Guidance on information requirements and chemical safety assessment

Chapter R.13: Risk management measures and operational conditions

October 2012

(Version 1.2)

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Guidance on information requirements and chemical safety assessment

Chapter R13*: *Risk management measures and operational conditions

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PREFACE

This document describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, and the chemical safety assessment. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation). . Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1] and its amendments as of 31 August 2011.

1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006).

DOCUMENT HISTORY

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Version 1	First edition	May 2008
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Version 1.2	Corrigendum: (i) replacing references to DSD/DPD by references to CLP (ii) implementing minor recommendations from nanomaterials according to the RIP-oN3 report (iii) further minor editorial changes/corrections	October 2012

Convention for citing the REACH regulation

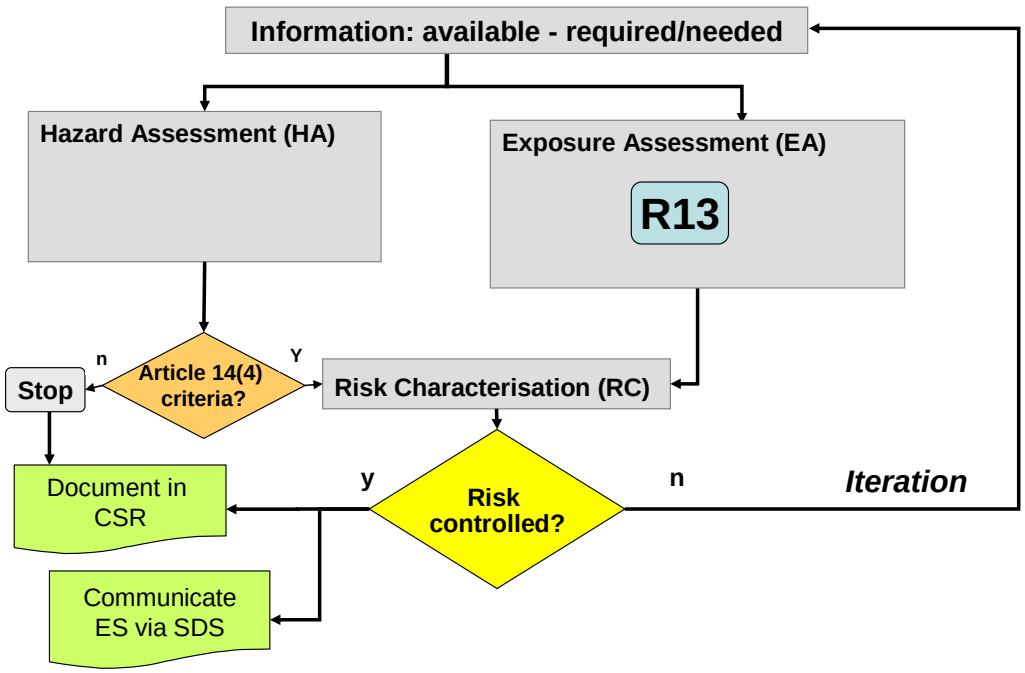
Where the REACH regulation is cited literally, this is indicated by text in italics between quotes.

Table of Terms and Abbreviations

See Chapter R.20

Pathfinder

The figure below indicates the location of Chapter R13 within the Guidance Document.



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R.13 RISK MANAGEMENT MEASURES

R. 13.1 Aim of section

While the concise guidance Part D has its focus on the process of exposure scenario building and exposure estimation, Chapter R.13 provides supporting guidance on the most common types of use conditions having an impact on exposure. This includes an overview on operational conditions and risk management measures related to exposure of workers (Section R.13.2.2), to consumers (Section R.13.2.3) and to the environment (Section R.13.2.4). Sections R.13.2.5 and R.13.2.6 provide guidance on how to address OC and RMMs related to the life cycle stages subsequent to manufacture and identified downstream and consumer uses: article service life and waste life stage. Each single section includes an overview on RMM and OC and some guidance how to use the risk management library and the available Tier 1 tools for exposure estimation when carrying out iterations.

Section R.13.3 provides guidance how the effectiveness of risk control measures can be taken into account. Finally, in Section R.13.4. the set-up of the RMM library is explained in more detail, and how to work with it.

R. 13.2 Operational conditions and risk management measures

This section describes in general terms some of the most common types of conditions of use that are relevant for exposure estimation and later have to be implemented in the registrant's own sites and communicated to the downstream users. M/I may see this as a collection of examples what to consider when building an ES.

R.13.2.1 Physical form of product and product specifications

The physical form of the product is important for the exposure potential to the substance, and can also be a relevant mean to reduce risks, e.g.:

- Solid substances or mixtures may be supplied as fine light powders (implies high dustiness), granular solids or agglomerated powders (implies medium dustiness), and pellet-type solids (implies low dustiness).
- Liquids may form aerosols or splashes when processed under input of mechanical energy. However processed in low energy processes and under good industrial hygiene conditions, exposure from charging, discharging and processing is mainly driven by vapour pressure and water solubility.
- For articles, the ratio of surface to volume is a key driver for the fraction of substance that may be released into the environment or is available for direct exposure of humans (oral or skin contact).

The product specifications, i.e. concentration/percentage of the substance in a mixture or article, may be directly linked to the exposure of humans and the environment, e.g.:

- The concentration in the product multiplied with product amount per activity determines the amount of substance present in that activity.
- Concentration can drive the fugacity of a substance in a product
- The concentration may directly impact on local exposure to skin.

R.13.2.2 Operational conditions and risk management measures related to workers

Duration and frequency of exposure

The duration of exposure on a day is usually a very important factor that determines the exposure over a working shift. The duration and frequency of use related to the human health and safety assessment should be the realistic worst case combination of duration and frequency of use for one worker. The duration and frequency can be defined case by case to reflect the current practise. This duration and frequency is then used both in exposure estimation and documented in the ES. In cases where there are no accurate enough specific data, duration and frequency for a worker should be stated as 220 days per year, each with 8 hours of work, although a process may be running continuously for 300 days a year with alternating crew.

