TECHNICAL GUIDANCE DOCUMENT FOR PREPARING THE CHEMICAL SAFETY ASSESSMENT

Chapter R.13

Risk Management Measures

"Technical Guidance Documents in support of the New EU Chemicals Legislation (REACH) – V: Development of a Technical Guidance Document for preparing the Chemical Safety Assessment (REACH Implementation Project 3.2-2)"

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R.13 RISK MANAGEMENT MEASURES

R.13.1 Introduction

Under REACH, Manufacturers and Importers are required to assess risks to human health and the environment from all stages in the life-cycle of a substance resulting from the manufacture and all identified uses. For those substances classified as dangerous or assessed as PBT or vPvB, exposure scenarios must be developed which describe how the substance is used and what are the recommended Risk Management Measures (RMMs) and Operational Conditions (OCs) required for safe use.

For human populations, adequate control of risk is defined as a situation where the estimated exposure does not exceed the appropriate Derived No-Effect Level (DNEL). For environmental emissions, adequate control of risk means ensuring that environmental concentrations do not exceed the Predicted No-Effect Concentration (PNEC). For each Exposure Scenario risks are characterised by comparing estimated exposures or environmental concentrations with the relevant DNEL or PNEC. If exposures or environmental concentrations exceed the limit (DNEL or PNEC) then additional RMMs may be recommended (see section D-3.6.7).

R. 13.1 Aim of section

Beside the guidance given in section D-3.6 on how to use risk management measures and operational conditions in the exposure scenario assessment process it is the purpose of this section to help the registrant in finding appropriate information about RMMs /OCs and their respective efficiencies by using the RMM library. This library has been developed as data base listing the most commonly used and established RMMs in the chemical manufacturing and using industries.

R. 13.2 Effectiveness of RMMs

R.13.2.1 Aim of the module

In the exposure assessment RMMs are used to reduce or eliminate risks of exposure or release into the environment. This requires a quantification of the effects the RMMs may have on the risk determining factors (e.g. resulting concentration of substance in air or water before and after application of the RMM). It is necessary to assume an objective, quantitative measure of the efficiency of RMMs in reducing exposure or environmental emissions in order to predict the resulting exposures or environmental concentrations. The aim of this section is to illustrate how to use publicly available information on RMM efficiency values or to quantify their effects in case sufficient reliable sources are not available.

R.13.2.2 Methodology

The methodology presented here is based on the FEICA case study (*REACH Exposure Scenario Exemplification, FEICA case study, Feb. 2007*). This presents three different Exposure Scenarios covering the use of 2-part epoxy adhesives – (A) epoxy repair adhesive for consumer use, (B) epoxy adhesive used in structural jointing in the automotive industry, and (C) epoxy floor covering for professional use. Two of the three Scenarios have been used in the Appendices to illustrate the approach.

The Exposure Scenarios were considered from the viewpoint of three potentially exposed groups or categories – Consumer, Worker, and Environment.

Both direct and indirect (via the environment) human exposure should be examined. The RMMs recommended in the Exposure Scenarios were evaluated and where possible a quantitative measure of efficiency was assigned from published literature. The environmental measures (not derived from the FEICA case) represent a list of possible measures, which might be implemented.

> ***RMM efficiency*** is defined as the percentage reduction in exposure concentration or emission (release) produced by application of the risk management measure.
>
> In practice, the efficiency of any RMM varies and cannot be adequately described by a single value. We propose that RMM efficiency is determined by two descriptors: a "**typical default value**" (an estimate of the 50th percentile) and a "**maximum achievable**" value (best practice).

RMM Efficiency values are expressed as the percentage reduction in exposure concentration or release due to the application of the specific RMM. This may be expressed mathematically as:

$$\frac{\text{(Concentration or release without RMM - Concentration or release with RMM)}}{\text{Concentration or release without RMM}} * 100\ \%$$

For example, consider a worker who is exposed to an airborne vapour at a concentration of 100 ppm. Introduction of a RMM (say LEV) may reduce this exposure to 10 ppm. The efficiency of the LEV will then be given by {(100 – 10)⁄100 * 100} = 90%.

The standard process for determining RMM Efficiencies is as follows (see for additional guidance in section D-3.6.6.2):

1. List all known, published RMM efficiency values for the RMM in question
2. Document the source of information and give a degree of confidence to it based on the amount and quality of validation data, whether the research study was properly designed and well-founded, confirmation in different situations, etc.
3. For RMMs with no published sources of information on efficiency, assign a semi-quantitative efficiency value based on expert judgement if possible and document the underlying justification.

