Secondary exposure:	Bystander inhalation of vapour / mist (winding)

Product type 14	Rodenticides
Primary exposure:	Mixing and placing rodenticide bait
Secondary exposure:	Child exposure to body fluid of domestic pet after its bait ingestion

Product type 18	Insecticides, acaricides, etc
Primary exposure:	Householder applying flea dust to pet bedding
Secondary exposure:	Child exposure playing indoors.

Product type 21	Antifouling products
Primary exposure:	Non-professional removal of expired antifoulant coating
Secondary exposure:	Home laundry of work-wear.

3 Examples of assumptions for patterns of use

Exposure estimates need clarity on the assumptions made. Otherwise, assessors will be unable to check the validity of estimates or the outputs from mathematical models reproduced. Examples are set out below.

Examples of **assumptions** used for Patterns of Use

Product type 2	Private area and public health area disinfectant, etc.
Scenario:	fumigation of glove box for pathogen handling
User:	professional
Pattern of use:	non dispersive
Controls expected:	containment and method statement, ventilation and contingency plans
Duration of exposure:	single event (10 minutes)
Frequency of exposure:	1/week
Route of exposure:	I, D
Quantity used:	200 ml concentrate

Product type 4	Food and feed area disinfectants
Scenario:	medium pressure foam application to walls and floors
User:	professional
Pattern of use:	non dispersive
Controls expected:	coveralls, waterproof gloves and footwear; eye protection (mixing).
Duration of exposure:	6 days/week
Frequency of exposure:	2 hrs/day
Route of exposure:	I, D
Quantity used:	200 litres diluted product

Product type 6	In-can preservatives
Scenario:	applying emulsion paint to ceiling and walls by roller
User:	non-professional
Pattern of use:	dispersive
Controls expected:	wash paint from skin after use
Frequency of exposure:	5 days sequence, once per year
Duration of exposure:	8 hours/10 liters
Quantity used:	10 litres

Product type 7 Film preservatives
Scenario: applying wallpaper paste to paper by brush
User: professional
Pattern of use: non dispersive
Controls expected: coveralls, wash paste from hands after use
Frequency of exposure: 5 days per week (worst case)
Duration of exposure: 6 hours, intermittent
Route of exposure: I, D
Quantity used: 10 litres made-up product/day

Product type 8 Wood preservatives
Scenario: industrial vacuum-pressure impregnation of fencing poles etc.
User: professional
Pattern of use: non dispersive
Controls expected: coveralls, protective gloves and footwear, health surveillance
Frequency of use: daily, 6 days per week. 3 treatment cycles per day
Duration of exposure: 30 minutes per cycle
Frequency of exposure: 3-5 per day
Route of exposure: I, D
Quantity used: not relevant, in view of the process

Product type 11 Preservatives for liquid-cooling and processing systems
Scenario: automatic dosing into cooling tower - reservoir drum change
User: professional
Pattern of use: non dispersive
Controls expected: gloves, coveralls, eye and face protection
Duration of exposure: intermittent dosage, event
Frequency of exposure: once a week
Route of exposure: I, D
Quantity used: not relevant

Product type 14 Rodenticides
Scenario: retrieving and pouring grain into baiting station in foul water drain
User: professional

Pattern of use:	non dispersive
Controls expected:	gloves, coveralls
Frequency of use:	12 times daily, several days per week
Duration of use:	2 minutes
Route of exposure:	D
Quantity used:	100 g baited grain

Product type 18	Insecticides, acaricides, etc
Scenario:	pre-pressurised insecticide air space spray for flying insects
User:	non-professional at work in office
Pattern of use:	dispersive
Controls expected:	office clothing (shirt / blouse and trousers / skirt)
Frequency of exposure:	daily use over a 3-month period
Duration of exposure:	20 seconds use plus post-use exposure
Route of exposure:	I, D
Quantity used:	7 g in-can product

Product type 21	Antifouling products
Scenario:	Ship painting
User:	professionals, they are well informed about hazards and risks, trained and they wear PPE
Pattern of use:	non dispersive
Controls expected:	clothing, waterproof gloves, PPE and RPE
Frequency of exposure:	5 days a week
Duration of exposure:	6 hours per day
Quantity used:	variable

In addition to these data, the typical default values selected for body-weight, inhalation rate, skin penetration value, room size, ventilation rate, etc. must be listed.

Note: the pattern of use is not necessarily relevant for estimating secondary exposure.

4 General exposure calculator

Since it is easy to make arithmetical errors in simple deterministic calculations, the following simple routine is recommended, to be reproduced in a spreadsheet.

CELL	A	B	C	D	E
1		**General exposure calculator**		**[title]**	
2		**Product**		**Calculation**	**Units**
3		active substance		D3	%
4		density		D4	g/ml (if w/v)
5					
6		**Potential dermal exposure**		value	
7		Indicative value	from model	D7	mg/min
8		duration		D8	min
9		potential dermal deposit		D7*D8	mg
10		clothing penetration	from model	D10	%
11		actual dermal deposit [*product*]		D9*D10/100	mg
12					
13		**Hand in gloves exposure**		value	
14		Indicative value	from model	D14	mg/min
15		duration		D8	min
16		actual hand deposit [*product*]		D14*D8	mg
17					
18		**Foot in shoe exposure**		value	
19		Indicative value	from model	D19	mg/min
20		duration		D8	min
21		actual foot deposit [*product*]		D19*D8	mg
22					
23		**Actual dermal exposure**			
24		product		D11+D16+D21	mg
25		active substance		D24*D3/100	mg
26					
27		**Skin penetration**		D27	%
28		active substance via the skin		D25*D27/100	mg
29					
30		**Exposure by inhalation**		value	
31		indicative value	from model	D31	mg/m^3
32		duration		D8	min
33		Inhalation rate		D33	m^3/min
34		inhaled volume		D33*D8	m^3
35		inhaled [*product*]		D31*D34	mg
36		active substance		D35*D3/100	mg
37					
38		**Dose**			
39		total		D28+D36	mg
40		body-weight		D40	kg
41		systemic dose		D39/D40	mg/kg bw

This calculator assumes all products have a density of 1.0. Errors in correcting for density are unlikely to exceed the errors in sampling. However, this single-event calculator produces erroneous results when multiple events are modelled. When the input values are taken from

data distributions, the magnitude of the error depends on the percentile and the number of events.

5 Examples of primary exposure estimates, database and mathematical models

A Database related examples, primary exposure

The examples cover only the "mixing and loading" or "application phase". The following table summarises the source data for the model calculations as set out in Appendix 5.1. No more than 3 significant figures are quoted.

Product Type	Scenario	Use *	Product	Model
2.01	Non-expert professional - wiping to disinfect body fluid spill (nursery)	5 min 2 x M&L + App	0.3% AS1 in water based RFU	HSE mixing TNO wiping
4	Professional trained user, space fogging disinfectant	30 min 1 x App	12% AS2 in RFU concentrate	HSE fogging
4	Professional trained user, area disinfection with hypochlorite foam	30 min 1 x App	2% AS3 via venturi mixer	HSE medium press. spray + Cl_2 model
6.02	Non-professional user, emulsion painting wall and ceiling with roller	240 min 1 x App	0.2% AS4 in RFU paint	HSE boat painting (amateur)
8.02	Professional user, remedial (curative) wood preservative spraying	40 min 2 x M&L + App	0.7% AS5 after dilution of concentrate	HSE medium pressure spraying
8.02	Non-professional user, painting fence using brush	155 min 1 x App	1.25% AS6 in solvent based RFU	HSE fence painting
14	Professional user, applying rodenticide dust in burrows	10 min 4 x M&L + App	0.1% AS7 - RFU dust	HSE spray and dust (low pressure)
18.02	Non-professional using hand-held aerosol space spray insecticide	0.1 min 4 x App	0.6% AS8 in RFU aerosol can	HSE amateur studies
21	Professional in aquaculture, net dipping and packing	60 min 1 x App	15% AS9 in sump from RFU drums	HSE dipping

* Use - indicates the pattern of use - e.g. 10 min - duration. 2 x M&L + App means two cycles of mixing and loading and application per day. AS - active substance. RFU - ready for use.

Common assumptions:

Bodyweight : default 70 kg for adult males and 60 kg for adult females;
ventilation rate of working adult males: default 1.25 m^3 / hr; 10 m^3 / day

(Ref: Technical guidance document in support of Commission Directive 93/67/EEC … part 1)

In several examples the adult weight is taken as 60 kg, since it might also reflect women; this is not always stated and perhaps not always right.

B ADDITIONAL EXAMPLES USING CONSEXPO AND BEAT

CONSEXPO, an example

Air space aerosol application

This example is based on a non-professional user who sprays an air space aerosol in the living room to control flies or mosquitoes. Part 2.3.5 provides default data and a default model for such application and the example is based on this information. A short description of the exposure scenario is as follows. The user sprays from the middle of the room in the direction of the upper corners. A daily use during a 3-month period is assumed, implying an environment rich in insects, such as wet areas with a lot of mosquitoes. This example concerns application, a post-application example is given separately.

Predicting exposures by means of a model involves three basic steps.

1. Model selection. An appropriate predictive model must be selected by means of the default data in Part 2.3.5 and the description of the predictive models in Part 2.3.4.
2. Data input. Input is needed to specify the use pattern (contact), the parameters needed to calculate the concentration of active ingredient and the parameters needed to calculate uptake or intake.
3. Exposure and dose calculation.

Model selection

Model selection is based on the defaults of Part 2.3.5. To calculate the exposure of the user during application, the CONSEXPO "spray cloud model" is used for the inhalation, the CONSEXPO "contact rate" model is used for the dermal exposure, and the "nonrespirable fraction" model for the oral exposure.

Data input

Contact. The use pattern is defined in terms of use duration, exposure duration and use frequency. The exposure duration is longer than the use duration because exposure will continue for the user after finishing the active application. In this case, the default data are followed, setting a use duration of 20 seconds, an exposure duration of 4 hours and a 90 applications a year.

Exposure. Input values for the exposure models is taken from the defaults and summarised in the table for the inhalation and dermal routes. Essentially, the parameters define how much formulation is released, what the characteristics of the room are, what the size of the aerosol cloud is and what size of droplets are produced. The arguments for a particular value are presented in Part 2.3.5. For the dermal route, the amount of formulation that contacts skin is set. The physico-chemical properties of the active ingredient (such as molecular weight and vapour pressure) and its weight fraction must be set from other sources, such as information from the producer or formulator. We will assume a 1% weight fraction of permethrin (molecular weight: 391 g/mol; vapour pressure: 1.20E-08 mm Hg; $\log K_{ow}$: 6.5; water solubility: 0.04 mg/litre).

Uptake. The example will confine itself to external exposure. For all routes of exposure, the uptake fraction is set to 100%, thereby equating external and internal exposures in the model outcome.

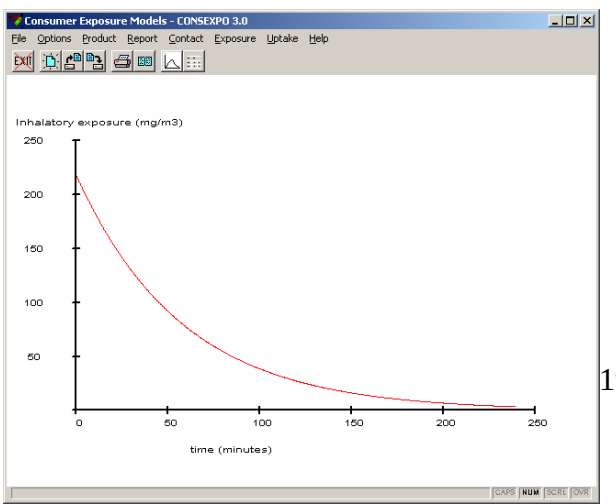
Table 1 Default values for application of air space aerosols from Part 2.3.5

Model	Parameter	Default value
Contact	frequency	90 year^{-1} a)
	use duration	20 sec
	total duration	4 hr
	start exposure	0
Inhalation exposure		
Spray: cloud model	emission rate formulation b)	0.35 g/sec
	density formulation	0.7 g/cm^3
	airborne fraction	100 %
	droplet size	5 µm
	release height	180 cm
	radius aerosol cloud	20 cm
	room volume	58 m^3
	ventilation rate	0.5 hr^{-1}
	surface	22 m^2
Dermal exposure		
Contact rate	contact rate formulation	16 mg/min
	density	0.7 g/cm^3
Inhalation Uptake		
Fraction Model	absorbed fraction	100%
	exercise level	light exercise
	respirable fraction	34.4%
Dermal & Oral Uptake		
Fraction Model	absorbed fraction	100%

a) daily use over a 3 month period
b) calculated parameter, see text

Exposure and dose calculation
The body weight is taken to be 70 kg. Model calculations, using CONSEXPO, return the following results

External exposure and dose	Value
4 hour average air concentration a.s.	52 mg/m^3
Chronic dose (year averaged)	1.1 mg/kg bw/day
Acute dose (day of application)	4.5 mg/kg bw/day



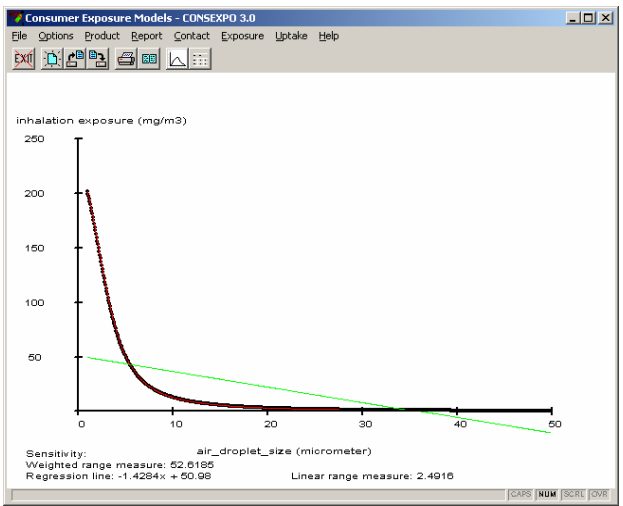


Figure 1. A. Exposure time course; B. sensitivity analysis of the parameter "radius cloud" which partly defines the volume of the cloud, and thus the exposure concentration because droplets are only present in the cloud. The reference line shows that the sensitivity (dots and red line) is far from linear

Result analysis

Model results can be analysed to reveal their uncertainty and sensitivity. On such analysis, the sensitivity analysis of the radius parameter is given in figure 1B. It shows that radius is a very sensitive parameter with regard to the exposure concentration. The reason is that it is an important determinant of the cloud volume that acts as the averaging volume for the aerosol droplets. A small volume implies a high concentration and vice versa. The sensitivity analysis shows that the radius of 20 cm implies a conservative estimate of the average exposure concentration, while lower values result in much higher concentrations. These concentrations are beyond available experimental values, e.g. from the HSE/HSL.