The duration of inhalation exposure is the time of presence of the individual in a certain work environment. Inhalation exposure stops when the individual leaves the exposed environment. This is not true for dermal exposure where the skin may be contaminated. Dermal exposure will end when the amount on the skin is fully absorbed or when the contamination is washed away. The frequency of exposure in terms of days per year is more relevant for the toxicological evaluation of the exposure. For the exposure during a day, it is generally acceptable to add the exposure episodes on a day weighted with respect to magnitude and duration of exposure.

Applied amount of chemical

The maximum amount relevant to consider for human exposure assessment is the realistic (occurring in practice: e.g. the 95^{th} percentile) maximum amount to which a worker will be exposed. In some situations, however, the exposure is related to certain activities (e.g. maintenance and repair of equipment) more than to the amount handled. This type of information may be used in the exposure estimation and has to be clearly stated in the ES.

Temperature

The temperature of a process is a major determining step for chemical reactions and will determine all sorts of other process characteristics. It may also affect the shielding conditions with respect to the process involved and the human behaviour with respect to use of PPE (as a risk management measure). With respect to exposure the most important issue is that volatility is dependent on temperature. This mainly affects inhalation exposure, but also formation of aerosols at elevated temperature could be relevant. Dermal exposure is largely due to deposition (from aerosols), direct contact, and contact with contaminated surfaces. Dermal exposure due to contact with gases or vapour is usually not biologically/systemically relevant

Containment of process

Containment of a process decreases the occupational exposure level by either avoiding any kind of manual manipulation during the process through automated control of closed process equipment or by encapsulating relevant handling areas by e.g. ventilated booths or glove boxes. The effectiveness of such containments can vary depending on the technique and operation of the setup (e.g. closed process equipment/glove box can reach up to 100 % effectiveness) and is thus important to be considered in the exposure estimation. It is crucial to describe detailed enough the level and means of containment assumed in the exposure estimation in the ES.

Capacity of surroundings

The surroundings where the substance is used should be specified, e.g. either indoor or outdoor use. For indoor use the room volume (and ventilation) has an impact on the concentration in the air. Default values will typically be applied for Tier 1 exposure estimation tools. However when calculating exposure based on room size, the distribution behaviour of the substance in the room needs to be evaluated. Often, even distribution cannot be assumed, and thus a conservative (small), virtual space around the worker must be assumed, or measurements are needed.

Risk management measures

For occupational risk management, the general measures necessary for safety and health protection of workers (article 6 of Directive 89/391/EC), the reduce-to-a-minimum principle (article 6 of Chemical Agents Directive 98/24/EC) and the hierarchy of RMM prescribed in the Chemical Agents Directive must be followed. This includes in particular: avoiding risks; evaluating the risks which cannot be avoided; combating the risks at source; giving collective protective measures priority over individual protective measures; replacing dangerous by non-dangerous or the less dangerous; giving appropriate instructions to workers. The recommended RMMs for the occupational setting should enable and support the employer to meet the goals of occupational safety and health protection.

M/I or DU should therefore consider measures needed for control risk in the order of the following hierarchy of the general workflow:

- Eliminate risks by limiting the use of the substance in market (to advice against certain use(s) or not to cover certain use(s) in the CSR) , or modification of process, by using intrinsically safe equipment or by automatisation;
- Reduce risk by limiting the concentration of a substance, and/or change form of physical state, and/or apply closed processes, and/or install effective local exhaust ventilation
- General area ventilation and other workplace related measures (like segregation of dirty departments, safe storage, fire/explosion protection and prevention, eyebaths/showers)
- Other collective RMMs aimed at protecting the population of workers, e.g., organisational measures limiting the number of exposed workers or the duration of exposure
- Personal protective equipment (respiration, skin, eyes) where exposure cannot be prevented by other means.

Apart from substance or process specific risk management measures, good industrial hygiene practice forms the basis to minimise exposure of workers during and after normal operations. Personal hygiene procedures (e.g. washing hands after handling of substances, changing contaminated cloths) and organisational settings (e.g. separation between exposure areas (black) and non exposure areas (white) should be supported by regular training / instruction of workers and consequent supervision. Application of PPE should be based on acceptance and a high level of comfort to achieve effective implementation.

R.13.2.2.1 Iteration of occupational RMMs and OCs

The following Table R.13-1 links the possible variables of the TRA tool related to occupational exposure to measures contained in the RMM library (see Section R.13.4). These links are meant to support iteration of the initial ES (see step 6-9 of the general workflow (See Section D.3.2). If M/I wishes to make use of the library in order to refine an initial exposure scenario he should consider whether any of the measures in column 2 are appropriate to iterate the default setting in the corresponding tier 1 tool.

Table R.13-1: Examples of conversion from risk management library to iteration at tier 1 (occupational)

	Type of RMM	Tier 1 tool input (TRA)	Corresponding measure of the library	Default effectiveness in Tier 1 tool
1	Prevent certain exposures	Process category	CW 7.01 – 7.11. CW 8	Prevention, 100%
2	Change physical state of product	Fugacity or volatility class	CW 2.01	Depends on process category
3	Limit concentration of substance in marketed mixture	Assumes application of 100% substance	CW 1.01	not yet foreseen in TRA; however, linear correlation between concentration and exposure allowed.
4	Limit concentration of mixture through dilution before spreading	Assumes application of 100% substance	CW 1.06	not yet foreseen in TRA; linear correlation between concentration and exposure allowed.
5	Limit time of working with the substance	4 categories of duration per shift	CW 4.04 CW 7.09	< 4 h: x 0.6 < 1 h: x 0.2 < 15 min: x 0.1
6	Work under LEV	Yes or no	CW 15-20	10
7	Work under light [heavy] respiratory protection	not available	CW 30	not yet foreseen in TRA tool
8	Reduce exposed skin surface by ……	Not available	CW 28, CW 29	not yet foreseen in TRA tool
9	Work area regularly cleaned ; tools new or regularly inspected	Not available		not yet foreseen in TRA tool

R.13.2.3 Operational conditions and risk management measures related to consumers

Duration and frequency of exposure

The duration of exposure for consumers should either be estimated as 24 hours per day as a worst case or by estimating the duration of the specific activities leading to exposure (e.g., cleaning of floor or manual dishwashing). For consumer products and articles, and especially in indoor situations, the duration of use is not the same as duration of exposure (e.g. in the case of painting).