A number of sources of information were used to research available knowledge on RMM efficiencies. These information sources are described in more detail in the RMM library. Examples for principal sources for each exposed group/category are shown below.

Occupational

- ECEL database: Goede H, Schinkel J, Meijster T, van Hemmen J, Tielemans E. Development and analyses of an Exposure Control Efficacy Library (ECEL). In Preparation.
- Stoffenmanager: Le Feber M, Marquart H, Brouwer D, Tielemans E, Tijssen S. Model om inhalatoire blootstelling te schatten in het MKB. TNO-Rapport V5520, 2003.
- Respiratory protective equipment at work: Health & Safety Executive, HSG53, 2005.

- Cherrie JW, Schneider T.: Validation of a new method for structured subjective assessment of past concentrations. Ann Occup Hyg 1999;43:235-245.

Environmental

- Infomill (2007) Factsheets on emission reduction techniques for waste gas streams. http://www.infomil.nl/legsys/ebtsh/index.asp
- IPPC (2003) Integrated Pollution Prevention and Control Reference Document on Best Available Techniques in Common Waste Water and Waste Gas Treatment / Management Systems in the Chemical Sector
- http://europa.eu.int/comm/environment/ippc/brefs/cww_bref_0203.pdf

Consumer

In the case of the consumer RMMs, no literature sources were identified in the FEICA case study and hence it is not appropriate to give a numerical value for the efficiencies. It is only possible to state whether the proposed RMM is expected to provide a high, moderate or low level of efficiency for certain types of consumer RMMs. It is also important to distinguish between measures that are under the control of the manufacturer or supplier and those which are not.

The former (e.g. product design) includes all measures that can be introduced and controlled by the manufacturer, such as packaging, size and formulation. Bruinen de Bruin et al. (2007) characterise this type of RMMs as “product integrated RMMs”. Although these RMMs are under control of the manufacturers, their efficiency must be characterised in detail for quantitative aspects. The latter ‘non-controllable’ type (e.g. recommendations given to consumers) includes all recommendations given by the manufacturer to the user (consumer). Bruinen der Bruin et al. (2007) characterize these RMMs as “communicated to consumers”. In another study, Heinemeyer et al. (2006) identified by means of a questionnaires that consumers behave differently. The authors’ key findings, from a representative study in Germany, were that only approximately 30% of interviewed persons said that they followed instructions of manufacturers when cleaning floors in their homes, whereas in the case of impregnation sprays this was approximately 80%. This means that high uncertainty exists about consumer behaviour, which obviously might be driven by potential hazards from the products they use. It is therefore nearly impossible to estimate efficiency values for consumer RMMs, which are communicated from manufacturers to the users. Efficiency of these RMMs therefore cannot be judged and should not be applied in consumer exposure scenarios.

The following references explain this in more detail:

- Bruinen de Bruin Y, Hakkinen B, Lahaniatis M, Papameletiou D*****, del Pozo C, Reina V, van Engelen J, Heinemeyer G, Viso AC, Rodriguez C, Jantunen M (2007). Risk management measures for chemicals in consumer products – issues and challenges for documentation, assessment and communication across the supply chain. J Environm Exp Anal, in press.
- Heinemeyer G, Scholz R, Lindtner O, Rüdiger T (2006). Evaluation of behaviour of consumers for exposure assessment by questionnaire studies. International Conference on Environmental Epidemiology and Exposure, Paris, 2006.

R.13.2.3 Results

Examples on how to conclude on RMM efficiencies are presented in the attached tables (Appendix 1-3).

R.13.2.4 Issues to be reflected in the choise of RMMs

- **Median (50th percentile) as typical value** – A 50th percentile of the distribution is suggested as reasonable descriptor of the efficiency of a particular RMM. However, in many cases the available exposure data is limited and it is thereby proposed, for such cases, that an estimate of the 50th percentile is used as an indication what can realistically be assumed when building the exposure scenario. In considering the appropriate measure of the typical value it should be recognised that the exposure estimation of the baseline situation (i.e. without RMM) and the efficiency of the RMM must be considered together. Multiplying two "worst case" values would result in extremely conservative and unrealistic estimates of risk. Following this line of reasoning, using a more conservative estimate for efficacy is not reasonable since the baseline exposure estimate of the ES is also based on a worst case.
- **Criteria for assessing quality of information sources** - the following categories are proposed for assessing the quality of RMM efficiency sources (see table Appendix 1-3):
  - Low: Efficiency estimates are based on expert judgment without any empirical underpinning.
  - Moderate: Efficiency estimates are mainly based on expert judgment supplemented or underpinned by limited empirical evidence from exposure studies.
  - High: Efficiency estimates are mainly based on good quality and consistent empirical evidence from exposure studies.