Post-application exposure following air space spraying

The exposure after application of an air space spray is described for crawling children present in the room after application. The group at risk are babies of about 10 months of age, who crawl on the floor and show extensive mouthing of objects and fingers. The droplets of the spray will float to the floor. It is assumed that the child (aged about ten months) crawls over the floor of the treated room and that residues are removed by means of cleaning once a week. As in the application example, predicting post-application exposure requires:

1. Model selection. An appropriate predictive model must be selected by means of the default data in Part 2.3.5 and the description of the predictive models in 3.4.
2. Data input. Input is needed to specify the use pattern (contact), the parameters needed to calculation the concentration of the active ingredient and the parameters needed to calculate uptake or intake.
3. Exposure and dose calculation.

Model selection

Post-application exposure involves dermal and oral exposure to deposited residues. From CONSEXPO, the dermal "transfer factor" and the oral "hand-to-mouth" models are selected, according to the defaults in Part 2.3.5.

Data input

Contact. The contact follows the application use pattern in term of frequency. The exposure duration is taken to be 7 days and the use duration is taken to be 1 hour to signal the period of crawling.

Exposure. The dermal model requests for the dislodgeable formulation, the transfer coefficient, the contaminated surface and a chemical half life and the oral model requests for the intake rate, all of which are summarised in table 2. The active ingredient, permethrin, its physico-chemical characteristics and weight fraction are copied from the application phase. It is assumed that no breakdown occurs and a very long half-life is entered in the model. For the hand-mouth contact, part 2, chapter 3.5 suggests to take 10% of the skin exposure. In this case, the dislodgeable amount on 0.6 m^2 is transferred to the skin per hour. As 380 mg/m^2 of dislodgeable formulation is present, this is 224 mg/hr. Orally, it is assumed that 10%, 22.4 mg/hr of formulation, is taken in.

Uptake. As in the application, we are concerned with external exposure and the uptake fraction is set to 100% to equate external and internal exposure.

Table 2. Default values for post- application exposure of air space spray from Part 2.3.5

Model	Parameter	Default value
Contact	frequency	90 days/life year^{-1} a)
	use duration	7 x1hr
	total duration	7 days
	start exposure	0
Dermal exposure		
Transfer coefficient	dislodgeable fraction formulation b)	380 mg/m^2
	transfer coefficient	0.6 m^2/hr
	surface	22 m^2
oral exposure		
hand-mouth contact	intake rate formulation	

a) daily use over a 3 month period (90 days per life if applied to babies)
b) calculated parameter, see text

Exposure and dose calculation
The body weight of children between 10 and 11 months is taken to be 8,69 kg, based on Dutch statistical data. The model calculations, using CONSEXPO, return the following results.

External exposure and dose	Value
Chronic dose (year averaged)	0.54 mg/kg bw/day
Acute dose (day directly after application)	0.31 mg/kg bw

BEAT EXAMPLE

Scenario: spray application of a water based disinfectant at approximately 10 bar using a hand held spray lance resulting in the spray nozzle being at arms length. BEAT uses the following user supplied information:

90% spray dispersion, 10% handling of contaminated objects.
Rate of application: 1 litre per minute.
Spray pressure: 10 bar.
Orientation of spraying: level.
Distance to source: arms length.
Carrier medium: water.
Segregation: none

BEAT predicts the distribution of potential body exposures (excluding hands) that might be experienced by a user.

BEAT output for predicted potential dermal exposure during

The following jobs are considered closely related:

Remedial biocides
Remedial biocides are applied to interior and external structural timber, masonry, surfaces and to wooden articles (fences sheds and seating). Whilst products may be applied by brush or a variety of manual methods, here the biocides have been applied at medium pressure (4-7 bar) using an electrical or fuel-driven pump-pressurised sprayer supplied from a reservoir. Mixing, loading and application are done as a single scenario.

Similarity	6.5
Number of exposure records	67

Anti-fouling spraying
Antifoulant paints are applied to ship hulls using high pressure airless spraying at up to 100 bar. Most contamination arises from impingement of the paint aerosol with the operator, but some contact with painted surfaces will occur. Exposure will be increased if the worker has to work in confined spaces such as in a well beneath the bottom of a vessel.

Similarity	4.0
Number of exposure records	27

Orchard spraying (uncabbed)
Spray application (including mixing/loading) of water based pesticide to orchard trees using tractor drawn or mounted spraying equipment. Tractors are uncabbed.

Similarity	3.3
Number of exposure records	7

PHI (liquids)
Public hygiene insecticides. These products are usually powders or concentrates for dilution and subsequent (low pressure) spraying. Lone working is common and jobs usually only last a few minutes.

Similarity	2.7
Number of exposure records	64

Predicted position in indicative distributions matrix

PROFILE	DEPOSITION RATE			
	Low 4mg/min	Medium 20 mg/min	High 100mg/min	Top 500 mg/min
Narrow	0	0	0	0
Intermediate	0.003	0.068	0.149	0.003
Wide	0	0.178	0.582	0.016

Most plausible distribution: high deposition rate (100 mg/min), wide profile (GSD=7.1)

Interpretation

Each cell in the indicative distribution matrix represents a different 'idealised' log normal distribution. The four different deposition rates represent four different geometric means whilst the differing profiles represent three different values for the geometric standard deviation. The entry in each cell represents the likelihood of the proposed scenario's exposure distribution being that particular log normal distribution *relative to the other eleven distributions.*

For the above BEAT predictions the single most likely cell has a 'high' deposition rate and 'wide' profile (median 100 mg/min, 75^{th} % 380 mg/min, 95^{th} % 2500 mg/min). BEAT's predictions suggest that this distribution is over 3 times more 'plausible' than a medium rate of deposition with a wide profile and 4 times more plausible than a high rate with a medium profile.

The above assessment leads to unambiguous predictions and risk assessments should be based upon percentiles chosen from the log normal distribution represented by a high rate and wide profile. In less clear-cut situations no hard and fast rules have yet been developed to accommodate the uncertainty in model predictions. In the absence of such guidance the default position should be to adopt the single most likely distribution. This is equivalent to current practise when using a conventional exposure data set: the sample 75th (typical) and/or 95th (reasonable worst case) percentiles are used without consideration of the uncertainty associated with sample size. Future research will address methods of incorporating this uncertainty into the risk assessment process.

Appendix 5.1 Calculation of exposure estimates

Format

Each estimate is derived through a format calculation to minimise the opportunity for error or omission of a necessary step. The format follows the spreadsheet proposal in Part 3.4, for each phase of exposure, as below and amended as appropriate:

Product	**Units**	**Nth-percentile**	**Xth-percentile**
active substance	%		
density	g/ml (if w/v)		
Potential dermal exposure			
clothing type			
indicative value	mg/min		
duration	min		
potential dermal deposit	mg		
clothing penetration	%		
actual dermal deposit [*product*]	mg		
Hand exposure			
gloves worn			
indicative value	mg/min		
duration	min		
actual hand deposit [*product*]	mg		
Foot exposure			
indicative value	mg/min		
duration	min		
actual foot deposit [*product*]	mg		
Actual dermal exposure			
product	mg		
active substance	mg		
Skin penetration	%		
active substance via the skin	mg		
Exposure by inhalation			
indicative value	mg/m^3		
duration	min		
inhalation rate	m^3/min		
inhaled volume	m^3		
mitigation by RPE	value		
inhaled [*product*]	mg		
active substance	mg		
Dose			
total per event	mg		
events per day			
total per day	mg		
body-weight	kg		
systemic dose	mg/kg bw/ day		

Example 2.01 Non-expert professional - wiping to disinfect body fluid spill (nursery)

Models - mixing and loading model 2, surface disinfection model 1

Product	**Units**	**Worst case**	**50-percentile**
active substance	%	0.3% AS1	0.3% AS1
density	g/ml (if w/v)	1.0	1.0
Hand exposure - mixing and load			
gloves worn		no	no
indicative value	mg/min	12.8 mg	1.1 mg
duration	min	event	event
actual hand deposit [*product*]	mg	12.8 mg	1.1 mg
Hand exposure - application			
gloves worn		no	no
indicative value	mg/min	70.2	36 (average)
duration	min	5	5
actual hand deposit [*product*]	mg	351	180
Actual dermal exposure			
product	mg	364	181
active substance	mg	1.09	0.54
Skin penetration	%	-	-
active substance via the skin	mg		
Dose			
total per event	mg	1.09	0.54
events per day		2	2
total per day	mg	2.18	1.08
body-weight	kg	-	-
systemic dose	mg/kg bw/day	-	-

(Note: this product containing AS1 has only local effects on the skin.)

Example 4a Specialised professional user, space-fogging disinfectant

Model - misting model 2 (waist level use)

Product	**Units**	**Worst case**	**75-percentile**
active substance	%	12% AS2	12% AS2
density	g/ml (if w/v)	1.0	1.0
Potential dermal exposure			
clothing type		coverall	coverall
indicative value	mg/min	35.5	21.8
duration	min	30	30
potential dermal deposit	mg	1070	654
clothing penetration	%	100%	20%
actual dermal deposit [*product*]	mg	1070	131
Hand exposure			
gloves worn		disposable	disposable
indicative value	mg/min	0.20	0.04
duration	min	30	30
actual hand deposit [*product*]	mg	6	1.2
Foot exposure			
indicative value	mg/min	0.04	0
duration	min	30	30
actual foot deposit [*product*]	mg	1.2	0
Actual dermal exposure			
product	mg	1080	132
active substance	mg	130	15.8
Skin penetration	%	100	10
active substance via the skin	mg	130	1.58
Exposure by inhalation			
indicative value	mg/m^3	79.5	70.2
duration	min	30	30
inhalation rate	m^3/min	0.021	0.021
inhaled volume	m^3	0.63	0.63
mitigation by RPE	value	none	APF 10
inhaled [*product*]	mg	50.1	4.42
active substance	mg	6.01	5.31
Dose			
total per event	mg	136	6.89
events per day		1	1
total per day	mg	136	6.89
body-weight	kg	60	60
systemic dose	mg/kg bw/day	2.27	0.11

Example 4b Specialised professional user, area disinfection with hypochlorite foam Model - spraying model 2 (4-7 bar), includes mixing and loading.

Product	**Units**	**95-percentile**	**75-percentile**
active substance	%	2% AS3	2% AS3
density	g/ml (if w/v)	1.0	1.0
Potential dermal exposure			
clothing type		coverall	coverall
indicative value	mg/min	2100	222
duration	min	30	30
potential dermal deposit	mg	63000	6660
clothing penetration	%	100	5
actual dermal deposit [*product*]	mg	63000	333
Hand exposure			
gloves worn		yes	yes
indicative value	mg/min	191	7.8
duration	min	30	30
actual hand deposit [*product*]	mg	5730	234
Foot exposure			
indicative value	mg/min	260 (worst)	5.4
duration	min	30	30
actual foot deposit [*product*]	mg	7800	162
Actual dermal exposure			
product	mg	76500	729
active substance	mg	1530	14.6
Skin penetration	%	100	10
active substance via the skin	mg	1530	1.46
Exposure by inhalation			
indicative value	mg/m^3	198	76
duration	min	30	30
inhalation rate	m^3/min	0.021	0.021
inhaled volume	m^3	0.63	0.63
mitigation by RPE	value	none	none
inhaled [*product*]	mg	125	47.9
active substance	mg	2.49	0.96
Dose			
total per event	mg	1530	2.42
events per day		1	1
total per day	mg	1530	2.42
body-weight	kg	60	60
systemic dose	mg/kg bw/day	25.5	0.04

Note. If hypochlorite is AS3, based on spraying model 7 (surface disinfection), the 95-percentile estimated exposure to chlorine is 0.65 mg/m^3 and to nitrogen trichloride at 0.8 mg/m^3

Example 6.02 Non-professional user, emulsion painting wall and ceiling with roller Model - brush painting model 4 (orientation as for roller coating underside of leisure craft)

Product	**Units**	**Worst case**	**75-percentile**
active substance	%	0.2% AS4	0.2% AS4
density	g/ml (if w/v)	1.0	1.0
Potential dermal exposure			
clothing type		minimal	light
indicative value	mg/min	108	50.8
duration	min	240	240
potential dermal deposit	mg	25900	12200
clothing penetration	%	100	50
actual dermal deposit [*product*]	mg	25900	6100
Hand exposure			
gloves worn		no	yes
indicative value	mg/min	76.6	3.77
duration	min	240	240
actual hand deposit [*product*]	mg	12000 (note)	905
Foot exposure			
indicative value	mg/min	0.11	0
duration	min	240	240
actual foot deposit [*product*]	mg	26.4	0
Actual dermal exposure			
product	mg	37900	7010
active substance	mg	75.8	14.0
Skin penetration	%	100	10
active substance via the skin	mg	75.8	1.40
Exposure by inhalation			
indicative value	mg/m^3		
duration	min	0.11	0.05
inhalation rate	m^3/min	0.021	0.021
inhaled volume	m^3	240	240
mitigation by RPE	value	none	None
inhaled [*product*]	mg	0.55	0.25
active substance	mg	0.001	0.001
Dose			
total per event	mg	75.8	1.40
events per day		1	1
total per day	mg	75.8	1.40
body-weight	kg	60	60
systemic dose	mg/kg bw/day	1.26	0.023

Note - the calculated quantity - 18 g- exceeds the realistic worst case default of 12 ml (12000 mg).

