Joint Task Force

ECHA Committee for Risk Assessment (RAC)

and

Scientific Committee on Occupational Exposure Limits (SCOEL)

on

Scientific aspects and methodologies related to the exposure of chemicals at the workplace

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EUROPEAN CHEMICALS AGENCY

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List of Abbreviations, Terms & Definitions

Standard term / Abbreviation	Explanation/Definition
AF(s)	Assessment Factor(s) (see also UF below)
ACGIH	American Conference of Governmental Industrial Hygienists
BGV	Biological Guidance value A biological guidance value (BGV) represents the concentration of the substance or a metabolite of the substance in any appropriate biological medium corresponding to a certain percentile (generally 90 or 95 percentile) in a defined, preferably occupationally non-exposed, reference population. If background levels cannot be detected, the BGV may be equivalent to the detection limit of the biomonitoring method, which then is to be specified in the document.
BLV	Biological Limit Value Biological limit values (BLVs) are health-based values for evaluating potential health risks in the practice of occupational health. A BLV is a tool for the control of such risks and should not be used for other purposes.
CAD/CMD	Chemical Agents Directive/ Carcinogens or Mutagens Directive
COM (EMPL, GROW, ENV)	Commission Directorate-Generals for Employment (DG EMPL), for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) and for the Environment (DG ENV)
DECOS	Dutch Expert Committee on Occupational Safety
DNEL	Derived No-Effect Level Defined in REACH Annex I, 1.0.1 *The objectives of the human health hazard assessment shall be […..] to derive levels of exposure to the substance above which humans should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL).*
ECETOC	European Centre For Ecotoxicology And Toxicology Of Chemicals
ECHA	European Chemicals Agency
LOAEL	Lowest observed adverse effect level
MAK	MAK Commission: The Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area in Germany. MAK value for chemical substances is the maximum permissible concentration of a substance as a gas, vapour or aerosol in the air at the workplace which, according to current knowledge, does not normally affect worker health or cause unreasonable nuisance even with repeated and long-term exposure, usually 8 hours a day, but assuming an average weekly working time of 40 hours.
MoA	Mode of Action
MoS	Margin of Safety

Standard term / Abbreviation	Explanation/Definition
NOAEL/NOAEC	No observed adverse effect level/ No observed adverse effect concentration. The NOAEL/NOAEC is defined as "*the level of exposure of an organism, found by experiment or observation, at which there is no biologically or statistically significant increase in the frequency or severity of any adverse effects in the exposed population when compared to its appropriate control*". (Ref.: U.S. Department of Health and Human Services).
OEL IOEL & BOEL	Occupational Exposure Limit: usually given as a time weighted average value (TWA)over 8 hours There are two different types of OELs set at EU level: Indicative Occupational Exposure Limit Values (IOELs) established in accordance with the Chemical Agents Directive usually simply called "OEL"s and, Binding Occupational Exposure Limit Values (BOELs) established in accordance with the Chemical Agents Directive and also the Carcinogens or Mutagens Directive.
OSH	Occupational Safety and Health
PoD	Point of Departure
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measures
SCOEL	Scientific Committee on Occupational Exposure Limits
STEL	Short Term Exposure Limit: exposure limit for 4 peak exposures per work-shift for each 15 min at maximum
SVHC	Substances of Very High Concern
TWA	Time Weighted Average
UFs	Uncertainty Factor(s)

1. Introduction

The European Chemicals Agency (ECHA) and the Scientific Committee on Occupational Exposure Limits (SCOEL) were requested by the European Commission on 6 July 2015 by way of an Article 95(3) of the REACH Regulation request and an Article 2(9) of Commission Decision 2014/113/EU[1], to create a Joint Task Force, composed of members from each of the ECHA Committee for Risk Assessment (RAC) and SCOEL, including representatives from the Secretariats.

The terms of reference for the Joint Task Force included three tasks, however it has been agreed that Tasks 1 and 3 (detailed below) will be addressed first and that Task 2[2] will be addressed separately at a later date.