In determining whether a data source fits into one of the above three categories, the evaluator needs to consider the document's accuracy, precision and relevance.

- **Quantity of material used / released** - for substances that are applied in exposure scenarios where a known fraction is released into the workplace, limiting the use of the substance can be considered as a Risk Management Measure. A simple approach is suggested to estimate the RMM efficiency in such Exposure Scenarios. It can be assumed that the reduction in exposure level is proportional to the reduction in the quantity used, and the efficiency of the risk management measure can defined as follows:

Reduction of quantity used with a factor x	RMM Efficiency = [100-100/x] %.

For example, halving the quantity used will result in a 50 % reduction in the exposure level, when assuming complete mixing of the gas/vapour throughout the workplace. This does not take into account differences between near field and far field and localised concentrations but it may be a reasonable assumption for open application of volatile materials, such as the floor covering ES example in the FEICA case study. If mixing is less than complete the reduction may be less and the approach can be refined by including a mixing factor.

- **Elimination of a task within the exposure scenario** - in the FEICA case study, providing the material in pre-weighed quantities was introduced as a RMM. By doing so the task of weighing the material before applying it for floor covering is eliminated. It therefore can be concluded that there is no longer exposure related to the weighing and as such the efficiency of this measure is 100% *for the weighing part*. The efficiency of the measure cannot be assessed for the overall exposure. However from the exposure assessment the contribution of the various tasks to the overall exposure should be known and in this way the registrant can easily calculate the impact of this measure on the overall exposure.

- **Human exposure via the environment** – emissions into the environment can have an impact on people through indirect exposure. Such impacts can occur through inhalation of substances present in the atmosphere in the neighbourhood of emission points as well as ingestion of drinking water or food, which has become polluted as a result of these emissions. A variety of routes can be considered, e.g. transfer of substances to food resulting from exposure of terrestrial and aquatic organisms in the relevant environmental compartments i.e., (bio)transfer to fish, crops, meat and milk followed by the intake as food. This means that assessment of exposure of man indirectly via the environment should include all possible exposure routes starting from the release sources through environmental distribution, leading to exposure of organisms in the relevant environmental compartments and food consumption patterns. Additional guidance on the assessment of indirect exposure of human via the environment can be found in Chapter R.16.

Risk management is most effectively done at the source of pollution and there are few risk management measures directly aiming at indirect exposure itself. As an example for a specific measure one might consider a ban on sales of certain food types or sending out warnings not to consume vegetables from one's garden, or even decontamination or clean-up of polluted sites. The few possible relevant measures in the exposure routes for man indirectly exposed can be aimed at the application of sludge to soil or the preparation of drinking water. But these measures are not directly linked to the (primary) source of pollution.

The effect of a measure at the (primary) source can be assessed only by estimating the contribution of the source to the total indirect exposure of man. The effect of the measure on the direct exposure route can be passed on proportionally but should be weighted relative to the contribution of the specific exposure route to the total indirect exposure for man. This can only be done in a proper way by modelling, and hence in the framework of an actual exposure scenario.

R. 13.3 RMM library

R.13.3.1 Aim of the module

This module provides details to the registrants on how they should select RMMs and OCs for incorporation into their exposure scenarios to demonstrate safe use. For this purpose, a RMM library has been created to facilitate identification of the required measures and controls to reduce exposure to a substance during its entire life cycle. The library addresses the control of direct exposure to consumers, environment and workers, as well as indirect exposure to humans *via* the environment.

R.13.3.2 RMM Library Description

The RMM library is an EXCEL spreadsheet that is 'made up' of three parts:

- The library containing RMMs / OCs and details of their efficiency; and
- Lists of information sources for consumers, environment and occupational measures.
- A practical guide to use the library

The criterion, which all entries should meet for inclusion into the library, is that they must help in the management of controlling risk to human exposure or environmental exposure, regardless of their primary purpose, because in their absence the likelihood of exposure is higher.