The product containing AS4 is certain to be less viscous than antifoulant.

Example 8.02a Professional user, remedial (curative) wood preservative spraying Model - spray model 2 (4 - 7 bar) - includes mixing and loading

Product	**Units**	**95-percentile**	**75-percentile**
active substance	%	0.7% AS5	0.7% AS5
density	g/ml (if w/v)	1.0	1.0
Potential dermal exposure			
clothing type		coverall	coverall
indicative value	mg/min	2100	222
duration	min	40	40
potential dermal deposit	mg	84000	8880
clothing penetration	%	100	5
actual dermal deposit [*product*]	mg	84000	444
Hand exposure			
gloves worn		yes	yes
indicative value	mg/min	191	7.8
duration	min	40	40
actual hand deposit [*product*]	mg	7640	312
Foot exposure			
indicative value	mg/min	260 (worst)	5.4
duration	min	40	40
actual foot deposit [*product*]	mg	10400	216
Actual dermal exposure			
product	mg	102000	972
active substance	mg	714	6.80
Skin penetration	%	100	10
active substance via the skin	mg	714	0.68
Exposure by inhalation			
indicative value	mg/m^3	198	76
duration	min	40	40
inhalation rate	m^3/min	0.021	0.021
inhaled volume	m^3	0.84	0.84
mitigation by RPE	value	none	APF 10
inhaled [*product*]	mg	166	6.38
active substance	mg	1.16	0.45
Dose			
total per event	mg	715	1.13
events per day		2	2
total per day	mg	1430	2.26
body-weight	kg	60	60
systemic dose	mg/kg bw/day	23.8	0.04

Example 8.02b Non-professional user, painting fence using brush

Model - brush painting fences model 3

Product	**Units**	**Worst case**	**75-percentile**
active substance	%	1.25% AS6	1.25% AS6
density	g/ml (if w/v)	1.0	1.0
Potential dermal exposure			
clothing type		minimal	light
indicative value	mg/min	63.3	16.9
duration	min	155	155
potential dermal deposit	mg	9810	2620
clothing penetration	%	100	50
actual dermal deposit [*product*]	mg	9810	1310
Hand exposure			
gloves worn		no	yes
indicative value	mg/min	56.3	0.3
duration	min	155	155
actual hand deposit [*product*]	mg	8730	46.5
Foot exposure			
indicative value	mg/min	0.24	0.05
duration	min	155	155
actual foot deposit [*product*]	mg	37.2	7.75
Actual dermal exposure			
product	mg	18600	1360
active substance	mg	232	17.1
Skin penetration	%	100	10
active substance via the skin	mg	232	1.71
Exposure by inhalation			
indicative value	mg/m^3	8.03	4.15
duration	min	155	155
inhalation rate	m^3/min	0.021	0.021
inhaled volume	m^3	3.26	3.26
mitigation by RPE	value	none	none
inhaled [*product*]	mg	26.2	13.5
active substance	mg	0.33	0.17
Dose			
total per event	mg	232	1.88
events per day		1	1
total per day	mg	232	1.88
body-weight	kg	60	60
systemic dose	mg/kg bw/day	3.87	0.03

Example 14 Professional user, applying rodenticide dust in burrows

Model - spraying / dusting model 1

Product	**Units**	**95-percentile**	**75-percentile**
active substance	%	0.1% AS7	0.1% AS7
density	g/ml (if w/v)		
Potential dermal exposure			
clothing type		coverall	coverall
indicative value	mg/min	251	92
duration	min	10	10
potential dermal deposit	mg	2510	920
clothing penetration	%	100	20
actual dermal deposit [*product*]	mg	2510	184
Hand exposure			
gloves worn		yes	yes
indicative value	mg/min	39.4	10.7
duration	min	10	10
actual hand deposit [*product*]	mg	394	107
Actual dermal exposure			
product	mg	2900	291
active substance	mg	2.9	0.29
Skin penetration	%	100	10
active substance via the skin	mg	2.9	0.029
Exposure by inhalation			
indicative value	mg/m^3	405	130
duration	min	10	10
inhalation rate	m^3/min	0.021	0.021
inhaled volume	m^3	0.21	0.21
mitigation by RPE	value	none	APF 10
inhaled [*product*]	mg	85.1	2.73
active substance	mg	0.085	0.003
Dose			
total per event	mg	2.99	0.032
events per day		4	4
total per day	mg	12.0	0.13
body-weight	kg	60	60
systemic dose	mg/kg bw/day	0.2	0.002

(This model has no data for feet exposure)

Example 18.02 Non-professional using hand-held aerosol space spray insecticide

Model - air space spraying model 1 (aerosol can). Indicative values refer to in-can product

Product	**Units**	**Worst case**	**75-percentile**
active substance	%	0.6% AS8	0.6% AS8
density	g/ml (if w/v)	1.0	1.0
Potential dermal exposure	legs, feet, face		
clothing type		minimal	light
indicative value	mg/min	233	113
duration	min	0.1	0.1
potential dermal deposit	mg	23.3	11.3
clothing penetration	%	100	50
actual dermal deposit [*product*]	mg	23.3	5.65
Hand exposure	hands, forearms		
gloves worn		no	no
indicative value	mg/min	432	156
duration	min	0.1	0.1
actual hand deposit [*product*]	mg	43.2	15.6
Actual dermal exposure			
product	mg	66.5	21.3
active substance	mg	0.4	0.13
Skin penetration	%	100	10
active substance via the skin	mg	0.4	0.013
Exposure by inhalation			
indicative value	mg/m^3	374	234
duration	min	0.1	0.1
inhalation rate	m^3/min	0.021	0.021
inhaled volume	m^3	0.002	0.002
mitigation by RPE	value	none	none
inhaled [*product*]	mg	0.79	0.49
active substance	mg	0.005	0.003
Dose			
total per event	mg	0.41	0.016
events per day		4	4
total per day	mg	1.64	0.064
body-weight	kg	60	60
systemic dose	mg/kg bw/day	0.03	0.001

Note - this model includes 30s residence in room post-spraying.

Example 21 Professional in aquaculture, net dipping and packing

Model - dipping 4 (antifoulant net) - viscous product.
Active substance AS9 irritates but does not penetrate skin. It is harmful by inhalation.

Product	**Units**	**Worst case**	**75-percentile**
active substance	%	15% AS9	15% AS9
density	g/ml (if w/v)	1.0 nominal	1.0 nominal
Potential dermal exposure			
clothing type		coverall	coverall
indicative value	mg/min	1500	73.9
duration	min	60	60
potential dermal deposit	mg	90000	4430
clothing penetration	%	100	5
actual dermal deposit [*product*]	mg	90000	222
Hand exposure			
gloves worn		yes	yes
indicative value	mg/min	16.7	2.98
duration	min	60	60
actual hand deposit [*product*]	mg	1000	179
Foot exposure			
indicative value	mg/min	5.66	0.92
duration	min	60	60
actual foot deposit [*product*]	mg	340	55.2
Actual dermal exposure			
product	mg	91300	456
active substance	mg	13700	68.4
Exposure by inhalation			
indicative value	mg/m^3	0.20	0.11
duration	min	60	60
inhalation rate	m^3/min	0.021	0.021
inhaled volume	m^3	1.25	1.25
mitigation by RPE	value	none	none
inhaled [*product*]	mg	0.25	0.14
active substance	mg	0.038	0.021
Dose			
total per event	mg	0.038	0.021
events per day		1	1
total per day	mg	0.038	0.021
body-weight	kg	60	60
systemic dose	mg/kg bw/day	0.0006	0.0004
skin surface dose	mg	13700	68.4

Exposure by ingestion is probable, though not modelled. Biomonitoring may indicate the degree of uptake by this route.

6 Examples of secondary exposure estimates

The examples suggested in Part 3.2 are as follows, with certain additions:

Product type 2	Private area and public health area disinfectant, etc.
Secondary exposure:	Infant inhaling airborne disinfectant residues / vapours
Product type 4	Food and feed area disinfectants
Secondary exposure:	Ingestion of food in contact with surface residues
Product type 6	In-can preservatives
Secondary exposure:	Child in contact with surface before paint has dried
Product type 7	Film preservatives
Secondary exposure:	Householder cleaning cured preserved mastic surface
Product type 8	Wood preservatives
Secondary exposure:	Machine sanding a preserved product (chronic)
Product type 9	Textile preservative
Secondary exposure	Repairing military tents treated with fungicide
Product type 11	Preservatives for liquid-cooling and processing systems
Secondary exposure:	Bystander inhalation of spray from preserved cooling water
Product type 14	Rodenticides
Secondary exposure:	Child exposure to body fluid of domestic pet after its bait ingestion
Product type 18	Insecticides, acaricides, etc
Secondary exposure:	adult in bedding treated for bed-bugs
	Child exposure playing with cat indoors after flea dusting animal bed
	Infant exposure to insecticide spray residue
Product type 21	Antifouling products
Secondary exposure:	Home laundry of 2nd layer of work-wear used for antifoulant spraying

The following table summarises the calculation results as set out in Appendix 6.1.

Type	Scenario	Route	Estimate
2.01	Infant vapour inhalation	Inhaled	0.003 mg/kg bw
4	Food contacts residues	Ingested	0.2 mg/kg bw
6.02	Contact with wet paint	Dermal	4 mg/kg bw
7	Clean / abrade mastic	Dermal	0.5 mg/kg bw
8.01	Machine sanding	Inhaled	0.002 mg/kg bw/day
9.01	Repairing military tents	Dermal	0.21 mg/kg bw/day
11.01	Preserved water spray	Inhaled	5.3E-06 mg/kg bw
14	Child contacts sick pet	Dermal	0.33 mg/kg bw
18.01	Adult contact with bedding	Dermal	0.023 mg/kg bw/day
18.02	Child contacts flea dust	Dermal	0.04 mg/kg bw
18.02	Child ingests overspray	Ingested	0.13 mg/kg bw
21	Adult - home laundry	Dermal	0.16 mg/kg bw

Note - other populations, scenarios and phases will need to be examined in full assessments.

Appendix 6.1 Calculation of exposure estimates

2.01	Infant vapour inhalation	Inhaled
4	Food contacts residues	Ingested
6.02	Contact with wet paint	Dermal
7	Clean / abrade mastic	Dermal
8.01	Machine sanding	Inhaled
11.01	Preserved water spray	Inhaled
14	Child contacts sick pet	Dermal
18.02	Child contacts flea dust	Dermal, Inhaled
18.02	Infant ingests overspray	Ingested
21	Adult - home laundry	Dermal

Example 2.01 Inhalation of vapour - infant

Product type 2 Private area and public health area disinfectant, etc.
Secondary exposure: Infant inhaling airborne disinfectant residues / vapours

Assumptions:
- Disinfectant saturated vapour concentration = 0.5 ppm, worst case = 0.05 ppm (1/10th of SVC), since surveys show extremely low air levels
- Disinfectant Mol. Wt = 150
- Duration of exposure - 60 minutes as air concentration decays to zero
- Infant (10 kg) inhales 4 m^3 / day : 0.17 m^3 /hr
- Inhalation at average 0.025 ppm = 0.16 mg/m^3 over 60 min, inhaled volume 0.17 m^3. Intake = 0.16 x 0.17 = 0.027 mg.

This *acute reference scenario* gives infant systemic exposure at 0.003 mg/kg bw.

Example 4 Ingestion following contact with surface residues - child

Product type 4 Food and feed area disinfectants
Secondary exposure: Ingestion of food in contact with surface residues

Assumptions and scenario development:

- Disinfectant film 0.1 mm thick contains 2% non-volatile active substance
- 10% dislodges to food over area of sandwich (150 cm^2)
- 15 kg child eats sandwich

Quantity dislodged = (150 x 0.01 cm^3 x 2% AS x 10%) = 0.003 g = 3 mg

This *acute reference scenario* gives child systemic exposure at 0.2 mg/kg bw.