Mandate Task 1 *Comparative critical assessment of REACH DNEL and OEL methodologies:*

- *Outline the present methodologies adopted by SCOEL and ECHA for the derivation of exposure values relevant for worker protection via the inhalation route. Identify the key principles and present the main steps and assumptions on which these are based.*
- *Identify and explain differences between the ECHA and SCOEL methodologies and fundamental principles and assumptions, with reference to the scientific literature and in particular to aspects of the two methodologies which relate to:*
    - *Selection of critical and/or leading health effects;*
    - *Selection of studies;*
    - *Use of dose descriptors and modification;*
    - *Dealing with uncertainty and the handling of inter- and intra-species differences, use of assessment and/or uncertainty factors and their scientific relevance;*
    - *Use of weight of evidence approach, including the scope for discretion of the actor establishing values to depart from defaults.*

Mandate Task 3 *Comparative assessment of the ECHA and SCOEL methodologies for dermal route exposure, skin notation and dermal DNEL:*

- *Outline and assess the approach used by SCOEL to identify the need for a 'skin notation' to be included in an OEL recommendation;*
- *Compare with dermal DNEL in terms of relevance and appropriateness and report on any areas of convergence and divergence between ECHA/RAC and SCOEL.*

As given in the mandate, "*The aim of this joint work is to improve mutual understanding of the different approaches and to work towards agreed common scientific approaches including through the further development of existing and new concepts as necessary in relation to workers' exposure to chemicals*".

This joint report is a reflection of the discussion of the Joint Task Force at its meetings in November and December 2016 and also in January 2017 when this draft report was discussed and agreed subject to final commenting and editing. The report reflects the

[1] Commission Decision 2014/113/EU of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC

[2] Mandate Task 2 "Comparative critical assessment of ECHA and SCOEL methodologies in relation to 'non-threshold' substances"

discussion on the different methodologies used by the two Committees for recommending DNELs and OELs and looks at areas of convergence as well as divergence as a basis for further development of how the processes could work together.

The report is the product of the Joint Task Force and is recommended for endorsement by the European Chemicals Agency's Committee for Risk Assessment (RAC) and by the Scientific Committee on Occupational Exposure Limits (SCOEL).

2. General

2.1 Differences and similarities in functions, legal frameworks and conditions

Occupational limit values are derived in different legal frameworks, namely the Chemical Agents Directive/ Carcinogens or Mutagens Directive CAD/CMD[3] and REACH[4]; OELs are implemented in the workplace to limit exposure, while worker DNEL's are used to assess 'adequate control' of risk and to recommend additional risk management measures (RMM) where necessary. Both legislations operate 'without prejudice' and are intended to protect workers. Substances in REACH Annex XIV, subject to authorisation can only be used in workplaces beyond the sunset date with such an authorisation, which includes DNEL setting as recommended by ECHA's RAC. The latter is considered by SCOEL members to be a clearly different approach as worker DNELs are used as a benchmark to set RMMs. However, RAC and SCOEL members were not convinced that these differences form any barrier to a more complementary/harmonised approach.

The more important question posed by the mandate is whether the methodologies, rather than the implementation, are comparable. It was confirmed that OEL setting and worker DNEL-setting follows the basic principles and steps of toxicological risk assessment, such as literature review, hazard assessment and characterisation of dose-effect and dose-response relationships. However various factors, as detailed in section 3, including as noted above the different legal frameworks, have resulted in different overall approaches which can also lead to different OELs and worker DNEL values; this is not *per se* to be understood as a conflict on the level of scientific analysis or methodology. Clearly in some recent cases, divergent opinions/different values have arisen (e.g. N-Methyl-2-pyrrolidone and 1, 2-dichlorobenzene)

The members of the Joint Task Force acknowledged that the presence of different limit values for the same substance that apply in the workplace could be confusing for workers and employers and agreed that, where possible this should ideally be avoided and may require a better communication of the different purposes of the limit values.