On this basis, it is possible to 'capture' both RMMs and OCs into one library structure (each RMM/OC is listed once and has been given a unique number). Further guidance on RMM and OCs for the specific target groups can be found in section D-3.6.2.

The data within the Library originates from a number of sources, in particular the exemplification case study exposure scenarios, 'Integrated Pollution Prevention and Control' (IPPC) and 'European Information System on risks from chemicals released from consumer products / articles' (EIS-ChemRisk).

For the purpose of this section of the concise-TGD, "RMM" will be the term used for both RMM and OC.

R.13.3.2.1 Worksheet "Individual Measures" *(worksheet 3)*

The RMM Library is contained within one large worksheet (this is the third worksheet). It has not been sub-divided into separate worksheets or sections since the primary purpose of the spreadsheet is simply a 'data bank' for the storage of RMMs rather than a 'front end' retrieval system. As it is not clear whether the RMM Library will subsequently be evolved into a 'user-friendly' IT database tool this description refers to the excel "version 17" of the RMM library.

In terms of structure, the library is organised according to the occupational hygiene concept of 'hierarchy of control', which is fundamental to reducing exposures in the workplace. The reason for adopting this as the structural basis for the Library is that it allows for one library containing occupational, consumer and environmental measures, as well as also ensuring that occupational RMMs can still be selected according to the priority order governed by the 'hierarchy of control' concept, as outlined in the Chemical Agents Directive. For consumer and environmental measures, the hierarchy is purely an organisational system for the storage of RMMs. The Chemical Agents Directive, Article 6, defines occupational 'hierarchy of control' in order of priority from the top down as:

Elimination;
Substitution;
Engineering work controls (e.g. design of work process);
Collective protection measures (e.g. adequate ventilation); and
Individual protection measures (e.g. personal protective equipment).

R.13.3.2.2 RMM/OC Category

In the Library, this organisational concept is referred to as the '**RMM/OC Category**'

There are nine categories, which are listed in the following order (this reflects the 'hierarchy of control' concept for occupational control):

- Product-substance related;
- Limitation of marketing and use;
- Process control /change;
- Ventilation control;
- General dilution ventilation;
- Organisational;
- Good hygiene practices & housekeeping;
- Personal protective equipment; and
- First aid measures

It is important that this order remains unchanged, so as not to create confusion when carrying out occupational risk assessments. Within this overall structure, it is believed that all RMMs (and OCs) for the control of exposure to consumers and the environment will fit.

R.13.3.2.3 Substance properties

RMMs listed in the Library may have limitations in its general applicability for a broad variety of different substances. Therefore - where appropriate - generic substance properties are indicated for which the RMM is applicable. Where no indication is given it must be checked on a case-by-case basis whether the RMM can be used for the specific situation as substance properties may have an influence on the efficiency and/or general applicability.

A particular column has been used to identify those RMMs which are suitable for managing risks stemming from physicochemical hazards (e.g. flammability / explosivity).

R.13.3.2.4 RMM/OC General Name

The categories are sub-divided into types, which are referred to as '**RMM/OC General Name** (Type)'. In the Library the types are highlighted as shaded bold green text and are located within the main body of the spreadsheet under the 'Categories' i.e. there is no individual column for this. Under each 'General Name (Type)' there are 'check' boxes containing 'crosses' (X) that are used to show the category in which it fits – e.g. the type "Automation and enclosure" is referred to in the "Process Control / Change" category. This heading allows for further organisation of the library records; for example, the category 'Product-Substance Related' is divided into:

- Limiting concentration of hazardous or non-hazardous ingredient;
- Change of physical state (e.g. powder → pellet);
- User friendly packaging (reducing handling); and
- Info / Guidance / Manual other than label and safety data sheet.

'RMM/OC General Names (Types)' are not fixed, thereby allowing for the possibility of adding further names (types) under each main 'Category' in the future, providing that there is a valid reason for doing so e.g. grouping of similar RMMs. For document control and audit purposes, it is recommended that only the library administrator should do this. It is envisaged that there will be a central control point / organisation that will have overall responsibility for maintenance and updating of the RMM Library.