Example 6.02 Dermal contact with wet paint by child

Product type 6 In-can preservatives.
Secondary exposure: Child in contact with surface before paint has dried

Assumptions (possibly not realistic for thickness and dislodgeing) and scenario development:

- Paint film 1 mm thick contains 3% active substance (AS)
- 50% of film dislodges on skin contact (200 cm^2)
- Cleaning off with thinner causes uptake via skin at 20% for 15 kg child

Quantity dislodged = (200 x 0.1 cm^3 x 50%) = 10 cm^3 containing 2*0.3/100 = 0.006 mg AS
Uptake via skin at 20% = dose of 60 mg..

This *acute reference scenario* gives child systemic exposure at 4 mg/kg bw.

Example 7 Dermal contact with surface bloom on preserved mastic - adult

Product type 7 Film preservatives.
Secondary exposure: Householder cleaning cured preserved mastic surface

Assumptions and scenario development

- Mastic bloom contains 1 mg active substance (AS) per cm^2 wiping 300 x 0.5 cm
- 10% of bloom dislodges to skin
- Uptake via skin at 20% for 60 kg adult

Quantity contacted = (300 x 0.5 cm^2 x 1 mg) = 150 mg AS
Uptake via skin at 20% = dose of 30 mg

This *acute reference scenario* gives adult systemic exposure at 0.5 mg/kg bw.

Example 8.01 Inhalation of dust - machine sanding preserved wood - adult

Product type 8 Wood preservatives.
Secondary exposure: Machine sanding a preserved product

Assumptions and scenario development

- 150 litres of preservative at 0.75% active substance per m^3 wood.
- preservative is evenly concentrated in outer 1 cm wood.
- article - 40 cm x 6 cm x 3 m posts (0.00072 m^3 wood, area 756 cm^2)
- sander generates 5 mg/m^3 dust for 360 minutes job total time.
- 60 kg adult inhales 1.25 m^3/hour.

Amount of AS in outer timber layer = 0.00072 m^3 x 150 l x 0.75% = 0.081 g in AS in outer 1 cm layer. Wood density = 0.8 g/ cm^3.

Concentration of AS is wood dust = 0.081 x 1000/(756 x 0.8) = 0.134 mg / g wood dust.
At 5 mg/m^3 over 6 hours = 37.5 mg dust inhaled = 0.05 mg AS uptake at 100%,

This *chronic reference scenario* gives adult systemic exposure at 0.00008 mg/kg bw/day

Example 9.01 Dermal contact with fungicide - adult

Product type 9 Textile preservative
Secondary exposure Repairing military tents treated with fungicide

Assumptions and scenario development

- Tents originally coated at a rate of 0.25 l / m^2 with 2% AS in solvent
- Repeated contact with 500 cm^2 skin at 50% transfer efficiency
- 10% uptake of dermal deposit

Area contamination = 250 x 2/100 = 5 g / m^2 with 50% transferred to hand.
Hand contamination = 5000 x 500/10000 x 50/100 = 2500 mg, and with 10% uptake = 250 mg.

This *chronic reference scenario* gives adult systemic exposure at 4.17 mg/kg bw/day.

Example 11.01 Inhalation of spray from once-through system - adult

Product type 11 Preservatives for liquid-cooling and processing systems.
Secondary exposure: Bystander inhalation of spray from preserved cooling water

Assumptions and scenario development

- Airborne concentration 10 mg/m^3 containing 50 ppm (50 mg/l) preservative
- Uptake at 100% for 60 kg adult over 30 minutes (0.63 inhaled)

Quantity inhaled = (0.63 x 10 x 50/10^6) = 3 E-04 mg AS

This *acute reference scenario* gives adult systemic exposure at 3 E-04 /60= 5.3 E-06 mg/kg bw.

Example 14 Dermal contact with body fluid from sick pet - child

Product type 14 Rodenticides.
Secondary exposure: Child exposure to domestic pet vomit after its bait ingestion

Assumptions and scenario development

- Pet vomit contains 50 g bait with 0.1% active substance (AS)
- Child (15 kg) uptake via skin = 10%

Quantity available = (50 x 0.1%) = 50 mg AS, at 10% uptake it is 5 mg AS

This *acute reference scenario* gives child systemic exposure at 5/15 = 0.33 mg/kg bw.

Example 18.01 Dermal contact with dust in barracks bedding - adult

Product type 18 Insecticides, acaricides, etc.
Secondary exposure: bedding treated for bed-bugs

Assumptions and scenario development

- Bedding in military barracks treated with 2% AS in dust at 35 g product / m^2 bed.
- Skin area = 1.94 m2, 50% in contact with bedding
- Transfer efficiency from bed to skin = 20%
- Uptake of dust via skin 1%

Quantity on skin = (35 x 1.94 x 50% x 20%) = 6.79 g product = 136 mg AS
Uptake via skin = 136 x 1% = 1.36 mg

This *chronic reference scenario* gives adult systemic exposure at 0.023 mg/kg bw/day.

Example 18.02a Dermal contact with flea dust in animal bedding - child

Product type 18 Insecticides, acaricides, etc.
Secondary exposure: Child exposure playing indoors with cat after flea dusting animal bed

Assumptions and scenario development

- Product contains 0.5% active substance (AS),
- Worst case dusting exposure (surface dusting - non-professional) at 8 mg/m^3 dust
- Child (15 kg) exposure = 60 minutes, inhaled rate 10 m^3 / day
- skin exposure equivalent to 12 ml spill (12 g)
- uptake of AS via skin = 1%

Quantity inhaled = (8 x 10 x 1/24) = 3.33 mg product = 0.017 mg AS
Quantity via skin = (12 x 1000 x 0.5%) x 1% = 0.6 mg AS

This *acute reference scenario* gives child systemic exposure at 0.04 mg/kg bw.

Example 18.02b Ingestion of insecticide overspray - infant

Product type 18 Insecticides, acaricides, etc.
Secondary exposure: Infant exposure to insecticide spray residue

Assumptions and scenario development

- wasp crawling near jam on kitchen table, treated with 1 second direct burst of spray.
- 1 g product discharged containing 0.25% active substance = 2.5 mg active substance.
- infant contacts sprayed jam and contacts 50% of spray deposit.
- infant sucks fingers removing 100% of contamination.

This *acute reference scenario* gives a single ingestion of 2.5 x 0.5 x 1 = 1.25 mg and a dose (10 kg infant) at 0.13 mg/kg bw.

Example 21 Home hand laundry of contaminated coveralls (2 days' use) - adult

Product type 21 Antifouling products.
Secondary exposure: Home laundry of 2nd layer of work-wear used for antifoulant spraying

Assumptions and scenario development

- 745 mg/min (95th %) x 6 hours spraying x 5% penetration of top clothing layer
- 7% AS in deposit - all extracts to washing water
- 1% of this is taken up by skin

Quantity of product = 745 x 6 x 60 = 268000 mg paint of which 13400 mg penetrates.
Quantity of AS = 13400 x 7 / 100 = 939 mg, 1% uptake = 9.39 mg

This *acute reference scenario* gives a single adult dose at 0.16 mg/kg bw.

7 Format for exposure estimates; four fully-worked examples

7.0 proposed format for reporting exposure estimates

INTRODUCTION
- Identity: product name, % a.s. in product , % a.s. in application
- Intended use and user sector

EXPOSURE DATA
- Industry data
- Regulator data

PRODUCT USE
- Phases of use review: process description
  - Mixing and loading (list the tasks in each phase)
  - Application (with the relevant task classification)
  - Post-application (descriptor from Part 2)
  - Disposal

PRIMARY EXPOSURE ESTIMATES
- Tier 1
  - All phases, all tasks (state assumptions, defaults, and models for each phase and task)
- Tier 2
  - All phases, all tasks (state assumptions, defaults, and models for each phase and task)

(models and calculations in Appendix)

SECONDARY EXPOSURE ESTIMATES
- Acute phase
  - Adults, children, infants (reference scenarios, exposure route)
- Chronic phase
  - Adults, children, infants (reference scenarios, exposure route)

(calculations in Appendix)

SUMMARY OF EXPOSURE ESTIMATES
- Table

REFERENCES

APPENDIX
- Models used
  - Reference and inputs
- Calculations
  - Table format

7.1 Wood preservative

The following example is based upon an UK biocide active substance review. The active substance is "WP1" in a product "Timbertreat".

TIMBERTREAT INDUSTRIAL WOOD PRESERVATIVE PRODUCT

INTRODUCTION

Identity

Timbertreat is a water-based product containing 2% w/w of the active substance "WP1", with co-formulants.

WP1 molecular weight = 320 and saturated vapour concentration = 0.03 Pa at 25 C.

Intended use and user sector

Timbertreat is intended for use in industrial preservation through the vacuum-pressure or the double-vacuum process. The intended uptake into the outer 1 cm layer of wood is 50 litres of product per m^3 of wood.

EXPOSURE DATA

Industry data

Industry supplied no data for human exposure to Timbertreat.

Regulator data

The UK Health and Safety Executive has collected generic information on human exposure to water-based industrial wood preservatives to inform its role of assessing exposure and risk to operators and others. The acquired information is of two types:

1. *The pattern of use* - the frequency and duration of potential exposure, the amount of product used and seasonal factors;

2. *Results from exposure surveys* - the median and realistic worst case exposures in applying products through site surveys of identified tasks or jobs.

The exposure studies informing HSE assessments of industrial wood preservatives in respect of Timbertreat have been reported in summary in "Dermal exposure to non-agricultural pesticides", (publication EH74/3), and in "Patterns of use for some non-agricultural pesticides", (an HSE internal document).

All HSE data are quoted in terms of the in-use product being applied, and are time-weighted over a cycle of work. Data are presented as ‘mg product $cycle^{-1}$’ for dermal exposure and ‘mg product m^{-3}’ for inhalation exposure, respectively.

HSE data are expressed in terms of distributions. For this example, the median value in the exposure distribution, moderated by the 'frequency' - the likelihood that exposure will occur at all - has been taken to represent the 'central tendency' value. The reasonable worst case is taken as the 95th percentile data point in the non-zero data distribution.

HSE data indicate that 12 % is a realistic figure to adopt for the penetration of timber preservative through a layer of typical work clothing.

PRODUCT USE

Phases of use review

Mixing and loading

Products are supplied by tanker as concentrates. These are diluted in process plant, or as ready-for-use solutions. Other than incidental exposure in connecting and disconnecting transfer lines, exposure is not foreseen. Incidental exposure is contact with product inside protective gloves and on taking off protective gloves. Users - trained professionals.

Descriptors: Task - 1.1.2 - transfer liquids
Determinants - barrier, distance, orientation, event, wet
Anticipated controls - gloves, coverall, foot protection, contained, trained
Time - event, 1 per week (estimate)
Exposure route - dermal

Application

Impregnation with water-based wood preservation product in industrial treatments by trained professional process operators.

Each treatment vessel will have a maximum 3 or 5 cycles of treatment in any day. The cycle times are for vacuum pressure operations, 3 per day, 3 hours per cycle default, and for double vacuum (oscillating pressure) operations, 5 per day, 1 hour per cycle default. Professionals spend only a fraction of their time using wood-preservatives; other jobs and paperwork all take time. Application includes all stages in preservation, from loading the treatment vessel to stacking the treated wood to dry. Some "accelerated fixation" processes take longer, so indicating fewer treatments per day.

The work is variable, being seasonal and demand driven.

Descriptors: Task - 1.4.4 automated dipping and impregnation
Determinants - barrier, frequency and extent of contact, wet
Anticipated controls - gloves, coverall, foot protection, trained
. Time - 3 cycles or 9 hours per day, daily
. Exposure route - inhaled, dermal - intermittent contact with wet objects

It is assumed that respiratory protective equipment is used only in event scenarios such as the need to clear fallen wood within the treatment vessel.

Post-application

Professional post-application exposure constitutes system maintenance. Non-professional post application exposure is all secondary exposure through using preserved wood

Descriptors:	Task - 1.6.1 maintenance, servicing, assembly and fitting Determinants - barrier, distance, frequency and extent of contact, wet Anticipated controls - permit to work procedures
.	Time - event
.	Exposure route - dermal - intermittent contact with wet objects

The scenarios for secondary exposure are examined below.

Disposal

Exposure in recycling or disposal is similar to post-application exposure.

PRIMARY EXPOSURE ESTIMATES

The model used and calculations made appear in Appendix 7.1.1

95-percentile

Assumptions:	adult body weight 60 kg WP1 penetration of PPE and skin 100% inhalation rate 1.25 m^3 per hour
Defaults:	5 x 1-hour treatment cycles per day
Models	HSE database for water-based timber treatment, 95^{th} % values

Mixing and loading

Assumptions:	the same gloves are used as for wood impregnation
Exposure	2.5 mg/kg bodyweight per event (not applied: automatic dilution by pumping transfer, exposure can be only accidental. Exposure is for those sampling)

Application

Assumptions	existing gloves are used for wood impregnation
Exposure	71 mg/kg bodyweight / day

Post-application

Assumptions:	new gloves are used
Exposure	11.5 mg/kg bodyweight per event

50-percentile

Assumptions:	adult body weight 60 kg WP1 PPE penetration 12% and skin penetration 1% inhalation rate 1.25 m^3 per hour

Defaults	5 1-hour treatment cycles per day
Models	HSE database for water-based timber treatment, 50th % values

Mixing and loading

Assumptions	new gloves are used
Exposure	0.001 mg/kg bodyweight per event

Application

Assumptions	existing gloves are used
Exposure	0.013 mg/kg bodyweight / day

Post-application

Assumptions	new gloves are used
Exposure	0.002 mg/kg bodyweight / day

SECONDARY EXPOSURE ESTIMATES

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

Acute phase reference scenarios

Adult	cutting and sanding treated wood - inhalation route.
Child	not relevant.
Infant acute	chewing wood off-cut - ingestion route.