2.1.1 Differences caused by the respective legislation

A structural difference between REACH and OSH legislation, which can lead to divergence of opinions on the same substance, is related to the manner in which REACH

[3] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

[4] 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 of 30 December 2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3)

Annex XIV (**Authorisations**) specifies the reason(s) leading to inclusion, classified as carcinogenic (C), mutagenic (M), toxic for reproduction (R), persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) and 'of equivalent concern'; in some cases, only one or two are listed. While, for a given substance, SCOEL using its comprehensive approach would consider all endpoints. For the purpose of authorisation RAC would only consider those actually listed in REACH Annex XIV. Where **Restrictions** under REACH are concerned, this difference does not exist.

2.2 Impact of Application of Assessment Factors/Uncertainty Factors (AFs/UFs)

The Joint Task Force agreed that the "level of protection" afforded by OELs (under OSH legislation) and worker DNELs (under REACH Regulation) was a policy issue for the Commission and would not be considered further.

2.3 Consistency, workability and reproducibility

With the intention of increasing transparency and consistency by allowing the steps taken in deriving any DNEL to be easily reconstructed, the DNEL procedure under REACH replaced an earlier Margin of Safety (MoS) rationale used under previous legislation. Standardisation of the process may need less reflection or knowledge to carry out a risk assessment and the procedure, especially the exposure assessment, may stop when safe use is demonstrated. A clear distinction between DNELs derived by RAC as part of its work in the scientific evaluation of restrictions and authorisations and those derived as part of registration dossiers was acknowledged.

It was noted, that the use of UFs and how uncertainties have been taken into account in setting OELs may have not been fully explained in all cases in the earlier SCOEL Recommendations. More recently however, numerical values have been given along with a clear explanation of the various aspects of uncertainty that had been considered. It was noted again that this is being considered in the ongoing revision of the SCOEL methodology. Any older SCOEL Recommendations, in which it was not fully clear how uncertainties were addressed could be readily revisited.

The Joint Task Force supported the view that the justification of the AFs and UFs used by the two Committees should be as transparent and consistent as possible.

It was noted that worker DNELs would need to be derived for many REACH Annex XIV substances (under REACH) in the coming years, for which there were no OELs at present and that a standardised approach was needed to manage the workload. RAC members pointed out that the ECHA Guidance on DNEL derivation grew out of a long history of using MoS to deal with uncertainty often including inconsistent results. Hence the necessity in dealing with large numbers of chemicals to use the default assessment factor (AF) framework, complemented with substance-specific information when appropriate.

SCOEL members pointed out that the SCOEL methodology for the development of OELs and BOELs uses current "best practice" and science as established by well-developed process used by many occupational health expert committees such as MAK, DECOS, ACGIH, etc. worldwide. It was also pointed out that when evaluating a chemical substance with limited or unreliable data, or other high uncertainties in the data, SCOEL may agree to not include a numerical value for an OEL in the Recommendation but instead describe the gaps or lack of scientific evidence that preclude the recommending of a reliable health-based OEL.

It was reiterated that in the past SCOEL, may have not clearly added detailed explanation for all the factors underpinning its choice of UF in some cases. The use of default AFs was further discussed and RAC members acknowledged that it was

recommended to substitute the standard default factors with chemical specific information whenever possible.

2.4 Short term exposure limit (STEL) and acute DNEL

The STEL concept was developed to protect workers against specific groups of chemicals, in particular irritating compounds, i.e. classical short term effects (based on a 15 minutes exposure estimate: STEL is the exposure limit for 4 peak exposures per work-shift for 15 min each at maximum). The STEL addresses possible 'peak effects' in workers, taking their tasks and movement in relation to emission sources into account.

On the MAK list a third of the substances had local irritation as a relevant endpoint (Brüning et al 2014[5]). For determining a STEL the toxicokinetic information on the substance and its Mode of Action (MoA) are key information.