Under the 'RMM/OC General Name (Types)' headings, names of specific RMMs can be found in the column '**RMM/OC Specific Name**'. Each entry is only listed once. Where possible, these are given in general terms rather than specific i.e. neither values nor parameters are used. As is the case for the 'RMM/OC General Name (Type)', the quantity of listed RMM names is not restricted. However, as has already been mentioned, document control is important to ensure that the text being used is also 'standardised' (where appropriate). For each RMM, a '**Brief Description**' is given to further define the RMM as well as ensuring that there is 'common' interpretation/understanding. This is particularly important, as the RMM Library will be used across Europe. For example, "Advice against misuse of product" (Specific Name (see C6.18)) has the following brief description:

> *"(i) Do not use for … . (ii) Do not mix with .... . (iii) Keep away from… e.g. heat. (To be specified by the manufacturer)"*

In addition to the above, each RMM is assigned a 'Unique Number' i.e. a reference number. The numbering is purely for future manipulation of RMMs into a database tool but may be used for communication purposes in the eSDS as well if reference to the library should be made to provide further details or links to additional information.

R.13.3.2.5 Integrated RMMs

The category "integrated RMM necessary" is intended to facilitate the development of a risk reduction strategy and is providing some links to other RMMs which may be needed to avoid shift of risk to other compartments. The examples given are indicative only and neither prescriptive nor exhaustive. They need to be checked against existing infrastructure at the production site or other boundary conditions (e.g. availability/capability of public treatment facilities). An example is given in the worksheet "integrated RMM" which explains the logic of RMM interdependencies.

R.13.3.2.6 RMM/ OC Efficiency:

In practice the efficiency of a variety of different RMMs varies due to its dependence on the conditions of use i.e. proper use, maintenance, substance type, substance properties etc and therefore cannot be adequately described by a single value. This is addressed within the Library through the use of two descriptors: a "**typical default value**" (an estimate of the 50th percentile) and a "**maximum achievable**" value (best practice). However, it is not always possible to assign a numerical value for efficiencies and in such cases the RMM efficiency is described as a text element: high efficiency (H), moderate efficiency (M), low efficiency (L), unknown (U) (for further "quantification of these qualitative indications see section D 3.6.6.2). In addition to these text characters, there is also a text element for when efficiency is not applicable (na) to specific RMMs. For example local extract ventilation is a measure that is used to control inhalation exposures in the workplace and is not used for consumer protection. If 'cells' within this section are not completed with either a numerical or text character(s) an efficiency indication has not been assigned yet.

The efficiency section of the Library is constructed in a manner that takes into account both the route of exposure and the exposure target group. By using this approach, multiple efficiencies can be covered since RMMs often have other benefits in reducing exposure, in addition to their primary control purpose e.g. a glove box is primarily used to prevent skin contact, yet it also reduces exposure by inhalation. The Library, however, does not address issue of differing efficiency values for different physical states, such as a dust or vapour e.g. protective clothing has different effectiveness depending on whether the substance is a dust or vapour.

In the Library, target groups are defined as:

- Consumer,
- Environment,
- Human exposure from the environment, and
- Worker.

Routes of exposure to humans are by:

- Inhalation,
- Dermal, and
- Oral.

Emissions to environment are into:

- Air,
- Soil, and
- Water.

R.13.3.2.7 Further Library Headings:

To the right of the efficiency section of the Library, there are three further columns: **'Remarks'**, **'Source'** and **'Details of Source'**. The first of these provides additional information on the use of the RMM such as details on the critical control points that should be followed when applying the RMM. The second column, 'Source', is self-explanatory. The final column contains either the 'standard exposure scenario' name from the exemplification case studies or details on the source reference e.g. for IPPC this is listed as "BAT (Best Available Technique) Reference Document - Chemical Sector". This ultimate column is particularly important since it provides details on the industry sector, as well as details on whether the RMM is used for protection of consumers, environment or workers. In this respect, the user of the library is able to search for specific RMMs that are typically used within their industry (this is covered in further detail within Section D.3.3.

R.13.3.3 Sector packages *(Worksheet 4)*

For ease of use, (sector) packages are listed in a different workbook to the 'Individual Measures'. The list contains packages of RMMs / OCs that are typically implemented within industry sectors. These packages are essentially 'collections' of measures that have been composed by Regulators such as COSHH Essentials (UK HSE), exposure scenario case studies and industry sector groups. The structure of the spreadsheet workbook is almost identical to that for the 'Individual Measures', with the difference being some additional columns at the front to allow for entry of industry sectors, product category, process and RMM package name to specify the exposure situation covered by this set of RMMs..