In the exposure estimation, it should be taken into account that exposure to a substance may also occur after application.

Applied amount of chemical

The applied amount of chemical is found by multiplying the handled weight of the product with the weight fraction of the substance in the mixture. For using a mixture after dilution (e.g., detergent concentrate), the handled weight of the diluted mixture is multiplied with the weight fraction in the diluted mixture,

The realistic maximum amount of chemical in use by consumers varies not only between consumer products but also between individuals. For certain types of products it should be assumed that some consumers use more than the recommended amount, because they expect a better product performance. In these cases, individually packed amounts (e.g. tablets or separate sachets) will ensure a constant use amount.

Temperature

For consumers, normally a working temperature of 20° C is used.

Capacity of surroundings

The size of the receiving compartments, normally a room in a flat or a house is representing one of the most important parameters for the exposure assessment. This descriptor of exposure is needed for tier 1 assessments.

Ventilation is difficult to control by consumers. When indicated on the label that the product should be used ‘in well ventilated areas’ or ‘outdoor’, this does not mean that a certain (high) ventilation rate is assured. The ventilation may be very low during hot summer days, even when a window is opened. For higher tier assessment, the exchange of air in a room could be described by a conservative default ventilation rate. Note, assessments should maximise the use of available information relevant for exposure estimation. For example, data on properties like odour tolerance levels or minimal air exchange rates based upon building characteristics can inform the exposure estimate.

Risk management measures

Experience shows that complex instructions are not suitable to ensure control of risk at consumer’s level. Only short and simple instructions are likely to be implemented by a relevant fraction of consumers. Thus, emphasis should be on measures that are integrated to the design of the product and how it subsequently is used.

This may for example be: limiting concentration of a substance, supplying a mixture in form of granules or tabs to reduce exposure to dust, fixed dose or ready-for-use package size. Compared to that, an RMM like “open windows to ensure a good ventilation” may be a useful advice to consumers but “good ventilation” should not be assumed when estimating the exposure. Increasing ventilation rates above default is not always a suitable option to iterate an exposure scenario for consumer uses, as adherence to the instructions cannot be guaranteed.

Basically two relevant types of RMMs can be distinguished for consumers (Figure R.13-1)

- Product integrated RMMs under the control of the supplier
- Consumer instruction/communication on safe use

Consumer instructions cannot be expected to be highly effective, unless consumer behavioural data suggest that a sufficient degree of implementation can be assumed. Therefore consumer RMMs that depend on instructions should as a general rule only be introduced when the use of such RMMs can be shown to be effective, necessary and well adhered to by consumers.

Consumer exposure assessment should also take into account reasonably foreseeable misuse and describe preventive risk management measures, like e.g. child safe fastenings.