Chronic phase reference scenarios

Adult	inhalation of volatilised residues indoors - inhalation route.
Child	playing on playground structure outdoors - dermal route.
Infant	playing on weathered structure and mouthing - dermal and ingestion.

Indirect exposure via the environment is considered to be of minor importance as the release to the environment is limited.

The calculations are set out in the appendix.

SUMMARY OF EXPOSURE ESTIMATES

Summary table - WP1

Primary exposure		**Secondary exposure**	
95-percentile	85 mg/kg bw/day	Adult acute	0.00001 mg/kg bw
50-percentile	0.016 mg/kg bw/day	Child acute	none
(simple summing of phases of exposure)		Infant acute	0.02 mg/kg bw
		Adult chronic	0.01 mg/kg bw/day
		Child chronic	0.003 mg/kg bw/day
		Infant chronic	0.05 mg/kg bw/day

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APPENDIX 7.1.1

Models used

HSE database model for water-based timber treatment

Indicative exposure values for contamination rates (mg/cycle and mg/m^3) water-based in-use industrial timber pre-treatment fluid

route	**% Results above limit of detection**	**Median of non-zero values**	**95% (or worst case)**
surface contamination	100% frequency	3990 mg/cycle	**32200 mg/cycle**
surface, weighted indicative value		**3990 mg/cycle**	
surface penetration	100% frequency	12%	
penetration, weighted indicative value		**12%**	
hands, old gloves	100% frequency	783 mg/cycle	**7570 mg/cycle**
hands, old gloves, weighted indicative value		**783 mg/cycle**	
hands, new gloves	100% frequency	135 mg/cycle	**2330 mg/cycle**
hands, new gloves, weighted indicative value		**135 mg/cycle**	
feet	86% frequency	**125 mg/cycle**	**2670 mg/cycle**
feet, weighted indicative value		**108 mg/cycle**	
inhalation	73% frequency	1 mg m^{-3}	**5.5 mg m^{-3}**
inhalation weighted indicative value		**0.7 mg m^{-3}**	

Calculations - primary exposure

Mixing and loading	**95-percentile**	**50-percentile**
Hands in protective gloves	Old	New
Dermal exposure to product	7570 mg	135 mg
2% WP1 in product	151 mg WP1	2.7 mg WP1
Dermal uptake	100%	1%
Dose via skin	151 mg	0.03 mg
Systemic dose per event	2.5 mg/kg bw	0.0005 mg/kg bw
Application, 5 cycles	**95-percentile**	**50-percentile**
Product on clothing	161000 mg	19950 mg
Penetration	100%	12%
Product on skin	161000 mg	2390 mg
Product on hands in gloves	Old - 37900 mg	Old - 3915 mg
Product on feet in boots	13400 mg	540
Total product on skin	212300 mg	3320 mg
2% WP1 in product	4250 mg WP1	66.4 mg WP1
Dermal uptake	100%	1%
Dose via skin	4250 mg	0.66 mg
Inhalation - duration	5 hours, 6.25 m^3 inhaled	5 hours, 6.25 m^3 inhaled
Inhaled product	34.4 mg	4.35 mg
2% WP1 in product	0.7 mg WP1	0.09 mg WP1
Inhaled uptake	100%	100%
Dose via inhalation	0.7 mg	0.09 mg
Total dose	4250 mg	0.75 mg
Systemic dose	71 mg/kg bw/day	0.013 mg/kg bw/day
Post-application	**95-percentile**	**50-percentile**
Product on clothing	32200 mg	3990 mg
Penetration	100%	12%
Product on skin	32200 mg	479 mg
Hands in new gloves	2330 mg	135 mg
Total product on skin	34530 mg	614 mg
2% WP1 in product	691 mg WP1	12.3 mg WP1
Dermal uptake	100%	1%
Dose via skin	691 mg	0.12 mg
Systemic dose	11.5 mg/kg bw/day	0.002 mg/kg bw/day

Calculations - secondary exposure, reference scenario approach.

Acute phase

Adult *sanding treated wood posts - inhalation route.*

Assumptions WP1 in outer 1 cm outer layer: 50 litres of Timbertreat per m^3 of wood
Articles 4 cm x 4 cm x 2.5 m treated posts (0.004 m^3 wood, area 40032 cm^2)
Task = hand-held power sanding surface of posts for outdoor play area
Exposure = 5 mg/m^3 dust for 60 minutes
Inhalation rate 1.25 m^3/hour, 60 kg adult

Amount of WP1 in timber = 0.004 m^3 x 50 litres x 2%
= 4 g per 40000 cm^3 wood = 0.1 mg / cm^3 wood dust

Exposure = 6.25 mg wood dust at density 0.8 g / cm^3 = 0.008 cm^3
= 0.001 mg WP1 by inhalation
= 1.3E05 mg/kg bw

Child acute *not relevant.*

Infant acute *chewing wood off-cut - ingestion route.*

Assumptions WP1 in outer 1 cm outer layer = 0.1 mg / cm^3 wood as above
Exposure = chewing 4cm x 4 cm x 1 cm offcut, extracting 10% of WP1
10 kg infant

Amount of WP1 in offcut = 16 cm^3 = 1.6 mg WP1, 10% extracted

Exposure = 0.16 mg WP1 per event
= 0.02 mg/kg bw ingested

Chronic phase

Adult *inhalation of volatilised residues indoors - inhalation route.*

Assumptions Wood installed indoors in moderately ventilated room (1% of SVC, 0.03 Pa)
Residence time = 18 hours / day, inhaling 18 m^3 air
60 kg adult

Airborne concentration = 0.0003 Pa x 9.8 = 0.003 ppm = 0.04 mg/m^3

Exposure = 0.04 mg/m^3 x 18 m^3 = 0.72 mg
= 0.01 mg/kg bw/day

Child *playing on playground structure outdoors - dermal route.*

Assumptions WP1 residue on surface = gross assumption 0.01 mg / cm^2
Hand surface area = 200 cm^2, prolonged and repeated contact
20% of hand contaminated at 100% of surface concentration
. 10% dermal uptake
bodyweight = 15 kg

Exposure	= 0.01 mg x 200 x 20% cm^2 x 10%
	= 0.04 mg uptake
	= 0.003 mg/kg bw/day

Infant playing on weathered structure and mouthing - dermal and ingestion.

Assumptions	WP1 residue on surface = gross assumption 0.01 mg / cm^2
	Hand surface area = 200 cm^2, prolonged and repeated contact
	20% of hand contaminated at 100% of surface concentration
.	10% dermal uptake
	100% ingestion of surface deposit on 5 x 10cm^2 of wood
	bodyweight = 10 kg
Exposure via skin	= 0.01 mg x 200 x 20% cm^2 x 10%
	= 0.04 mg uptake
Exposure via ingestion	= 0.01 mg x 50 cm^2 = 0.5 mg uptake
	= total 0.54 mg = 0.05 mg/kg bw/day

7.2 Rodenticide

The following example is based upon a Danish active substance review, though the exposure estimates differ from that review as EASE is not considered to be adequate for estimating exposure via the skin.

The active substance is "RT2" in a product "Exvermin".

INTRODUCTION

Identity

Exvermin is an emulsifiable vegetable oil based concentrate containing 0.5% of the active substance RT2 with other co-formulants including 'Bitrex' repellent.

RT2 molecular weight = 393 and saturated vapour concentration = 3E-04 Pa at 60 C.

Exvermin pre-prepared wax blocks contain 0.01% of RT2.

Intended use and user sector

Exvermin is intended for use as a pre-prepared wax bait for use by professionals and non-trained professionals in buildings and sewers, and as a concentrate for preparing food and water baits for indoor use by professionals only. The maximum in-use concentration in baits is 0.01% w/w.

Bait is supplied ready for use. Liquid concentrate is supplied in a 100 ml bottle capable of dispensing either 2 ml (50 doses) or the whole contents of the bottle. One bottle can prepare 5 kg of bait.

This product is not intended for large scale mixing, e.g. using industrial mixing equipment

EXPOSURE DATA

Industry data

There are no exposure data available. The risk of skin contact is very limited when the active substance is encapsulated in bait blocks. Skin contact is possible when handling liquid concentrates. Non-professionals may use wax blocks, with a risk of exposure similar to that for non-trained professionals.

Regulator data

There are no exposure data available and deterministic models are used for exposure estimation. All estimates are subject to an unquantified level of uncertainty.

PRODUCT USE

Phases of use review

Mixing and loading

There is no mixing and loading for pre-prepared bait.

Liquid concentrates are supplied in a dose dispenser, a dose consisting of 2 ml concentrate with 100 g liquid or solid foodstuff. The liquid concentrate is applied by a dose dispenser directly into a bowl and hand mixed with drinking water or pieces of feed such as peanut butter, grain, dried fruit.

Users: professional pest controllers
Duration: 5 minutes per mixing, loading and placing
Frequency: 2 placings per site, 8 sites per day (2 to place, 6 to inspect), seasonal

Descriptors: Task - 1.2.1 - mixing and diluting
Determinants - rate, barrier, distance, wet
Anticipated controls - gloves, coverall, trained
Time - 5 minutes per site, 2 sites per day (estimate)
Exposure route - dermal

Application

Pre-prepared bait

Wax blocks are fat-containing blocks in which impregnated grain and a small hook are embedded. The size of a block is 12 x 5 x 4 cm (240 cm^3) weighing 200 g, packed in a cardboard tube. Wax blocks are typically used as baits in drains and sewage systems and in enclosed bait stations. For application in drains, a steel wire is used to suspend the bait about 10 cm above the rat access route, but not above running water.

Users: professional pest controllers
Duration: 5 minutes
Frequency: 4 placings per site, 8 sites per day (2 to place, 6 to inspect), most days

Descriptors: Task - 1.1.4 - handling dry objects
Determinants - barrier, distance, frequency, properties
Anticipated controls - gloves, trained
Time - 5 minutes per placing, 4 places, 2 sites per day = 40 min per day
Exposure route - dermal

Users: professional ancillary (e.g. farmers, smallholders, food shops, restaurants etc.)
Duration: 5 minutes
Frequency: 2 placings per site, in rat access routes and in locked bait stations. Done once.

Descriptors: Task - 1.1.4 - handling dry objects
Determinants - barrier, distance, frequency, properties
Anticipated controls - gloves
Time - 10 minutes per day
Exposure route - dermal

Liquid concentrate based bait

Descriptors: Task - 1.1.3 - handling wet objects
Determinants - rate, barrier, distance, extent, wet
Anticipated controls - gloves, coverall, trained
Time - 5 minutes per placing, 4 places, 2 sites per day = 40 min per day
Exposure route - dermal

Post-application

Post application exposure is limited to cleaning protective equipment and disposal. This will not be considered further.

Disposal

Disposal relates to the collection and disposal of uneaten or part-eaten bait, and poisoned rat carcasses. Bait, carcasses, paper wipes and empty concentrate containers are placed in polythene bag for disposal by incineration.

Users: professional pest controllers
Duration: 30 minutes per site
Frequency: 2 sites per day, most days.

Descriptors: Task - 1.1.4 - handling dry objects
Determinants - barrier, distance, frequency, properties
Anticipated controls - gloves
Time - 20 minutes per day
Exposure route - dermal

Non-professionals dispose of uneaten wax blocks in domestic refuse.

PRIMARY EXPOSURE ESTIMATES

In all cases, the risk of exposure by inhalation is negligible (10^{-5} mg/m^3).

Unprotected

Assumptions: adult body weight 60 kg
RT2 penetration of PPE and skin penetration 100%

Models deterministic calculations

The models used and calculations are set out in the Appendix.

Mixing and loading - liquid concentrate

Assumptions: bare hands
Exposure 0.004 mg/kg bodyweight /day

Application - wax block

Assumptions bare hands
Exposure 0.002 mg/kg bodyweight / day

Application - baited foodstuff or drinking water

Assumptions	bare hands
Exposure	0.008 mg/kg bodyweight / day

Disposal of uneaten bait, waste, dead rats

Assumptions	bare hands
Exposure	0.002 mg/kg bodyweight / day

The models used and calculations are set out in Appendix 7.2.1.

Protected

For this example, no detailed assessment is required. It is assumed that disposable protective gloves are worn for all operations, reducing exposure ten-fold.

SECONDARY EXPOSURE ESTIMATES

In all cases, the risk of exposure by inhalation is negligible (10^{-5} mg/m^3).