STELs protect worker health where the use of the 8 hour Time Weighted Average (TWA) alone (for chronic effects) does not protect sufficiently against acute harmful effect such as respiratory irritation or narcosis, which may be caused by short-term (peak) exposure situations. The STEL should reflect the upper bound of the exposure variability. Both the TWA and the STEL must be complied with in the workplace, because the one does not substitute for the other.

The acute systemic DNEL (for some substances) takes account of effects that can occur after a single peak exposure, thus in practise relating to the inhalation route. An acute DNEL should be derived if an acute toxicity hazard has been identified and there is a potential for high peak (inhalation) exposure (ECHA Guidance IR&CSA, Chapter R8 Appendix R.8-8). In addition, if relevant, an acute local DNEL can be set for e.g. sensory or respiratory tract irritation, but the long-term DNEL is normally sufficient to ensure that these effects do not occur. Chapter R8, notes that risk characterisation need not be conducted for all relevant health effects, but only for the leading health effect(s). While this does not rule out deriving a separate DNEL for short term effects when needed; however, this is currently not common practise for RAC.

2.5 Biomonitoring

Whilst not a central part of the mandate, the Joint Task Force agreed that a focus on biomonitoring was important in protecting workers, as when analytical methods are available, it can make up for deficiencies in knowledge on uptake of a substance via dermal exposure, hand to mouth pathway and also in the case of poor data on air monitoring (e.g. as is often the case when contextual information on emission sources is missing or the jobs/tasks/activities of workers are multiple and/or unclear). At its simplest biological monitoring of exposure helps occupational health professionals to induce workers to change behaviour by identifying poor occupational practices. It was noted by SCOEL members that for certain substances and or working conditions, biomonitoring was more important and informative about worker exposure than air monitoring.

Biomonitoring is a key tool in occupational hygiene for assessing overall systemic exposure and particularly important to risk assessors and occupational hygienists when assessing actual worker risk, as air monitoring alone may seriously underestimate the total uptake of certain substances. Biological monitoring may thus help in the interpretation of a worker's airborne exposure related an OEL for those substances where particularly skin uptake but also gut uptake are relevant.

[5] Brüning et al 2014, Arch Toxicol (2014) 88:1855–1879

The SCOEL Biological Limit Value (BLV) can be either health-based or exposure-based. For a health based BLV derived directly from human studies containing data on cohorts with dose response effects or early biological effects, the BLV may not necessarily have a relationship with the OEL but rather with the levels at which the potential adverse health effects are observed in the study(ies). Another option is to derive the BLV from the OEL on the basis of established correlations between air levels and biomarker level. Background contextual information such as time of sampling, analytical method etc. are essential to interpret biomonitoring data. BLV have similarity to Biological Exposure Indices (BEI values) in the US (ACGIH) and Biological Tolerance Values (BAT values) in Germany.

When the data cannot support a health-based BLV, Biological Guidance Values (BGVs)[6] are usually calculated as the 95 percentile of a population background level and BGVs therefore are used to assess exposure and not risk; BGVs are also relevant for assessing workers' exposure to non-threshold carcinogens, particularly where environmental (air) monitoring data may not be available or sufficient.

It was noted that there is an increased use of biomonitoring data both by SCOEL and RAC in the Authorisation and Restriction processes and that this is an area of common interest for both Committees. SCOEL commented that the use of biomonitoring data for deriving limit and guidance values has been well established and is performed regularly whenever feasible and validated methods are available. It was also noted that biomonitoring was useful for worker protection in relation to carcinogens and it was proposed to re-visit this when addressing Task 2.