It is indeed the responsibility of the respective sector to ensure that the RMM package identified for an exposure scenario is generally accepted within the sector and suitable to manage the risks. If alternative RMMs are possible indication should be given in the package as such or an additional package should be added to the worksheet.

R.13.3.4 Lists of RMM Information Sources *(Worksheets 7-10)*

Key-information sources, for the RMMs within the Library, are provided in these worksheets. The listed sources are intended to provide a starting point to the user on good practice guidance. Quoted sources are mainly freely available and website links are provided for many of these. These lists are not fixed, meaning that further source materials could be added into future versions of the RMM Library. Actual given entries are just providing those sources which have been currently used to underpin the RMM specified in this library.

For each source, the following details are given:

- Reference;
- Title / Source;
- Description;
- Web link; and
- Comments (for occupational, conclusions from the Work Package 1 (WP1) scoping study - "Development of the concept of Exposure Scenarios" are also given).
- Accuracy / Reliability / Strength of data

The listed sources of RMM information are organised into one of four worksheets:

- Worksheet 7 – occupational sources (workplace exposures including professional users);
- Worksheet 8 – environmental sources (external to the workplace);
- Worksheet 9 – consumer sources; and
- Worksheet 10- general references (providing generic guidance on RMMs)

Sources listed in the occupational worksheet are organised under the following headings:

- General reference;
- Physicochemical hazard (fire, explosion, reactive chemistry);
- PPE
- Ventilation (general dilution and control);
- Exposure monitoring;
- Health Surveillance; and
- Industry sector / branch specific guidance.

For environmental and consumer RMMs, the number of source materials listed are considerably fewer. The environmental list also contains details on the status of the IPPC BAT Reference (BREF) documents. Recommendations taken from the BREFS are helpful as basic information, but it must be noted that these are solely guidance documents.

In compiling these lists, the following criteria were used for selecting source materials:

- Credibility i.e. the source is of an authoritative nature; and
- Ease of availability.

The list is not exhaustive and it deliberately does not include measures such as worker education/qualification, organisational level of know-how (e.g. professional/industrial *vs.* non professional) and availability of management systems (e.g. OHSAS 18001). Many of the references quoted have been taken from the Final Report of the Scoping Study for WP1 (Development of the concept of Exposure Scenarios).

R. 13.4 Using the RMM Library

Upon opening the spreadsheet, the user will be presented with the 'Guidance on using library' worksheet (this is the first worksheet). This "guidance" is providing practical advice on how to use the various worksheets based on some screenshots. By choosing the worksheet buttons or the links given at the top ("click here to") the Library user will be taken to the respective sections by clicking on the text.

The second work page ("RMM library introduction") also tabulates the nine 'RMM/OC Categories' and the sub-divisions of these, which are referred to as the 'RMM/OC General Names (Types)'. To make the Library more user-friendly the 'General Names (Types)' have been linked with the actual section of the Library on the third worksheet. For example, if a user were to click on "Change of physical state" they will be taken to the RMMs within that section of the Library.

R.13.4.1 Finding RMM information

Finding appropriate information about individual RMMs/OCs or RMM packages the user of the library can choose either

- the respective worksheet and start searching for specific details for individual RMM measures or
- use the RMM package worksheet for sector specific/ exposure specific combination of individual RMMs to packages which have proven its functionality in practical life.

If the registrant uses different RMMs compared to those given within a particular exposure scenario he can use the unique numbering given in the left column to find suitable alternatives in the worksheet "individual measure" by using the hyperlink or he can either carry out a general search by going through the most appropriate section of the Library or he could use the 'Find' function within EXCEL (located under the 'Edit' drop-down tab) to search for more specific information.

Navigation and Printing

To aid the user in navigating though the RMM Library, the worksheet has been set-up to allow vertical scrolling whilst maintaining the title headings at the top of the screen. In addition, the columns to the right of the 'RMM/OC Specific Name' are set up for horizontal scrolling thus enabling the user to see other data columns whilst keeping reference to the actual RMM/OC being looked at. Furthermore, for ease of printing the work sheet is set-up so that all column headings (titles) will be printed at the top of each page.