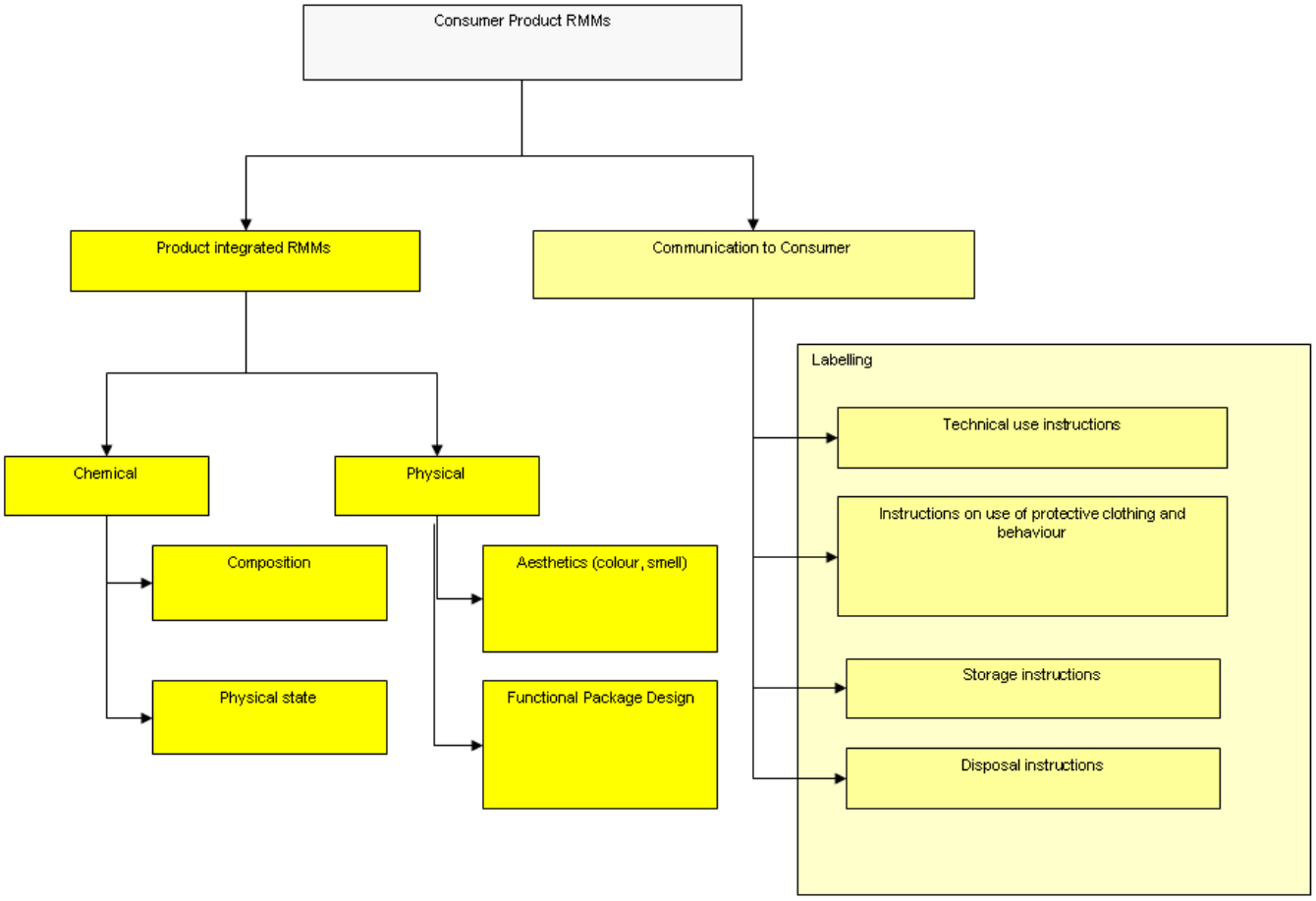

Figure R.13-1: Product-integrated and consumer instruction/communication RMMs that can be considered in the ES (adapted from Bruinen de Bruin et al., 2007).

R.13.2.3.1 Iteration of RMMs and OC related to consumers

The following Table R.13-2 links the possible variables of the ConsExpo tool to measures contained in the RMM library. These links are meant to support iteration of the initial ES (see step 6-9 of the general workflow Section D.3.2). If M/I wishes to make use of the library in order to refine an initial exposure scenario he should consider whether any of the measures in column 2 are appropriate to iterate the default setting in the corresponding tier 1 tool.

Table R.13-2: Examples of conversion from risk management library to iteration at tier 1 (consumer)

	Type of RMM	Tier 1 input parameter ConsExpo	Corresponding measure in the library	Default effectiveness expressed at Tier 1 level
1	Prevent certain exposures	Mixture or article and exposure pathway	CW 7.01 – 7.11. CW 8	Prevention, 100%
2	Change physical state (or viscosity) of product to prevent or reduce inhalation, skin contact, ingestion or splashes.	Selection of relevant exposure pathway	CW 2.01	Proportional changes in exposure, however may need higher tier assessment
3	Limit concentration of substance in marketed mixture	Concentration of substance in product	CW 1.01	Linear to changes in the concentration
4	Reduce max. amount used (e.g. by specific packaging or instructions)	Amount per application	CW 3	Linear to changes in the amount
5	Limit skin contact by type of packaging	Skin contact area	CW 3	Linear to changes in skin contact area and skin contact time
6	Limit migration from articles by changing matrix properties	Migrating fraction or migration rate		Depends on changes in migration fraction or migration rate

R.13.2.4 Operational conditions and risk management measures related to the environment

Environmental releases may occur as a result of any process or activity during the life cycle of a chemical. The most common determinants of exposure are: The applied amount of substance per time, the release factors from processes and products (before abatement), the emission pathways, the effectiveness of waste water and waste air treatment, the spatial dispersion of emission sources and the time pattern of release.

Containment of process

Running a production process in containment aims to prevent emission into the environment, including prevention of waste or waste water streams to be treated outside the containment. However such strictly contained processes are rare in practice. Thus, the level of containment of a process should be considered case by case. Such consideration will result in defining the type of containment in the exposure scenario and assuming an emission factor > 0 in the exposure estimate. Please note: Containment to prevent exposure of workers does not necessarily prevent emissions to the environment!

Duration and frequency of exposure

For point sources, it is useful to differentiate between continuous, frequent and intermittent release. Releases of a substance occurring every production day would typically be characterized as a continuous release occurring e.g. 300 days/year. However, if the substance is frequently released directly to surface water within a limited time period, it may be more appropriate to characterize the release by using the actual duration of the release (e.g. kg/day). Intermittent releases are related to

activities that occur less frequently (less than at least one day per month, e.g. discharges due to the yearly cleaning of production equipment.

For intermittent releases, the actual duration of the release is used, i.e. if for example the release is considered from a cleaning operation occurring 5 days once a year, a duration of 5 days can be assumed.

Wide dispersive uses lead to a continuous release, 365 days per year.

Applied amount of chemical

Characterise the applied amount of a chemical for the relevant Exposure Scenarios. Depending on the case amount per time or amount per activity or both can be relevant.

Temperature

Temperature has an impact on the releases of the chemical especially into air, as volatility increases with increasing temperature, however, there seldom is enough information to enable to take this into account in the exposure estimation. Where that is the case it may be relevant to define the temperature range in which the activity should happen in the ES.

Capacity of surroundings

The standard values for the capacity of the receiving environmental compartments can be selected according to Chapter R.16. For site-specific exposure assessment, but not for wide-dispersive use, the capacity factor or the dilution factor of the surface water system and also the sewage system could be an option for refinement.

Risk management measures

The prevention and reduction of emissions of dangerous substances by process integrated measures are usually preferred over end-of-the pipe techniques.

Environment related RMMs cover different measures that aim to prevent losses from processes and/or clean up the streams leaving the processes, e.g. recycling of solvents, re-use of process water in vent gas scrubbers, closing the process water circulation, different waste water and waste gas treatment methods, restriction in spreading of sludges. When considering environmental risk management measures, the possible shift of risk from one emission route to another should be taken into account. Reducing air emission of a dangerous substance by factor of 10 for example usually needs follow up risk management related to the amounts filtered out.