Acute phase reference scenarios

Adult	handling dead rodents
Child	handling dead rodents
Infant acute	transient mouthing of poison bait treated with repellent

Chronic phase reference scenarios

Adult	not relevant
Child	not relevant
Infant	not relevant

Indirect exposure via the environment is considered to be of minor importance as the release of rodenticides to the environment is limited

SUMMARY OF EXPOSURE ESTIMATES

Summary table - RT2

Primary exposure		**Secondary exposure**	
Unprotected	Up to 0.044 mg/kg bw/day	Adult acute	0.002 mg/kg bw
Protected trained, concentrate user	4.2E-04 mg/kg bw/day	Child acute	0.007 mg/kg bw
Protected trained, wax bait user	1.7E-05 mg/kg bw/day	Infant acute	0.0001 mg/kg bw
(simple summing of phases of exposure)		Adult chronic	none
		Child chronic	none
		Infant chronic	none

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APPENDIX 7.2.1

Models used

The US-EPA has published a working draft for standard operating procedures for residential exposure assessment (US-EPA, 1997). These standard operating procedures have been developed using the Pesticide Handlers Exposure Database PHED 2.0. However, that database was developed for agricultural uses and is not appropriate to this scenario.

For mixing and loading, Mode 2 dispensing and diluting (worst case 12.8 mg)

Calculations - primary exposure

Mixing and loading	**Unprotected**	**Protected**
Concentrate - splash	12.8 mg estimate	12.8 mg estimate
Gloves	none	worn, 90% protection
0.5% RT2	0.06 mg RT2	0.006 mg RT2
Events per day	2	2
Uptake via skin	100%	10%
Dose via skin	0.13 mg	0.001 mg
Systemic dose per event	0.002 mg/kg bw/day	2E-05 mg/kg bw/day
Application - wax block	**Unprotected**	**Protected**
Dislodged to skin per day	1 g estimate	1 g estimate
0.01% RT2	0.1 mg RT2	0.1 mg RT2
Gloves	none	worn, 90% protection
Uptake via skin	100%	10%
Dose via skin	0.1 mg	0.001 mg
Systemic daily dose	0.002 mg/kg bw/day	1.7E-05 mg/kg bw/day
Application - mixed bait		
Dislodged to skin per day	50 mg estimate	50 mg estimate
5% RT2 (part-dried)	2.5 mg RT2	2.5 mg RT2
Gloves	none	worn, 90% protection
Uptake via skin	100% mg	10%
Dose via skin	2.5 mg	0.025 mg
Systemic daily dose	0.04 mg/kg bw/day	0.0004 mg/kg bw/day
Post-application	**As application**	**As application**

Secondary exposure (all acute phase)

Adult and child, handling dead rodents

- The equivalent of 1 g of wax is dislodged to the skin. This contains 0.01% of RT2
- 100% uptake via the skin - dose = 0.1 mg RT2
- systemic dose = = 0.002 mg/kg (60 kg adult), 0.007 mg/kg bw (15 kg child)

Infant acute transient mouthing of poison bait treated with repellent

- The equivalent of 0.01 g of wax is ingested. This contains 0.01% of RT2.
- 100% uptake by 10 kg infant = dose of 0.0001 mg/kg bw.

7.3 Antifoulant

The following example is based upon an UK active substance review. The active substance is "AF3" in a product "Negfoul".

INTRODUCTION

Identity

Negfoul is a solvent-based antifoulant product containing 25% copper oxide and 5 % AF3 active substance. The dry film contains 10% w/w AF3. It is supplied in 5 and 25 litre lidded metal containers. It is supplied also in 50 ml aerosol spray cans, for application to propellers.

AF3 has a molecular weight of 244 and a saturated vapour pressure equivalent to 2 ppb.

Intended use and user sector

Use for professional spray application and for non-professional application by brush and roller. Non-professionals may also use the spray can product.

EXPOSURE DATA

Industry data

No industry data are available to inform the assessment of antifoulant preparations such as Negfoul that contain AF3.

Regulator data

Since 1994, the Health and Safety Executive has gathered information on human exposure to antifouling products in the professional and non-professional sectors, to inform its role of assessing exposure and risk to operators and others. The information takes two forms:

- the pattern of work - the frequency and duration of potential exposure, the areas coated per session, the amount of product used and seasonal factors;
- the exposure - the median and realistic worst case exposures in applying the products and identified tasks or jobs.

All HSE surveys took place in the north of England or Scotland. Three-quarters of the products found being used in the 1994/5 survey were free-association (i.e. the active ingredient leaches from the antifoulant) and one-quarter self-polishing (i.e. the active ingredient is bound in a copolymer antifoulant which hydrolyses slowly in sea water). HSE has no reliable data relating to exposures in the military sector.

HSE data are normalised and in the forms ‘mg product h^{-1}’ for dermal exposure and ‘mg product m^{-3}’ for inhalation exposure, respectively (ACP 1 257/98 and EH74/3). The sampling methods for potential dermal exposure using patches have been validated for spraying activities (Unpublished, Tannahill, 1996; Unpublished, Glass, 1998). However, they have not been validated for painting or paint handling.

There are no data for other immersed structures (e.g. oil-rigs, jetties, fish-farm installations), nor on exposure in stripping expired antifoulant from ships.

HSE data indicate a median 4% penetration of the outer layer of work clothing, which is usually a coverall. More than one layer of work clothing will provide better protection. Sprayers take precautions to prevent antifoulants contacting exposed skin. Custom within the antifouling industry is for operators to protect themselves well, and often to wear two sets of coveralls. At the higher levels of contamination, the penetration through coveralls and clothing, and then onto the skin, may be about 1%. This value is the *practical lower limit* for modelling as there will always be the potential for contact of product with exposed skin (e.g. around wrists, face and neck and through handling previously contaminated clothing). The ability of protective clothing to reduce potential exposures by at least two orders of magnitude has been demonstrated in the studies by the IOM and is supported by the experimental findings related to penetration compared to challenge which are built into the UK POEM model.

However, where non-professionals use products, it is assumed that they wear minimal clothing and may not wear gloves.

The UK Environment Agency commissioned a report on environmental problems from antifouling agents that contained information on patterns of use. (*Environment Agency Research and Development Technical Report P215 1998: Survey of Manufacturers, Chandlers (Suppliers) and treatment Sites: WRc plc ISBN 1 873160 74 7*). This showed that Chandlers may offer a service for leisure craft owners, in removing expired antifoulant and applying fresh antifoulant by brush or roller.

PRODUCT USE

Professionals spend much of their time carrying out vessel refitting. Such jobs take place while a vessel is in dry dock and it may be there for a number of weeks. Consequently, exposure to antifouling paints is irregular with long intervals between exposure. The most realistic worst case exposure scenario is that a sprayer may be exposed for no more than two or three days a month, but not every month, and then not to the same active substance. The same applies to stripping of expired antifoulant coatings. The pattern-of-use survey indicated that up to 10 % of employees' time might be spent in working with antifoulants. Antifouling is applied using airless spraying at up to 100 bar. Sufficient sprayers are employed to ensure that one coat is applied in one work day. Rarely are more than two coats applied.

Non-professionals tend to coat leisure craft over two days in the spring, through painting sessions on consecutive days. Only one boat is likely to be coated.

Phases of use review

Professional application of antifoulant requires 2 to 4 persons per spray position. There are three basic tasks, as pot-man, sprayer, or ancillary worker.

Mixing and loading

This is the task of the pot-man, removing antifoulant from the supply container to the high-pressure pump reservoir and ensures a continuous supply to the spray gun.

Descriptors: Task - 1.1.2 - transfer liquids
Determinants - barrier, distance, frequency, wet
Anticipated controls - gloves, coverall, foot protection, trained

Time - 184 minutes, 3 consecutive days per month using 240 litres product
Exposure route - dermal and inhaled overspray

Application

There are two main jobs. The sprayer applies the coating to the vessel hull. The ancillary worker attends to keeping paint lines free and may also manoeuvre the mobile access platform (cherry picker).

Descriptors: Task - 1.3.4 - spraying for surface coating
Determinants - application pressure, barrier, distance, orientation, wet
Anticipated controls - full PPE and RPE, trained
Time - 184 minutes, 3 consecutive days per month using 240 litres product
Exposure route - dermal and inhaled overspray

Post-application

This task relates to clearing the lines and reservoir of antifoulant. There are practically no data for this and it is assumed that this task is indistinguishable from mixing and loading.

Disposal

The removal of expired coatings from hulls using abrasive or high-pressure water. There are no data for this - the following is assumption.

Descriptors: Task - 1.3.4 - spraying for surface coating (removal)
Determinants - application pressure, barrier, distance, orientation, wet
Anticipated controls - full PPE and RPE, trained
Time - 8 hours per day, one day per month
Exposure route - inhaled residues

Non-professional application of antifoulant requires 1 person, applying product by brush or roller. Minor, very short-term applications are by pre-packaged aerosol spray.

Mixing and loading

This covers stirring product and if coating the surface by roller, decanting it to a paint tray. Exposure is considered integral with application.

Application

Application by brush or roller to the underside of leisure craft.

Descriptors: Task - 1.2.6 - coating by brush or roller
Determinants - application rate, distance, orientation, wet
Anticipated controls - none
Time - 90 minutes, 2 consecutive days per year using 4 litres product
Exposure route - dermal and inhaled droplets

Application by aerosol spray can.

Descriptors: Task - 1.3.4 - spraying for surface coating
Determinants - application rate, distance, wet
Anticipated controls - none
Time - 5 minutes, once per year
Exposure route - dermal and inhaled

Post-application

Not relevant

Disposal

The removal of expired coatings (10% AF3) from hulls using hand-held or powered tools. There are no data for this - the following is assumption.

Descriptors: Task - 1.2.3 scrubbing surface with abrasive
Determinants - distance, orientation, dusty
Anticipated controls - none
Time - 2 hours, one day per year
Exposure route - inhaled dust only, 10 mg/m^3. Dermal dust is not absorbed.

PRIMARY EXPOSURE ESTIMATES

Modelling uptake is subject to overestimates because only a proportion of the skin deposit is available for uptake if the deposit is spots or blobs. Active substance will be contained within the matrix of the dried-on product. And users normally remove antifoulant residues after work.

95-percentile

Professionals, spray applications

Assumptions: adult body weight 60 kg
AF3 penetration of PPE and skin 100%
inhalation rate 1.25 m^3 per hour

Defaults: 184 minutes per day (480 for stripping expired coatings)

Models HSE database as modified, 95^{th} % values

Mixing and loading

Assumptions: pot-man only
existing gloves are used
the duration includes application and post-application exposure

Exposure 35.3 mg/kg bw/day

Application

Assumptions sprayer and ancillary worker (sprayer's exposure only modelled)
existing gloves are used

Exposure	115 mg/kg bw/day

Disposal

Assumptions	exposure by inhalation to overspray / abrasive as for antifouling spray spray contains 10% stripped surface coating, containing 10% AF3
Exposure	0.12 mg/kg bw/day

Non-professionals (and Chandlers), brush and roller applications and stripping

Assumptions:	chandler uses gloves solid abraded paint contains 10% AF3
Exposure	14.7 mg/kg bw/day (non-professional), 9.5 mg/kg bw/day (chandler)

75-percentile

Professionals, spray applications

Assumptions:	adult body weight 60 kg AF3 penetration of double layer PPE 1% and skin 10% inhalation rate 1.25 m^3 per hour RPE with APF 40 (sprayer), 10 (pot-man)
Defaults:	184 minutes per day (480 for stripping expired coatings)
Models	HSE database as modified, 75^{th} % values

Mixing and loading

Assumptions:	pot-man only existing gloves, RPE and single coverall are used the duration includes application and post-application exposure
Exposure	0.10 mg/kg bw/day

Application

Assumptions	sprayer and ancillary worker (sprayer's exposure only is modelled) existing gloves, RPE and double coverall are used
Exposure	0.07 mg/kg bw/day

Disposal

Assumptions	exposure to overspray / abrasive as for antifouling spray, x40 RPE spray contains 10% stripped surface coating containing 10% AF1
Exposure	0.003 mg/kg bw/day

Non-professionals and Chandlers, brush and roller applications and stripping

Assumptions: all use gloves, all wear light clothing
solid abraded paint contains 10% AF3

Exposure 0.3 mg/kg bw/day

The models and calculations are set out in Appendix 7.3.1

SECONDARY EXPOSURE ESTIMATES

Acute phase reference scenarios

Assumptions For professional applications, adult co-workers wearing coveralls and gloves could be exposed to overspray for 30 min at a rate less than for ancillary workers.

Exposure 0.01 mg/kg bw

For amateur applications, passers by within a congested yard could contact the hulls of freshly treated boats. However the probability of acute secondary exposure is low and accordingly, no exposure estimate is necessary.

Chronic phase reference scenarios

There is no foreseeable chronic exposure, unless there is exposure via the environment through eating seafood exposed to eroded coatings. This is not modelled.

SUMMARY OF EXPOSURE ESTIMATES

Summary table - AF3

Primary exposure		**Secondary exposure**	
95-percentile professional pot-man	35.4 mg/kg bw/day	Adult acute	0.01 mg/kg bw
95-percentile professional sprayer	115 mg/kg bw/day	Child acute	none
95-percentile professional stripping expired AF	0.11 mg/kg bw/day	Infant acute	none
95-percentile professional chandler strip & paint	9.5 mg/kg bw/day	Adult chronic	none
95-percentile non-professional painter	14.7 mg/kg bw/day	Child chronic	none
75-percentile professional pot-man	0.1 mg/kg bw/day	Infant chronic	none
75-percentile professional sprayer	0.07 mg/kg bw/day		
75-percentile professional stripping expired AF	0.003 mg/kg bw/day		
75-percentile non-professional painter	0.07 mg/kg bw/day		
75-percentile chandler strip & paint	0.05 mg/kg bw/day		

(simple summing of phases of exposure)

Exposure reduction measures

Respiratory protective equipment (RPE) with an assumed protection factor of at least 40 is required for sprayers and for ancillary workers. This RPE should provide head and face protection. Disposable RPE with an assumed protection factor of at least 10 is required for pot-men.