R.13.4.2 Data Usage

Once the RMM/OC has been identified, the user will need to first check that this is suitable for the intended control purpose i.e. that it is suitable to protect the target group (consumer, environment, human exposure from the environment or workplace) identified within the exposure scenario and whether he has to consider shift of risks between target groups. If it is suitable, the user will then need to check whether there is a numerical value (percentage) for efficiency i.e. a default value and / or maximum achievable value.

For cases where this is available, the user should first take the default efficiency value and check it against the predicted exposure or emission concentration from the Exposure Scenario and calculate the resulting decrease in concentration. This can be compared with the DNEL/PNEC to see whether this is sufficient to demonstrate adequate control. If not, the Registrant must then look at

the maximum achievable value. However, before this can even be considered the Registrant must ensure that the downstream user can adequately demonstrate they have in place other control measures such as training, good management systems, and supervision. In addition, this may require confirmation that the downstream user has the capability for carrying out monitoring programmes for determining human exposure and/or emission concentrations (this obviously does not apply to consumers). If this is suitable, i.e. the protection measure reduces concentration to below the DNEL/PNEC, the Registrant must ensure that the downstream user is capable of operating at best practice (this may require specific substance testing such collection of 'real-life' monitoring data). In case the downstream user is depending on RMMs which are beyond his own control (e.g. municipal waste water treatment) he needs to check the efficiency of this RMM before it can be

APPENDIX 1 – OCCUPATIONAL EXPOSURE

Proposed RMM Efficiency values for the FEICA case study – Annex 4, structural jointing in automotive industry.

RMM	RMM Efficiency values*	Source	Quality of source	Remark
Supervision	-	NA	NA	A generic statement with respect to efficacy of this RMM is impossible. Supervision should be defined in more detail. Supervision and other behaviour interventions might have a substantial impact on exposure. Yet, this is to a large extent dependent on local workplace circumstances, organisational aspects and background of the workers. There are studies showing significant impact of organisational and behavioural factors, although the size of the effect varies.
Quantity used	-	NA	NA	A generic statement with respect to efficacy of this RMM is not possible. There is a relation between "quantity" and "exposure" (e.g. the determinant is incorporated in COSHH Essentials). Yet, an exact relationship is not determined and a percentage reduction of exposure due to X kg substance reduction can not be given.
Enclosure of the source	Default: 96% Maximum achievable: 99.4%	ECEL**	Low-moderate	The "default" reflects the median efficacy value and "maximum achievable" reflects the 10th percentile of efficacy values found in ECEL for this RMM. The confidence of the source is rated "low-moderate" since only a few records were available for this RMM in ECEL.
PPE dermal	Single layer of clothing or coverall: 90% Gloves: 90%	Gerritsen-Ebben et al. 2006**	Low-moderate	The amount of empirical information reflecting efficacy of PPE for dermal exposure in the field is very limited.
PPE inhalation	75% (e.g. filtering half mask FFP1) – 97.5% (e.g. full face mask and filter P3)	BS 4275**	High	Assigned protection factors for different designs of respiratory protective devices are based on substantial empirical evidence from the field.
Local exhaust ventilation	Default: 80% Maximum achievable: 96% 90% Carefully designed: 90% Less carefully designed: 70%	ECEL** Stoffenmanager (version 2.0)** Cherrie (1999)**	Moderate Low-moderate Low-moderate	The "default" reflects the median efficacy value and "maximum achievable" reflects the 10th percentile of efficacy values found in ECEL for this RMM. For this example, all LEV data are analysed on an aggregated level. More refined categories of LEV may result in other figures. Efficacy value is based on expert judgement. The rationale behind this value is not clearly described Efficacy value is based on expert judgement. The rationale behind this value is not clearly described.
General ventilation	Default: 40% Maximum achievable: 80%	ECEL**	Moderate	The "default" reflects the median efficacy value and "maximum achievable" reflects the 10th percentile of efficacy values found in ECEL for this RMM.

459 * This is expressed as the percentage reduction in exposure due to the specific RMM:

460 ((exposure without RMM-exposure with RMM)/exposure without RMM)*100%

461 **Sources:

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APPENDIX 2 – ENVIRONMENTAL EMISSIONS

Proposed RMM Efficiency values for the FEICA case study – Annex 4, structural jointing in automotive industry.