Good housekeeping can address both occupational and environmental exposure and can be based on sector specific process recommendations or definition of Best Available Techniques (BAT) under the Integrated Pollution Prevention and Control (IPPC) Directive. It comprises e.g. regular cleaning of equipment and floors, follow up of the process parameters relevant for emissions, record keeping on near-miss-situations. Risk management can also be supported by environmental management systems. Some technical measures, as municipal waste water are to some extent outside the control of M/I or DU. Here, M/I can give advice whether or not to dispose of the substance through a certain route, define what type of treatment plant is required or what capacity it should at least have or define the possible necessity of pre-treatment. Technically achievable efficiencies for environment protection techniques in various industry sectors are described in BREF documents under the IPPC Directive and the emission scenario documents of the OECD (see RMM library).

R.13.2.4.1 Iteration of RMMs and OC related to the environment

The following Table R.13-3 links the possible variables of the EUSES tool for environment to measures contained in the RMM library. These links are meant to support iteration of the initial ES (see step 6-9 of the general workflow Section D.3.2). If M/I wishes to make use of the library in order to refine an initial exposure scenario he should consider whether any of the measures in column 2 are appropriate to iterate the default setting in the corresponding tier 1 tool.

Table R.13-3: Examples of conversion from risk management library to iteration at tier 1 (environment)

Environment related RMM accessible through ERCs and …..				
	Type of RMM	**Tier 1 input parameters (ERCs/EUSES)**	**Corresponding measure of the library**	**Default effectiveness expressed at tier 1**
1	Prevent certain exposures	Product category linked to relevant ERCs	CW 7.01 – 7.11. CW 8	Depends on fraction of that use compared to total volume
2	Limit daily amount used per local site	Local amount per day	CW 7.09	Linear to changes in daily tonnage
4	Treatment of emission via water in municipal STP	Substance properties and connection rate to STP	E 13.23	Calculated with SIMPLETREAT based on biodegradability, log Pow and log H.
5	Reduce emission via air/water/waste through process engineering controls	% of reduction related to process controls before end-of-pipe RMMs		20 default emission factors (before RMM)
6	Reduce air emission by waste gas treatment	% of reduction related to abatement after process controls	E 12	no defaults
7	Reduce water emission by on-site waste water treatment	% of reduction related to abatement after process controls	E 13	Except for STP, no defaults
8	Dispose of residues to external treatment	% of reduction related to abatement after process controls	E 14 (partly in library)	no defaults
9	Emit less than once a month for not more than 24 hours	Use short term PNEC for deriving RCR		The PNEC can be increased by a factor of 10 since recovery of ecosystem is assumed
10	Limit substance concentration in waste water by using an equalising basin	Local amount per day.	W22	No default; linear correlation t/d

R.13.2.5 Operational conditions and risk management measures related to substances in articles

Substances in articles need to be considered as part of the life-cycle of a substance, when incorporation into articles is one of the identified uses of a substance. The registrant needs to cover the exposures resulting from the service-life of such articles in his exposure estimation and to develop exposure scenarios for the service-life. It should be noted that users of articles are not downstream users under REACH and they do not receive an ES.

During the service life of articles, substances can be released into the environment e.g. via evaporation or wear-and-tear mechanisms. Workers and consumers can be exposed to substances due to their presence in the articles directly via oral, inhalation or dermal uptake or via environment. The magnitude of exposure is strongly related to the physicochemical properties of the substance and the bonding capacity of the surrounding matrix material the substance is contained in.

As the M/I will in many cases not have detailed knowledge about the characteristics of the articles produced and use conditions during service-life of these articles he may need to collect information from his downstream users on issues which are relevant for his exposure estimation and may consequently need to be defined in the ES, in particular the following:

- Total quantity of the substance incorporated into the article and weight fraction of substance in the article, which defines the overall emission potential during the entire service life.
- Indication of which fraction of this total substance volume is used under the following conditions:
    - Duration of article use which determines the potential exposure during service life: A long service life could mean accumulation in a specific use domain (e.g., electronics)
    - Surface area/ volume ratio, influencing the evaporation/migration potential of substances from the article surface: articles with high surface area/volume ratio (e.g. plastic sheets) may have higher emissions for the same substance than those with a low surface area/volume (depends on substance properties and interaction with matrix)
    - Accelerated wear and tear or factors enhancing emissions: exposure to light, temperature, weathering or erosion, intense use (e.g., brake pad)
    - Estimated material lifetime loss which describes the amount of the substance (in percent or weight dimension) expected to be released from the article during service life (intended release or unintended release)

With this information, the M/I will need to carry out an exposure estimate (see Chapter R.17). Also the importer or producer of article who has duties under article 7 of REACH may need to carry out exposure estimates related to substances contained in the article. The M/I needs to document the relevant factors in his ES for article service-life stages.

Risk management measures

The recipients of articles will not get the ESs related to the service-life of articles since they are no downstream users under REACH. The main addressees of these ESs are:

- formulators producing raw material for certain types of articles
- industrial end-users incorporating substances or mixtures into an article.

- Thus, the RMMs will mainly address product-integrated risk management measures rather than instructions how to handle articles. However, the producer of articles may use the information in the ES he receives when designing the use instructions he submits to his customers.

Such measures may include e.g.:

- limit the concentration of substance xxx in the article;
- design the article-matrix in such way that the loss of substances is not higher than x% over lifetime;
- don't use the substance in articles for outdoor or abrasive uses;
- use in articles only for which efficient re-collection systems exist.