3. Task 1: DNEL/OEL methodology

Mandate Task 1 *Comparative critical assessment of REACH DNEL and OEL methodologies:*

- *Outline the present methodologies adopted by SCOEL and ECHA for the derivation of exposure values relevant for worker protection via the inhalation route. Identify the key principles and present the main steps and assumptions on which these are based.*
- *Identify and explain differences between the ECHA and SCOEL methodologies and fundamental principles and assumptions, with reference to the scientific literature and in particular to aspects of the two methodologies which relate to:*
    - *Selection of critical and/or leading health effects;*
    - *Selection of studies;*
    - *Use of dose descriptors and modification;*
    - *Dealing with uncertainty and the handling of inter- and intra-species differences, use of assessment and/or uncertainty factors and their scientific relevance;*
    - *Use of weight of evidence approach, including the scope for discretion of the actor establishing values to depart from defaults.*

The various aspects of the methodologies are compared in summary below, although the order is different from the mandate text above. It was confirmed that the current 'Methodology for the Derivation of Occupational Exposure Limits' (SCOEL, 2013; version

[6] BGVs are not health-based and therefore do not set a limit between absence or presence of adverse health effects.

7[7]), could be considered as the latest update and would have to be used for reference by the Joint Task Force even though it is currently undergoing revision. The methodology used by RAC is the ECHA Guidance[8]

3.1 Selection of Studies

Whilst in principle both RAC and SCOEL have access to the same data sources, it may happen that the databases used for the substance may differ for the Committees. In this case divergent opinions may occur. Therefore, communication and comparison of the data available (study/report/literature) to each of the two Committees to ensure a similar starting point, could be a first step in avoiding diverging opinions. However, it is noted that in the case of N-Methyl-2-pyrrolidone the database reviewed by RAC and SCOEL were essentially the same.

3.2 Selection of critical/leading health effects

3.2.1 PoD

The Joint Task Force considered the differences between 'critical' effect (SCOEL) and 'leading' effect (ECHA Guidance) as significant. Schenk and Johanson (2011) describe these terms as follows: *'The OEL- hazard assessment basically aims at identifying the critical effect, i.e. the first adverse effect that appears as dose (or exposure level) increases. The underlying assumption is that if exposure is kept below the critical effect level, neither the critical effect nor other more serious effects appear. In contrast, in the derivation of DNELs, according to the REACH framework, several endpoint-specific DNELs have to be calculated, one for each identified adverse health effect and relevant exposure route. The lowest of the endpoint –specific DNELs for each relevant exposure route is then chosen as the final DNEL, the corresponding effect being called the leading effect.'*

The PoD might be derived from epidemiological studies but in the absence of human data it could be derived from animal studies. SCOEL members expressed a general preference for good quality human studies, in keeping with the closer relevance of the data to humans (less need for the uncertainties of the extrapolation of effects from animal investigations) and the occupational health backgrounds of many SCOEL members. The way in which workers are likely to be affected by exposure to the chemical in question is important, an example being the chemo-sensory/irritant properties, as often this is the first sign of effect of some substances and can therefore often provide the optimal starting point in protecting workers. SCOEL members noted that about 30% of OELs are based on the acute irritating properties of the chemical in question. RAC acknowledged this approach as important in the workplace. It was also acknowledged that there was more scepticism when using human data among RAC members due to frequently encountered challenges in interpreting the available evidence, e.g. small sample size studies and the presence of confounding factors.

For worker DNEL derivation, human data are used when available and of sufficient quality but in the absence of such information, animal data are used with a standard

[7] Available on Commission webpage on SCOEL [http://ec.europa.eu/social/main.jsp?catId=148&intPageId=684&langId=en]

[8] Guidance on IR & CSA, Chapter R.8: Characterisation of dose [concentration]-response for human health (v2.1 November 2012) [https://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf/e153243a-03f0-44c5-8808-88af66223258]

modification of the dose descriptor to extrapolate to workers. It was noted that for endpoints, such as reproduction toxicity, human data may be scarce. Moreover, human studies with a small number of workers do not (or only to a limited extent), address effects on, for instance, reproduction toxicity and other systemic effects. However, RAC members expressed their willingness to look more into human data in the future.