RMM	Exposure Route	RMM Efficiency values*	Physical state of the treated substance	Type of substance	Source	Confidence source	Remark
Thermal oxidiser	Air	95-99%	Vapour	Organic	Infomill	High	Efficiency refers to VOCs in waste gas streams
Carbon filter	Air	80-95%	Vapour	Organic	Infomill	High	Efficiency refers to VOCs in waste gas streams
Biofilter	Air	75-95%	Vapour	Organic	Infomill	High	Efficiency refers to VOCs in waste gas streams
Vapour recovery unit	Air	80-95%	Vapour	Organic	Infomill	High	Efficiency refers to VOCs in waste gas streams
Carbon filter	Water	5-95%	Suspended/dissolved Organic compounds	Organic	IPPC	High	Efficiency refers to Organic components in waste water streams
Sand filtration	Water	50-99%	Suspended matter	Organic/ Inorganic	IPPC	High	Efficiency refers to Suspended Solids in waste water streams
Sedimentation	Water	60-90%	Suspended matter	Organic/ Inorganic	IPPC	High	Efficiency refers to Suspended Solids in waste water streams
Chemical oxidation	Water	20-80%	Suspended/dissolved Organic compounds	Organic/ Inorganic	IPPC	High	Efficiency refers to Organic components in waste water streams
RO membrane	Water	70-99%	Dissolved organic compounds	Organic/ Inorganic	IPPC	High	Efficiency refers to Organic components in waste water streams. Pretreatment required with respect to suspended solids

* This factor is expressed as the percentage of reduction of the "exposure level with RMM"

**Sources:

Infomill (2007) Factsheets on emission reduction techniques for waste gas streams.

URL: http://www.infomil.nl/legsys/ebtsh/index.asp

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482 Many abatement or exposure reduction techniques are specific or proven for one compound or certain groups of compounds. This may be related
483 to certain physico-chemical properties or the chemical behaviour. Abatement techniques may be specific for the physical state of the pollutant to
484 be removed as well.

485 Relevant Physical states for air and waste water streams

Air	Water
Gaseous	Dissolved
Aerosols	Emulsion
Drops	Liquid
Dust	Suspended solids

Possible relevant substance groups

Organic	Inorganic
Acid	Acid
Base	Alkaline
Halogenated hydrocarbons	Heavy metals
Phenols	Phosphates
Hydrocarbons	Sulphates
Resins	Fluorides
Oil	
Sulphides	
Carbonates	
Esters	
Amides	
Detergents	
Polycyclic Aromatic Hydrocarbons	

APPENDIX 3 – CONSUMER EXPOSURE

Proposed RMM Efficiency values for the FEICA case study – Annex 1, consumer use of repair adhesive.

RMM	Route	RMM Efficiency default value	RMM Efficiency maximum value	Source	Confidence source	Remark
RMM associated with product design:						
Quantity used	Dermal and inhalation	High	High			Exposure of consumers to product supplied in a form requiring manual handling of the product itself is directly dependent on the unit pack size. Pack sizing that is greater than the requirements for single use offers the probability of overexposure. Reduction in pack size to correspond to typical minimum single use requirements reduces the exposure via this route to the minimum possible. Supply in multipack format enables optimum quantity selection where greater than the minimum is required
Physical state of product	Dermal	HIGH	High			Changing from a paste form to a liquid form will enable mixing without manual handling – either by use of a spatula or, with redesigned packaging, by containment within the packaging itself. However, use of a liquid form will increase the potential inhalation exposure
Packaging	Dermal and Inhalation	High	High			Redesign of the packaging to enable mixing within the packaging itself may be expected to significantly reduce exposure. This RMM becomes more effective if the viscosity of the substances is reduced
Reformulate	Dermal and Inhalation	High	High			ES indicates it is feasible to reformulate using non-irritant and non-sensitising substances. However, the technical drawbacks – slower cure rate – may prompt the consumer to seek an alternative product that does not benefit from this RMM
RMMs communicated to consumers:						
PPE gloves	Dermal	Not applicable	Not applicable			Use of this RMM is dependent on take up by the consumer and cannot be guaranteed e.g. use of gloves is uncomfortable to the consumer and instruction is likely to be ignored
Time to cure	Dermal and Inhalation	Not applicable	Not applicable			The efficiency of this RMM cannot be predicted. Increased time to work with the product offers the possibility of increased exposure unless accompanied by another RMM, such as reformulation or PPE