R.13.2.6 Operational conditions and risk management measures related to the waste life stage

Article 2 (2) of REACH provides that *"waste as defined in Directive 2006/12/EC of the European Parliament and of the Council is not a substance, mixture or article within the meaning of Article 3 of this Regulation."* Therefore, REACH requirements for substances, mixtures and articles do not apply to waste, and waste operations are not downstream uses under REACH. Risks in waste operations are to be primarily controlled based on requirements set by waste legislation. Nevertheless manufacturers and importers of substances, downstream users and eventually recipients of articles have a number of duties under REACH related to substances in waste. This is to complement waste related requirements with substance-specific measures to control risk, if needed.

According to Article 3(37) exposure scenarios refer to control of risk during the entire **life-cycle of the substance**. This includes considerations related to the waste stage of substances as confirmed in Annex I paragraph 5.2.2 where the life-cycle is explicitly said to cover the waste stage. In addition, Annex I paragraph 5.1.1 of REACH also makes it clear that the risk management measures in an exposure scenario *should cover waste management measures to reduce or avoid exposure during waste disposal and/or recycling.*

The duties of M/I under REACH with regard to the waste life stage can be summarised as follows:

- M/I shall document in the registration dossier available information on the amount of waste resulting from manufacture of the substance, from the identified uses and from use in articles, including composition of the waste streams. For the purpose of clearly identifying the wastes, suitable waste codes should be used, preferably those of the European waste catalogue. For guidance which waste streams to cover, see section R.18.2 to R.18.5 in Chapter R.18.
- For dangerous substances > 10 t per year, the waste life-stages resulting from manufacture and identified uses need to be covered in M/I's chemical safety assessment (see Annex I of REACH). This includes exposure estimation, and measures for control of risk for substance in waste to be communicated downstream with the exposure scenario and in Chapter 13 of the

extended safety data sheet (see Annex II of REACH). The details of exposure assessment related to the waste life stage are explained in Chapter R.18.

Consequently, it is the duty of downstream users i) to consider the waste life-stage related information received with the exposure scenario, ii) to take action if the internal handling of waste and the chosen route for recovery or disposal is outside the conditions set in the ES, and iii) to communicate the relevant information to further downstream users. The tasks for M/I and DU under REACH with regard to handling and treatment of waste are limited to the following:

- Implement waste related measures with regard to M/I's own activity, as stated in the exposure scenario.
- Implement waste related measures with regard to DU's own activity, as stated in the exposure scenario received from the supplier.
- Forward waste related information received with the ES from the supplier to the next downstream user, if relevant.
- Choose waste treatment operations, in line with what is recommended in the supplier's exposure scenario.

As a matter of principle, exposure scenarios and recommended risk management measures cannot be used to reduce or modify any obligations arising under waste legislation. Any user of the substance for which the exposure scenario was prepared will have to comply with all requirements from waste legislation. In order to assist downstream users, exposure scenarios should as far as possible describe legal requirements under waste legislation. But there are limits to the amount of detail which can go into exposure scenarios. It will be impossible to cover all national and local provisions as well as all possible indirect implications of waste legislation (e.g. implications of recycling targets). Moreover, requirements may change over time and it will always be challenging to keep exposure scenarios up to date.

However, this is neither required nor the purpose of exposure scenarios. Exposure scenarios should focus on the specificities of the substance and its risks during the waste stage and give recommendations on how best to control these risks. These recommendations should lead to the safe recovery or disposal of the substance and reduce the risks to human health and emissions to the environment, in addition to the requirements from waste legislation. For this purpose, the exposure scenarios may contain a number of different waste treatment options which may be applied depending on local or national conditions or legislative requirements. Whatever treatment option is proposed, control of risk is to be demonstrated in M/I's CSA. If the measures suggested in the exposure scenario are in conflict with requirements set by local or national waste authorities, the inappropriateness of the measures should be communicated up the supply chain (analogue article 34 (b) of REACH..

When developing the section on waste management in the exposure scenario, M/I is advised to evaluate whether the properties and the use of the substance is connected with specific risks during waste operations. This is to target the CSA to risks related to the waste life stage. Thus M/I should make himself aware on what particular risk could arise. Appendix R.13-1 contains a list of indicative examples that may assist M/I to identify such risks. If any of the cases listed or similar situation apply, M/I are advised to develop specific measures for the waste life stage, based on which control of risk during waste operations can be demonstrated. The corresponding measures are to be communicated down the chain with the extended safety data sheet.

Operational conditions in waste management

Waste treatment operations may include destruction (thermal or chemically) of substances, immobilisation of substances, separation of waste components for tailor-made treatment, separation/cleaning of material to be recovered, extraction of components to be recovered. Depending on the type of the waste operation, the availability of substances in the waste stream for exposure may be increased or decreased. Typical operational conditions in waste treatment potentially leading to an increase of exposure potential of substances contained in the waste stream include:

- Milling operations may lead to increased availability of substance for exposure due to dust formation and releases due to elevated temperature.
- Manual dismantling of vehicles (cars, ships, trains, airplanes) and equipment may lead to release of fluids from contained systems, dust (e.g. brake systems) or fumes (from welding)
- Thermal treatment of waste may lead to increased availability of metals for exposure and to formation of persistent products of incomplete combustion.
- Water based cleaning, extraction and separation processes may lead to emission of substances contained in waste streams via waste water.
- Long term storage in the environment in landfills or other waste permitted sites may lead to releases due to leaching or air emissions.

Risk management measures

The principal risk management options in waste operations are largely the same as in other industrial and professional uses. However, there are a few relevant differences with regard to end of the pipe treatment of collected mixed waste streams (e.g. incinerators, landfills).