It was noted that although the "starting point" (i.e. the critical effect/leading effect) for each Committee is the same, the manner of selection is different, which may in turn lead to different OEL and DNEL values. There are three possible reasons for the differences: (i) the PoD, (ii) the adjustment for exposure and (iii) the choice of AF. SCOEL considers the totality of the health and toxicity database accounting for the nature, adversity, severity and reversibility, consistency (across studies, strains and species) and MoA of the critical effect(s) and the relevance for the workplace before including modification of the dose (if needed) or accounting for the uncertainties and variabilities. In comparison, the ECHA Guidance selects all the relevant effects for workers, assess the nature, severity, consistency, mode of action and thereafter modifies the doses and addresses uncertainty (following the AF framework described in the REACH guidance) and then, as a final step, selects the lowest worker DNEL i.e. RAC derives several DNELs from different PoDs and selects the lowest. It was felt that the way in which the adjustment of the PoD for exposure was carried out could be more critical to the final result than previously thought.

The Joint Task Force acknowledged that the two approaches to selecting the point of departure can contribute to different numerical OEL and worker DNEL values.

It was pointed out that the differences between RAC and SCOEL, observed for a given chemical (only a handful of chemicals have been compared in any depth), are generally small.

3.3 Use of dose descriptors and modification (correction of the PoD)

Standard modification of the starting point (dose descriptor) such as allometric scaling were not considered as uncertainties, albeit formally part of the AFs, but as a necessary extrapolation to get from a dose in an animal study to a human equivalent dose and that remaining uncertainty should be considered separately. RAC members indicated that allometric scaling is included in their application of AFs which is therefore reflected in the overall AF. SCOEL members pointed out that allometric scaling had been agreed by SCOEL for implementation when needed already in 2014. It was acknowledged by the Joint Task Force that this could help to identify similarities and differences in this regard.

It was concluded that the different application of correction factors to modify the dose descriptor could also be a source of divergence.

3.4 Dealing with uncertainty and inter/intra species differences, assessment factors (AFs) and uncertainty factors (UF) and their scientific relevance

SCOEL members reiterated their strong preference for avoiding fixed default AFs/UFs and using all of the available scientific data, dealing with uncertainty as a whole and expressed by a single justified number. They noted that typically, the substances they were requested to evaluate were data-rich. RAC members noted that REACH considers all chemicals with a wide variation from data rich to data poor, but many are data poor and the same methodology is applied in a flexible manner to ensure consistency for all substances (this includes the Registration process in REACH as well as Authorisation and Restriction).

ECHA Guidance applies a standard intra-species AF:

- for worker (AF 5) and
- for the general population (AF 10).

It was considered by RAC that the multiplication of default or specific AFs/UFs was a broadly supported and well-developed approach; the defaults are only used when there are no robust substance specific data available, with which to work. RAC members expressed the view that if the uncertainties in a dataset are not transparently stated it may not be possible to reconstruct the underlying arguments.

RAC members acknowledged that it was recommended to substitute the standard default factors with chemical specific information whenever possible and sufficiently justified.

SCOEL members commented that a chemical-specific, and sometimes lower, but still sufficient margin of exposure can be established in a comprehensive approach, weighing up all the factors together in a transparent manner, in setting the OELs without relying on a framework of default AFs/UFs.

4. Task 3: dermal DNELs and SCOEL skin notation

Mandate Task 3 *'Comparative assessment of the ECHA and SCOEL methodologies for dermal route exposure, skin notation and dermal DNEL'.*

- *Outline and assess the approach used by SCOEL to identify the need for a 'skin notation' to be included in an OEL recommendation;*
- *Compare with dermal DNEL in terms of relevance and appropriateness and report on any areas of convergence and divergence between ECHA/RAC and SCOEL.*

4.1 SCOEL skin notation

SCOEL issues a skin notation indicating a possible significant uptake through the skin. This indication is used during the tripartite dialogue for policy development and also implemented in workplaces e.g. as advice or warning that dermal exposure should be avoided, i.e. prevented in the workplace by appropriate RMM.

A skin notation also alerts risk assessors and occupational hygienists in the interpretation of workplace air monitoring results that may not reflect the total uptake of the substance if skin contact or gut uptake occurs due to workplace practices or usage. Simply put, keeping worker exposure below the OEL may not be adequately protective in such cases.