Professionals should wear protective gloves, disposed regularly. The work clothing should comprise a disposable coverall worn over cotton coveralls of a contrasting colour to the product being applied. Outer coveralls should be discarded after each spray session. Inner coveralls should be changed on signs of breakthrough. Impervious footwear is required.

REFERENCES

ACP 1 257/98 (a report on HSE information with model exposure data) and EH74/3 (Health and Safety Executive, Exposure Assessment Document EH74/3, Dermal exposure to non-agricultural pesticides. HSE, UK (1999) ISBN 0717617181

SC10580 (patterns of use for some non-agricultural pesticide products)

SC10657 (Exposure of amateurs painting wood preservatives and antifoulants) has been assumed to apply also to professionals for roller and brush painting.

Environment Agency Research and Development Technical Report P215 1998: Survey of Manufacturers, Chandlers (Suppliers) and treatment Sites: WRc plc ISBN 1 873160 74 7

APPENDIX 7.3.1

Models used

Mixing and loading database model 6 HSE Surveys

Spraying database model 3 HSE Surveys

Brush painting database model 4 HSE Surveys

Aerosol surface spraying model 2 HSE Studies

Inhalation - estimate for sanding at 10 mg/m^3

Calculations - Primary exposure estimates

Assumptions: professionals, 184 minutes' work per day, non-professionals 90 minutes. stripping - exposure by inhalation to overspray / abrasive as for spraying spray contains 10% stripped surface coating at 10% AF1. Task = 8 hours.

Pot-man		
Mixing and loading	**95-percentile**	**75-percentile**
Product on clothing rate	222 mg/min	92 mg/min
Clothing penetration	100%	4% - single coverall
Skin deposit via clothing	40850 mg	677 mg
Hands in gloves rate	8.2 mg/min	2.7 mg/min
Hand exposure	1510 mg	497 mg
Total deposit on skin	42360 mg	1170 mg
5% AF3 in product	2120 mg AF3	58.7 mg AF3
Uptake via skin	100%	10%
Dose via skin	2120 mg	5.87 mg
Exposure by inhalation	17 mg/m^3	1.9 mg/m^3
Inhaled volume	3.83 m^3	3.83 m^3
RPE protection	none	X 10 RPE
Product inhaled	65.2 mg	0.73 mg
5% AF3 in product	3.26 mg AF3	0.036 mg AF3
Systemic dose	35.4 mg/kg bw/day	0.099 mg/kg bw/day
Post-application - cleaning	**Included within above estimate**	
Sprayer		
Product on clothing rate	745 mg/min	250 mg/min
Clothing penetration	100%	1% double coverall
Skin deposit via clothing	137100 mg	460 mg
Hands in gloves rate	3.95 mg/min	2.04 mg/min
Hand exposure	727 mg	375 mg
Total deposit on skin	137800 mg	835 mg

5% AF3 in product	6890 mg AF3	41.8 mg AF3
Uptake via skin	100%	10%
Dose via skin	6890 mg	4.18 mg
Exposure by inhalation	64.6 mg/m^3	17.3 mg/m^3
Inhaled volume	3.83 m^3	3.83 m^3
RPE protection	none	X 40 RPE
Product inhaled	247 mg	1.66 mg
5% AF3 in product	12.4 mg AF3	0.08 mg
Systemic dose	115 mg/kg bw/day	0.07 mg/kg bw/day
Disposal - stripping (all exposure by inhalation)		
Exposure by inhalation	64.6 mg/m^3	64.6 mg/m^3
Inhaled volume	10 m^3	10 m^3
RPE protection	none	x 40 RPE
Stripping spray inhaled	646 mg	16.2 mg
10% paint in spray, 10% AF3	6.46 mg AF3	0.16 mg AF3
Systemic dose	0.11 mg/kg bw/day	0.003 mg/kg bw/day
Non-professional brush & roller application + 5 minutes spray aerosol		
Application - brush / roller	**Worst case**	**75-percentile**
Product on clothing rate	108 mg/min	50.8 mg/min
Clothing penetration	100%	50%
Skin deposit via clothing	9720 mg	2290 mg
Gloves	none	worn
Hand exposure rate	76.6 mg/min	3.77 mg/min
Deposit on hands	6890 mg	339 mg
Application - spray		
Dermal exposure rate	200 mg/min	200 mg/min
Clothing penetration	100%	50%
Deposit on skin	1000 mg	500 mg
Total skin deposit	17610 mg	839 mg
5% AF3 in product	881 mg AF3	42 mg AF3
Uptake via skin	100%	10%
Dose via skin	881 mg	4.2 mg
Exposure by inhalation -	0.11 mg/m^3 (painting 90 min)	0.05 mg/m^3
	49.5 mg/m^3 (spraying 5 min)	8.1 mg/m^3
Inhaled aerosol	0.21 + 5.16 mg	0.09 + 0.84 mg
5% AF3	0.27 mg AF3	0.007 mg AF3
Total systemic dose	14.7 mg/kg bw/day	0.07 mg/kg bw/day
Chandler - 2 hours stripping old coating, 90 minutes brush and roller application		

Product on clothing rate	108 mg/min	50.8 mg/min
Clothing penetration	100%	4% (coverall)
Skin deposit via clothing	9720 mg	182 mg
Gloves	worn	worn
Hand exposure rate	18.5 mg/min	3.77 mg/min
Deposit on hands	1670 mg	339 mg
Total skin deposit	11400 mg	521 mg
5% AF3 in product	570 mg AF3	26.1 mg AF3
Uptake via skin	100%	10%
Dose via skin	570 mg	2.61 mg
Exposure by inhalation -	0.11 mg/m^3 (painting 90 min)	0.05 mg/m^3
Inhaled aerosol	0.21 mg	0.09 mg
5% AF3	0.01 mg AF3	0.005 mg AF3
Exposure by inhalation	10 mg/m^3 (stripping 120 min)	10 mg/m^3
Inhaled volume	2.5 m^3	2.5 m^3
RPE protection	none	X 4 dust mask
Stripping dust inhaled	25 mg	6.25 mg
10% AF3 in dust	2.5 mg AF3	0.63 mg AF3
Dose via inhalation	2.5 mg	0.64 mg
Systemic dose	9.6 mg/kg bw/day	0.054 mg/kg bw/day

SECONDARY EXPOSURE ESTIMATES

Acute phase reference scenarios

Assumptions: Professional adult co-workers wearing coveralls and gloves could be exposed to overspray for 30 min at a rate equivalent to the 50th percentile for sprayers.

Potential dermal exposure	103 mg product / minute
Penetration	4% - coverall
Hand-in-glove exposure	none
Total skin exposure, 30 min	124 mg product, 5% AF3, uptake via skin 10%
Exposure via skin	0.62 mg AF3
Inhalation exposure	4.13 mg product (30 min, 1.25 m^3 / hour) 0.09 mg AF3
Uptake	0.21 + 0.62 = 0.83 mg AF3
Dose	0.01 mg/kg bw

7.4 Insecticide

The following example is based upon an UK active substance review. The active substance is "AD4" in products "Barnspray" and "Bugdust".

INTRODUCTION

Identity

AD4 is a carbamate insecticide active substance used in two products. "Barnspray" is a wettable powder at 40% w/w AD4, marketed in 25 litre polypropylene kegs. "Bugdust" is a ready-for-use dusting product at 1.5% w/w AD4, marketed in 1 kg cartons and 100 g puffer packs.

AD4 has a molecular weight of 239 and a saturated vapour concentration of 2E-04 Pa at 25C.

Intended use and user sector

"Barnspray" wettable powder is used as an insecticidal spray for animal husbandry, and food storage applications. Barnspray is intended for professional use only.

"Bugdust" dusting powder is used as an insecticidal dust for insect control (litter beetle, hide beetle) in poultry house litter. The 1 kg cartons are for professional use.

The 100 g "Bugdust" puffer packs are for household crack and crevice use, to control silverfish, cockroach and ant infestations, indoors or outdoors. It contains Bitrex repellent.

EXPOSURE DATA

Industry data

JKL Control Ltd.

The mixing rate for "Barnspray" is 50 g product with 5 l water (4 g AD4 / litre). The product is to be applied as a surface spray (walls, ceilings) using powered spray with an application rate 1 litre per 20 m^2 of surface. The pattern of use is an average 40 litres per session, each job taking at least one hour (20 minutes actual spraying).

The airborne aerial concentrations of "Barnspray" was measured for test spraying a surface with a suspension at 5 g / litre using a knapsack sprayer, over a period of 3.3 minutes (10 m^2 of surface). No post-application sampling was undertaken. Of the results, 10/12 airborne concentrations of AD4 were below the limit of detection (0.04 $mg.m^{-3}$) with just two detectable results, the highest being at 0.07 $mg.m^{-3}$. These data cannot be interpreted successfully for the purposes of this review.

PSA Dusts plc

"Bugdust" dusting powder is used neat in a bulb duster or dust gun, with the nozzle in the animal house litter. The application rate is 0.01 kg/m^2 of surface.

There are no equivalent data for the non-professional use. The pack instructs the user to direct the fine dust jet at cracks where insects are expected.

Regulator data

Since 1992, the Health and Safety Executive has gathered information on human exposure to public hygiene insecticide products in the professional and amateur user sectors, to inform its role of assessing exposure and risk to operators and others. The information takes three forms:

- the pattern of use
- exposure surveys
- workshop-based exposure studies, principally for consumer products.

HSE holds no direct information on the patterns of use for food storage, animal husbandry or consumers' patterns of use. But research (HSE, 1997) has indicated that consumer behaviour in using products can vary considerably from the instructions on the product label.

Summaries of the exposure surveys and studies informing HSE assessments of public hygiene insecticides have been published in EH74/3 and ACP paper SC 11000. The surveys of pressure spraying surface biocides are considered to show a very similar mode of use to pressurised spraying of animal housing and grain stores. The surface biocide model is also reported in EH74/3.

All HSE data are quoted in terms of the insecticide product being applied, and are time-weighted. Data are normalised in the forms "mg product min^{-1}" for dermal exposure and "mg product m^{-3}" for inhalation exposure. The sampling methods for potential dermal exposure using patches have been validated for spraying activities (Unpublished, Tannahill, 1996; Unpublished, Glass, 1998).

Clothing penetration

Data indicate that 20% is a realistic figure to adopt for the penetration through a single layer of typical protective workwear when low spray pressures and volumes are involved; and 4% for higher spray pressures and volumes. The 20% value will be used for professional dusting and the 4% value for pressurised spraying. Non-professional users may wear a long sleeved shirt and long trousers (and household gloves). However it is assumed that no effective protection is worn (worst case; 100% penetration) and for the central tendency, long shirt and trousers or skirt, 50 % clothing penetration with no gloves.

Based on Industry data and Regulator best estimates, the following patterns of use are proposed for use in this review:

Animal husbandry and food storage area spraying by pressurised sprayer.

In-use concentration:	4 g AD4 / litre of water (50g product at 40% AD4 in 5 litres).
Application rate	1 litre per 20 m^2 surface.
Quantity used	40 litres per session, treating 800 m^2 surface.
Frequency	fortnightly (animal husbandry), annual (grain store).
Duration	20 minutes for spraying.

Animal husbandry dusting by motorised duster.

In-use concentration	1.5% as supplied.
Application rate	10 g / m^2 surface.
Quantity used	10 kg per session, treating 1000 m^2 surface (estimate).
Frequency	once every two months.
Duration	120 minutes (estimate).

For both of these applications, contractors may be employed. It is considered to be unlikely for a contractor to conduct more than 3 treatments per day, not every day, but year-round. Spray application requires site preparation time, to remove gross accumulations of detritus that would prevent the liquid spray contacting the fabric of the building. Bystander (secondary) exposure is unlikely because areas should be vacated before treatment.

Domestic use of puffer pack.
There are no secure data. The estimated frequency of use is once per week.
Although the HSE default is 7 minutes' use and 375g discharged, the small pack size suggests that no more than one pack would be used at any one time.
The duration is taken as 2 minutes using 100 g. The product is used mainly in the warmer seasons of the year, though cockroach treatments could take place at any time.

PRODUCT USE

Phases of use review

"Barnspray" - animal husbandry and food storage applications

Mixing and loading

The product is supplied as a wettable powder which is scooped into the spray reservoir, mixed to a paste with a small amount of water, then made up to volume with fresh water. The process takes a few minutes only per application.

Descriptors: Task - 1.2.1 - mixing and diluting
Determinants - barrier, distance, event, dusty
Anticipated controls - gloves, coverall, foot protection, trained
Time - event, 3 per day (maximum)
Exposure route - dermal

Application

Mixed product is applied by pressurised sprayer, typically at between 4 and 7 bar and occasionally at pressures up to 10 bar. The spray lance is 1.5 metres long. Product is applied to walls and ceilings of animal houses and grain stores once gross contamination has been physically removed

Descriptors: Task - 1.3.1 - spraying liquids for surface treatment
Determinants - Application rate and pressure, distance, orientation, wet
Anticipated controls - gloves, coverall, head / face protection, foot protection, trained, respirator available
Time - 20 minutes, 3 per day (maximum), 40 litres used per session
Exposure route - dermal, inhaled

Post-application

Product is sprayed until it has been used up. Washings are also sprayed, to clean lines. The main post-application scenario is maintenance - wettable powders can block spray nozzles.