- The operational conditions must be suitable for working with unknown substances, since even waste declarations cannot make fully transparent what types of substances a certain waste stream contains. Thus substance specific, DNEL-driven occupational risk management will be an exception. The emphasis is on measures minimising/preventing contact with the waste in waste treatment Reference can be made to standard RMMs and OCs required in waste treatment.
- Keeping waste separate in order to facilitate efficient recovery or optimal disposal can be a key risk management advice to be communicated in the exposure scenario.
- Related to the environment, largely the same risk management techniques like in other industrial processes are applied. But the variable inputs on the waste side (quantities and qualities) require particular management efforts to optimize the way how the different waste batches are fed into the treatment processes. This limits the scope of generating substance or waste specific risk management advice at M/I level addressed to the operator of a treatment plant.

Further guidance on how the information related to waste operations contained in an exposure scenario may look like is provided in Appendix R.18-2.

R. 13.3 Effectiveness of RMMs

Both Risk Management Measures (RMMs) and Operational Controls (OCs) may be used to reduce or eliminate risks of exposure. This requires a quantification of the effects the RMMs may have on the risk determining factors. It is necessary to assume an objective, quantitative measure of the effectiveness of RMMs in reducing exposure or environmental emissions in order to predict the resulting exposures or environmental concentrations.

The standard process for determining RMM effectiveness is as follows, although it should be noted that the effectiveness of an RMM is generally strongly related to the site and/or personal behaviour:

- List all known, published RMM effectiveness values for the RMM in question, including specific conditions under which the effectiveness is established.
- 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.
- For RMMs with no published sources of information on effectiveness, assign a semi-quantitative effectiveness value based on expert judgement, if possible, and document the underlying justification.

The effectiveness of risk management measures can markedly vary depending on the expertise of the RMM user to install and apply the measures. In many cases engineering expertise is necessary to achieve optimal design of a technical setup or to provide competent advice on how to effectively implement RMMs. It is therefore indispensable to describe the effectiveness achievable with a specific RMM by taking into account realistic assumptions about its proper application. Organisational measures, such as management systems, training schemes, operating practises and monitoring, that covers both the operation and maintenance of the process and risk management equipment can support in ensuring that the RMMs are effective.

The same basic principles to define RMM effectiveness are applicable for all three potentially exposed groups or categories – consumer, worker and environment. The effectiveness of RMMs that is used in the exposure estimation and recommended in the Exposure Scenarios has to be evaluated and quantified, or there quantification is not possible, described qualitatively. (See text box below for definition).

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

The effectiveness values for some single RMMs or RMM packages can be retrieved from open literature, or from information sources of sector organizations or authorities. A number of such information sources are described in more detail in the RMM library and are cross-referenced to individual RMMs for which numerical effectiveness values have been provided (see Section R.13.4.2.6). Both the companies manufacturing and importing risk management equipment and users of these equipment may have measured data on effectiveness. The source of the effectiveness information that is used in final exposure estimation has to be documented in the CSR.

It is useful to consider the degree of confidence in the effectiveness values based on the amount and quality of validation data, whether the study/measurement was properly designed and well-founded, confirmation in different situations, etc. Where it is not possible to have a quantified effectiveness figure, a qualitative description with adequate justification should be given. For instance categories high/moderate/low with a case-specific description can be used. For consumer uses it is important to distinguish between measures that are under the control of the manufacturer or supplier and those which are not but rely on action by a consumer.

Effectiveness related considerations when selecting RMMs

- **Influence of substance properties** - Often the effectiveness of measures relates to the substance properties, such as the effectiveness of respiratory protection which can be limited in its use to dusts or vapours. The library indicates such limitations by assigning applicability to general substance properties in a separate category. Engineered RMMs, however, like waste water treatment (e.g. aerobic biological degradation) or exhaust gas treatment (wet scrubber) may need detailed cross-check of biodegradability or absorption behaviour of a given substance before assigning an effectiveness value.
- **Median (50^{th} percentile) as typical value** – A 50^{th} percentile of the distribution is suggested as reasonable descriptor of the effectiveness 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 50^{th} 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 effectiveness 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 effectiveness is not reasonable since the baseline exposure estimate of the ES is also based on a worst case.
- **Quantity of material used / released** - For substances that are applied in exposure scenarios where a known fraction is released into the workplace or into the environment, limiting the use of the substance can be considered as a RMM. When defining the effectiveness of such measure, it should be considered whether the reduction in exposure level is proportional to the reduction in the quantity used.
- **Elimination of a task within the exposure scenario** - Measures which eliminate parts of or entire process steps- e.g. providing the material in pre-weighed quantities- can be introduced as a RMM. By doing so the exposure related to this specific task is effectively eliminated and will not contribute anymore to the overall exposure. The effectiveness of this measure is assumed to be 100%.
- **Degree of capture** - There may be a variety of release sources at a single facility. Releases from single process steps, unit operations or equipment may be captured effectively. Diffuse releases for instance from leakages at pipes and connections are however difficult to capture.

- **Effectiveness of consumer RMMs -** It is difficult to estimate real effectiveness values for consumer RMMs that depend on an action by a consumer. High uncertainty exists about consumer behaviour, which might be driven by consumers' perception of the potential hazards of the products (e.g. in a study by Heinemeyer et al. (2006) 30% of German consumers followed instructions of manufacturers when cleaning floors, whereas in the case of impregnation sprays this was 80%). Efficiencies of these RMMs can therefore only be applied with caution in consumer exposure estimation, e.g. by giving the range of exposure level illustrating exposure when RMMs are applied- RMMs not applied.

R. 13.4 RMM library

R.13.4.1 Aim of this section

This section provides details to the registrants on how to use RMM library to find suitable RMMs and OCs for incorporation into their exposure scenarios to demonstrate control of risks. The library addresses the control of exposure to consumers, environment and workers. The following chapters give a brief introduction into the functionalities of the RMM library whereas a more detailed explanation of the practical use of the library is provided in the library itself.

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

R.13.4.2 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 effectiveness; 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 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). Worksheet "Individual Measures" *(worksheet 3)*

The core part of 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.