The assessment whether a skin notation is required considers various types of information and is necessarily qualitative. It can include the following:

- health effects observed in workers following skin exposure;
- internal exposure, most likely as a result of dermal exposure, demonstrated by biomonitoring;
- dermal absorption studies (*in vitro*, *in vivo*, and human).;
- physicochemical properties – mainly solubility properties (e.g. aprotic solvents dissolving in both lipid and water).

Usually, SCOEL issues a skin notation when it can be assumed that dermal exposure may contribute to about 10 % or more of the body burden by inhalation exposure at the OEL.

4.2 Dermal DNELs

In recommending risk management conditions for specific workplaces applying for authorisation under REACH Annex XIV of REACH, RAC evaluates modelled dermal exposure data provided by applicants against a dermal DNEL. Generally, the risk characterisation ratio's observed reflect the proportion of manual activities carried out in the workplace, signalling potential for exposure and in some cases triggering further risk management measures. It was however recognised that there are weaknesses in the models applied to calculate dermal exposure. However, it is recognised that RiskOfDerm, a higher tier model produced by an EU funded project and recommended by ECHA Guidance, is still the most advanced model, albeit with the limitation of providing estimations with a wide margin of variability.

4.3 Areas of convergence and divergence between skin notation and dermal DNELs

RAC and SCOEL members agreed that the assessment of dermal exposure remains problematic and measured exposure data are rarely seen in practice. Therefore, measures to prevent such exposures should have (within reason) a prevention/preventive character as achieved through a skin notation.

The joint task force share the view that the current means under both OSH (skin notation) and REACH (dermal DNEL) legislation of identifying potential for dermal exposure can work in a complementary manner and that both trigger risk management measures as appropriate. The Joint task force also agreed that in the case of dermally absorbed chemicals biomonitoring, if available, would be a key component for the assessment of exposure.

Aside from Registrations, dermal DNELs are also derived for REACH restriction and authorisation applications to take account of skin exposure. In the former, proposals originating from Member States or ECHA, largely on data-rich compounds, can derive a robust dermal DNEL based on substance specific information, as in the case of a recent RAC opinion on Bisphenol-A; the dossier contained extensive dermal exposure data and/or dermal penetration studies, allowing skin absorption and metabolism to be fully taken into account. However, such data are often lacking and when determining a dermal DNEL (for most substances), default AFs may need to be used (skin absorption is allocated defaults of 10% (in some cases up to 100%) unless they can be overridden with substance specific data.

In authorising continued use of substances of very high concern (SVHC), the dermal risk assessment can provide a clear confirmation of well managed workplaces, avoiding further RMM conditions, while for poorly organised workplaces, such information can help to confirm the need for additional conditions. One RAC member raised the issue of studying surface contamination as an indirect method to assess dermal exposure (in the context of antineoplastic drugs occupational exposure). This method can be used to assess potential exposure from a contaminated surface and allows to obtain information about causes of contamination and to monitor contamination trend when RMMs are applied.

5. Conclusions

The following conclusions have been agreed:

5.1 Task 1

The Joint Task Force acknowledges that various factors have resulted in different overall approaches, which can also lead to different OELs and worker DNEL values which is not

per se to be understood as a conflict on the level of scientific analysis or methodology. The Joint Task Force share the view that:

- in principle both RAC and SCOEL have access to the same data sources. However it may happen that the databases finally used for the evaluation of the substance differs for the two Committees in which case divergent opinions/different values may be derived;
- On a general level, OEL and worker DNEL-setting follows the same basic principles and steps of toxicological risk assessment, such as literature review, hazard assessment and characterization of dose-effect and dose-response relationships. SCOEL members felt that important differences exist in the criteria applied and how the assessment is performed;
- the two approaches to selecting the point of departure or critical/leading health effect can contribute to different numerical OEL and worker DNEL values;
- allometric scaling is used in both processes,
- where possible, default AF values should be replaced with chemical specific data; the justification of the AFs (RAC) and UFs (SCOEL) used by each Committee should be as transparent and consistent as possible;
- the multiplication of default or specific AFs/UFs is a broadly supported and well-developed approach under REACH;
- SCOEL has a preference for using good quality human data and uses the animal data as supportive evidence in a comprehensive approach taking account of the MoA; since SCOEL usually makes recommendations mainly on data-rich compounds, there are often data available on effects in humans.
- RAC has a similar preference; for worker DNEL derivation on less data rich substances, animal data is primarily used as the starting point with a standard modification of the dose descriptor to extrapolate to workers;
- there is an increased use of biomonitoring data both by SCOEL and RAC and that this is an area of common interest for both Committees; the use of biomonitoring data for deriving limit and guidance values has been well established (for SCOEL) and is performed regularly whenever feasible and validated methods are available;
- the prevention of acute reversible effects such as pre-narcosis and respiratory tract irritation which may be caused by intermittent exposures above the 8 hour OEL are dealt with by SCOEL with the recommendation of a STEL (usually 15 minutes 4 times per work shift) which prevents or limits the occurrence of these peak exposures to supplement the OEL;
- to some extent, for example for REACH Authorisations, the legal framework may also lead to differences by focusing on specific endpoints.

5.2 Task 3

The Joint Task Force share the view that the current means under both OSH (skin notation) and REACH (dermal DNEL) legislation of identifying potential for dermal exposure can work in a complementary manner and that both trigger risk management measures as appropriate.

6. Recommendations

The following recommendations are made:

6.1 General

- ECHA-RAC and SCOEL Secretariats to ensure continuing collaboration between the two Committees as addressed in the Commission Decision 2014/113/EU and the REACH Regulation[9];
- communication and comparison of the data available (study/report/literature) to each of the two Committees to ensure a similar starting point could be a first step in avoiding diverging opinions;
- to ensure transparency and consistency of OELs and worker DNELs, each step needs to be carefully and fully described, including selection of the point of departure, modification of the dose descriptor, the uncertainties taken into account when setting the OEL/DNELs and when selecting the final worker DNEL from the different endpoint-specific DNELs.

6.2 For RAC

- to look more closely into human data;
- to assess the need to review ECHA Guidance on IR&CSA Chapter R8 , to better reflect workplace risk assessment needs.

6.3 For SCOEL

- to explain and clarify how uncertainties have been taken into account in recommendations for OELs;
- to conclude ongoing work on the update of the methodology.

[9] Article 95 of the REACH Regulation specifies that the Agency (ECHA) must address conflicts of opinion with those of other bodies established under Community law. Similarly, Article 2(9) and Articles 5 (5) of Commission Decision 2014/113/EU, specify that the Secretariat must ensure effective cooperation of SCOEL with other bodies and must address conflicts of opinion.

Appendix 1. Members of the Task Force & Commission Observers

RAC Task Force Members

- Lina Dunauskiene
- Betty Hakkert
- Sonja Kapelari
- Ruth Moeller
- Bert-Ove Lund
- Elodie Pasquier *
- Tiina Santonen **
- Susana Viegas

ECHA Secretariat

- Tim Bowmer (RAC chairman)
- Anniek van Haelst
- Stella Jones

SCOEL Members

- Len Levy (chairman)
- Maurizio Manno (vice-chairman)
- Gunnar Johanson (vice-chairman)
- John Cocker
- Sebastian Hoffmann
- Edgar Leibold
- Angelo Moretto
- Tiina Santonen **
- Alain Simonnard
- Hermann Bolt ***
- Helge Johnsen ***

SCOEL Secretariat

- Christoph Klein

KEY

* Elodie Pasquier's RAC membership ended in December 2016
** Tiina Santonen is a member of SCOEL and RAC
*** SCOEL observers

Commission Observers

Giuseppina Luvara (DG ENV)
Christian Heidorn (DG ENV)
Mariana Fernandes-de-Barros (DG GROW)
Alick Morris (DG EMPL)
Tim Harris (DG EMPL)