Descriptors: Task - 1.6.1 - servicing
- Determinants - distance, wetness
Anticipated controls - coverall, foot protection, trained
- Time - 5 minutes per event (single event)
- Exposure route - dermal.
The ingestion route - blowing nozzles clear by mouth - is deliberate misuse.

Disposal

Not relevant.

"Bugdust" - poultry house dusting

Mixing and loading

The product is supplied as a ready for use powder that is loaded into the motorised duster.

Descriptors: Task - 1.1.1 - transfer, filling dusts
Determinants - barrier, dusty
Anticipated controls - gloves, coverall, foot protection, respirator available, trained
Time - event, 3 per day (maximum)
Exposure route - dermal, inhaled

Application

Animal husbandry dusting in surface of bedding litter by low pressure (1 to 3 Bar) motorised duster with a 1 metre long dust lance.

Descriptors: Task - 1.3.6 - injection of ducts at and below surfaces
Determinants - rate, pressure, barrier, distance, down, dusty
Anticipated controls - gloves, coverall, foot protection, respirator available, trained
Time - 120 minutes, 3 per day (maximum)
Exposure route - dermal, inhaled

Post-application

Not relevant.

Disposal

Not relevant.

Bugdust - household crack and crevice use puffer pack

Mixing and loading

The product is supplied in a ready-for use container. Mixing and loading is not relevant.

Application

Application is by puffing dust into cracks and crevices where insects are entering, travelling or residing. Many treatments comprise a single puff of the pack, but for assessment purposes it is assumed that an entire pack is discharged.

Descriptors: Task - 1.3.2 - spraying dusts for surface treatment
Determinants - amount, distance, down, dusty
Anticipated controls - none effective
Time - 2 minutes using 100 g
Exposure route - dermal, inhaled.

Post-application

Not relevant.

Disposal

The empty pack is disposed to domestic waste and this is not relevant for exposure estimation. *Children using the empty pack as a water pistol is deemed deliberate misuse*.

PRIMARY EXPOSURE ESTIMATES

95-percentile

Professionals mixing and loading and spray application

Assumptions:	adult body weight 60 kg AD4 penetration of PPE and skin 100% inhalation rate 1.25 m^3 per hour
Defaults:	3 x 20 minutes per day
Models	HSE database for surface biocides as modified, 95^{th} % values
Exposure	X mg/kg bw/day

Professionals post-application maintenance (nozzle blocked)

Assumptions:	adult body weight 60 kg AD4 penetration of PPE and skin 100%
Defaults:	5 minute event, 1 per day
Models	10% of worst case 6 ml spill per hand; this about the maximum amount that can 'stick' to the hands
Exposure	X mg/kg bw

Professionals mixing and loading and motorised dusting injection application

Assumptions:	adult body weight 60 kg AD4 penetration of PPE and skin 100% inhalation rate 1.25 m^3 per hour
Defaults:	3 x 120 minutes per day

Models	HSE database for public hygiene insecticides, 95th % values
Exposure	X mg/kg/day

Non-professionals using crack and crevice puffer pack

Assumptions:	adult body weight 60 kg AD4 penetration of PPE and skin 100% inhalation rate 1.25 m^3 per hour
Defaults:	2 minutes per day
Models	Hand-held dusting pack, non-professional model 2, worst case values
Exposure	X mg/kg/day

75-percentile

Professionals mixing and loading and spray application

Assumptions:	adult body weight 60 kg AD4 penetration of PPE and skin 10% inhalation rate 1.25 m^3 per hour
Defaults:	3 x 20 minutes per day
Models	HSE database for surface biocides as modified, 75th % values
Exposure	X mg/kg bw/day

Professionals post-application maintenance (nozzle blocked)

Assumptions:	adult body weight 60 kg gloves worn, AD4 penetration of PPE and skin 10%
Defaults:	5 minute event, 1 per day
Models	HSE database handling (model 1 - wet objects), 75th % value
Exposure	X mg/kg bw

Professionals mixing and loading and motorised dusting injection application

Assumptions:	adult body weight 60 kg AD4 penetration of PPE and skin 10% inhalation rate 1.25 m^3 per hour
Defaults:	3 x 120 minutes per day
Models	HSE database for public hygiene insecticides, 75th % values
Exposure	X mg/kg/day

Non-professionals using crack and crevice puffer pack

Assumptions:	adult body weight 60 kg AD4 penetration of PPE and skin 10% inhalation rate 1.25 m^3 per hour
Defaults:	2 minutes per day
Models	Hand-held dusting pack, non-professional model 2, 75^{th} % values
Exposure	X mg/kg bw/day

The models and calculations are presented in Appendix 7.4.1 and summarised below.

SECONDARY EXPOSURE ESTIMATES

Acute phase reference scenarios

Professional uses

There are no relevant acute phase scenarios for professional applications where bystanders are kept out of the treatment areas until spray aerosols have dispersed or dusts have settled.

Child: Child contact with wet sprayed surface (10% of body area) - dermal

Non-professional uses

Adult: Not relevant, since considered less at risk than child

Child: Present in room during application - inhalation while dust settles

Infant: Present in room during application - inhalation while dust settles

Chronic phase reference scenarios

Professional uses

Adult: Adult working in treated animal barn, moving litter and raising dust - inhalation

Child: Not modelled

Infant: Contact with parent's contaminated work clothing - dermal and ingestion

Non-professional uses

Adult: Cleaning up overspill dust with vacuum cleaner - inhalation

Child: Contact with overspill dust - dermal

Infant: Contact with overspill dust - dermal and ingestion.

The calculations are presented in the Appendix 7.4.1 and summarised below.

SUMMARY OF EXPOSURE ESTIMATES

Summary table - AD4

Primary exposure		**Secondary exposure**	
95-percentile professional "Barnspray"	10.3 mg/kg bw/day	Adult acute, professional use	-
95-percentile professional "Bugdust"	260 mg/kg bw/day	Child acute, professional use	1 mg/kg bw
Worst case non-prof. "Bugdust"	0.005 mg/kg bw/day	Infant acute, professional use	-
75-percentile professional "Barnspray"	0.01 mg/kg bw/day	Adult acute, non-professional use	-
75-percentile professional "Bugdust"	0.49 mg/kg bw/day	Child acute, non-professional use	0.0003 mg/kg bw
75-percentile non-prof. "Bugdust"	0.0001 mg/kg bw/day	Infant acute, non-professional use	0.0005 mg/kg bw
		Adult chronic, professional use	0.01 mg/kg bw/day
		Child chronic, professional use	-
		Infant chronic, professional use	0.68 mg/kg bw
		Adult chronic, non-professional use	0.0001 mg/kg bw
		Child acute, non-professional use	0.0002 mg/kg bw
		Infant acute, non-professional use	0.002 mg/kg bw

(simple summing of phases of exposure)

REFERENCES

HSE reports EH64 and UK-ACP papers.

APPENDIX 7.4.1

Models used

Spraying database model 2 HSE Surveys ('Barnspray')
Cleaning - hands in gloves as for spraying ('Barnspray') or 10% of 2 x 6 ml spill = 1200 mg
Spraying database model 1 HSE Surveys ('Bugdust')
Surface dusting model 2 HSE Studies ('Bugdust')

Calculations - Primary exposure estimates

Assumptions: professionals, 60 minutes' work per day for barn spraying, 5 min maintenance.
professionals 360 minutes' work per day dusting
non-professionals, 2 minutes dusting per day (week)

"Barnspray" is used at 0.4% w/w AD4 and "Bugdust" at 1.5% w/w AD4

Barnspray		
Mixing, loading & application	**95-percentile**	**75-percentile**
Product on clothing rate	2100 mg/min	222 mg/min
Clothing penetration	100%	6%
Skin deposit via clothing	126000 mg	799mg
Hands in gloves rate	191 mg/min	7.8 mg/min
Hand exposure	11460 mg	468mg
Feet in boots rate	260 mg/min (worst)	5.4 mg/min
Foot exposure	15600 mg	324 mg
Total deposit on skin	153100mg	1590 mg
0.4% AD4 in product	612 mg AD4	6.36 mg AD4
Uptake via skin	100%	10%
Dose via skin	612 mg	0.64 mg
Exposure by inhalation	198 mg/m^3	76 mg/m^3
Inhaled volume	1.25 m^3	1.25 m^3
RPE protection	none	X 10 RPE
Product inhaled	248 mg	9.5 mg
0.4% AD4 in product	0.99 mg AD4	0.04 mg AD4
Systemic dose	10.2 mg/kg bw/day	0.01 mg/kg bw/day
Post-application - cleaning		
Hands in gloves rate	-	7.8 mg/min
Hand exposure	1200 mg	-
Total deposit on skin	-	39 mg
0.4% AD4 in product	4.8 mg AD4	0.16 mg AD4
Uptake via skin	100%	10%
Systemic dose via skin	0.08 mg / event	0.0003 mg / event

Bugdust - professional		
Mixing, loading & application	**95-percentile**	**75-percentile**
Product on clothing rate	251 mg/min	92 mg/min
Clothing penetration	100%	44%
Skin deposit via clothing	90360 mg	14900 mg
Hands in gloves rate	39.4 mg/min	10.7mg/min
Hand exposure	14150 mg	3850 mg
Total deposit on skin	104500mg	18740 mg
1.5% AD4 in product	1568 mg AD4	281 mg AD4
Uptake via skin	100%	10%
Dose via skin	15680mg	28.1 mg
Exposure by inhalation	405 mg/m^3	130 mg/m^3
Inhaled volume	7.5 m^3	7.5 m^3
RPE protection	none	X 10 RPE
Product inhaled	3040mg	97.5 mg
1.5% AD4 in product	45.6 mg AD4	1.46 mg AD4
Systemic dose	260 mg/kg bw/day	0.49 mg/kg bw/day
Bugdust - non-professional)		
Application - puffer pack	**Worst case**	**75-percentile**
Product on skin rate	4.18 + 6.56 mg/min	2.83 + 2.15 mg/min
Clothing penetration	100%	50%
Skin deposit	21.5 mg	4.98 mg
1.5% AD4 in product	0.32 mg AD4	0.07 mg AD4
Uptake via skin	100%	10%
Dose via skin	0.32 mg	0.007 mg
Exposure by inhalation	8.01 mg/m^3	1.78 mg/m^3
Inhaled volume	0.04 m^3	0.04 m^3
Product inhaled	0.32mg	0.07 mg
1.5% AD4 in product	0.005 mg AD4	0.001 mg AD4
Total uptake	0.33 mg	0.008 mg
Systemic dose	0.005 mg/kg bw/day	0.0001 mg/kg bw/day

Calculations - Secondary exposure estimates

Acute phase reference scenarios

Professional uses

There are no relevant acute phase scenarios for adults or infants in professional applications where bystanders are kept out of the treatment areas until spray aerosols have dispersed or dusts have settled.

Child: Child contact with wet sprayed surface (10% of body area) - dermal
Child body area = 7800 cm^2, 10% contaminated - 780 cm^2
Surface concentration 1 litre (4 g) per 20 m^2 surface, = 200 mg / m^2, 100% dislodged.
Child skin deposit = 16 mg AD4, uptake = 100%, dose = 1 mg/kg bw

Non-professional uses

Adult: Not relevant

15 kg Child: Present in room during application - inhalation while dust settles
Exposure equivalent to adult applying product - 0.32 mg product inhaled, 0.005 mg AD4
Systemic exposure 0.0003 mg/kg bw

10 kg Infant: Present in room during application - inhalation while dust settles
Exposure equivalent to adult applying product - 0.32 mg product inhaled, 0.005 mg AD4
Systemic exposure 0.0005 mg/kg bw

Chronic phase reference scenarios

Professional uses

Adult: Adult working in treated animal barn, moving litter and raising dust - inhalation
Assume unprotected exposure by inhalation at 20 mg/m^3 contains 50% of "Bugdust", 4 hours' exposure. Uptake = 50 mg product = 0.63 mg AD4, dose = 0.01 mg/kg bw/day

10 kg Infant: Contact with parent's contaminated work clothing - dermal and ingestion
Assume contact and ingestion of dust contamination on 100 cm^2 of coveralls
Contaminant = 90360mg x 100/20000 = 452 mg Bugdust = 6.8 mg AD4.
Dose = 0.68 mg/day.

Non-professional uses

Adult: Cleaning up overspill dust with vacuum cleaner - inhalation
Model non-professional surface dusting - vacuuming
worst case 0.8 mg/m^3, 30 minute exposure = 0.5 mg Bugdust = 0.008 mg AD4
Dose = 0.0001 mg/day

Child: Contact with overspill dust - dermal
Estimate of contaminated skin area = 20 cm^2, dust load estimate = 0.2 g Bugdust = 0.003 mg AD4. Uptake 100%, dose = 0.0002 mg/kg bw

Infant: Contact with overspill dust - dermal and ingestion.
Estimate of contaminated skin area = 100 cm^2, dust load estimate 1g Bugdust = 0.015 mg AD4. Uptake 100%, dose = 0.002 mg/kg bw