In terms of structure, the library is organised according to the occupational hygiene concept of 'hierarchy of control' as outlined in the Chemical Agents Directive. 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. 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[2];
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.13.4.2.1 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;
- Marketing and use related;
- Process control /change;
- Ventilation/discharge control;
- General dilution ventilation;
- Organisational;
- Good hygiene practices & housekeeping;
- Personal protective equipment; and
- First aid measures

Within this overall structure, all RMMs (and OCs) for the control of exposure to consumers and the environment have been allocated to the respective categories.

R.13.4.2.2 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 effectiveness 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).

[2] Elimination and substitution of a substance are not a RMM to be reflected in an ES as the registrant will not provide an ES for uses in which the substance is substituted. In such cases the registrant will either not cover the use in his CSR or he advices against the use.

R.13.4.2.3 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) 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 extended SDS as well if reference to the library should be made to provide further details or links to additional information.

R.13.4.2.4 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.13.4.2.5 Estimation and documentation of RMM effectiveness in the library

Effectiveness of individual RMMs is quantified in the library in those cases where technical/scientific evidence is available. Only in cases where an exposure could be excluded by the nature of the production/application process or by technical or organizational means a 100 % effectiveness value would be assumed.

In practice the effectiveness of different RMMs varies due to its dependence on several factors e.g. proper 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).

Often the effectiveness of measures relates to the substance properties, such as the effectiveness of respiratory protection which can be limited in its use to dusts or vapours. The library indicates such limitations by assigning applicability to general substance properties in a separate category. Engineered RMMs, however, like waste water treatment (e.g. aerobic biological degradation) or exhaust gas treatment (wet scrubber) may need detailed cross-check of biodegradability or absorption behaviour of a given substance before assigning an effectiveness value. The effectiveness of a measure may also be related to the starting concentration and thus generic figures on effectiveness of measures should be associated with information on the related concentration ranges.

Specifically in relation to nanomaterials, particle size can affect the performance of RMM and the effectiveness should not be assumed to be the same for nanomaterials as for substances in general. Such assumptions must be based on appropriate justification.

For some RMMs it would be inappropriate to give any figure due to the fact that no quantitative information is available or because these are strongly dependent on the local operational conditions and the skills of the user. In those cases a qualitative assessment can be given to indicate the potential of risk reduction by introducing a qualitative scale (Low; Medium; High) to indicate the: "potential" of the RMM in given (ideal) conditions:

- High: reduction in exposure of more than one order of magnitude can be achieved (> 90% effectiveness)
- Moderate: In practice, reduction in exposure is less than one order of magnitude (<90%) and very dependent on the circumstances of use. But in general the measure is considered suitable for the context defined in the library.
- The "low" effectiveness indicates that the RMM will usually not have a major effect on exposure or emission reduction.

In addition to these text characters, there is also a text element for when effectiveness is not applicable (na) to specific RMMs. For example local exhaust ventilation is a measure that is used to control inhalation exposures in the workplace and is only seldom used by consumers. If 'cells' within this section are not completed with either a numerical or text character(s) an effectiveness indication has not been assigned yet.

The effectiveness 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.

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.13.4.2.6 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.

R.13.4.2.7 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.13.4.2.8 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 RMMs 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.13.4.3 Using the RMM Library

Upon opening the spreadsheet, the user will find 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") 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.13.4.3.1 Finding RMM information

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

- the respective worksheet and start searching for specific details for individual RMM measures or
- the RMM package worksheet for sector specific/ exposure specific combination of individual RMMs 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.13.4.3.2 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 effectiveness i.e. a default value and / or maximum achievable value.

For cases where this is available, the user should first take the default effectiveness 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 control of risks. If not, the Registrant must then look at the maximum achievable value. If this is suitable, i.e. the risk management measure reduces concentration to below the DNEL/PNEC, the Registrant must ensure that the downstream user is capable of operating at the assumed level of RMM effectiveness (this may require specific substance testing such collection of 'real-life' monitoring data).

Appendix 13-1 Indicative list of substance-specific risks during waste life stage

- Thermal decomposition and particle emission: Incineration of metal containing waste can lead to wide disperse emission of metals to air and water. Make sure that these emissions are taken into account in the exposure assessment. Inform DUs about the recovery schemes applicable to their products. Inform DU about any threshold related to metal inputs into waste or co-incineration.
- Evaporation or leaching out of substances with PBT properties: Substances regarded as PBTs or vPvBs in the CSA or which are listed according to article 59 due to equivalent level of concern need particular attention regarding the waste life stage. Establish, case by case, the emission from any waste disposal operation relevant for this substance.
- Formation of break-down products during thermal treatment: Certain substances could form toxic, persistent and bioaccumulative break down products under thermal stress during recovery or other waste treatment operations (e.g. halogenated flame retardants in plastic/copper composite material). Make sure that the CSA addresses this source of emission and exposure, based on the available literature. Inform the DU about the required conditions during treatment of the substance in its waste life stage (in preparation or article) to avoid formation of such products
- Water-soluble contaminants: Depending on the applied processes and activities, substances may be contained in aqueous waste streams after downstream use. Make sure that these fractions are taken into account in emission and exposure assessment. Inform DUs about substance properties impacting on the distribution behaviour in waste separation techniques and biological treatment. Provide advice where chemical-physical destruction techniques may be needed.
- Formation of separate organic phase: Organic substances used in paints for spray applications may be contained in the water phase of paint sludge from overspray to be treated in waste operations.
- Formation of emulsions: Organic substances used in lubricants may be contained in the water phase of oil-water mixtures or emulsions to be treated in waste operations.
- Exposure to dust or fume during high energy stripping: Dismantling of articles containing the substance may be connected with exposure of workers to dust or fumes. Make sure that the CSA covers a suitable exposure scenario related to occupational exposure. This may be particularly relevant with regard to dismantling of vehicles, electric/electronic goods and buildings.