



norden

Nordic Council of Ministers

Ved Stranden 18
DK-1061 Copenhagen K

www.norden.org

NORDISKE ARBEJDSPAPIRER

N O R D I C W O R K I N G P A P E R S

Exposure Evaluation Guidance for REACH

<http://dx.doi.org/10.6027/NA2014-919>
NA2014:919
ISSN 2311-0562

This working paper has been published with financial support from the Nordic Council of Ministers. However, the contents of this working paper do not necessarily reflect the views, policies or recommendations of the Nordic Council of Ministers.

Exposure Evaluation Guidance for REACH Processes

Nordic Exposure Group Project 2013:

In-depth compliance checks of REACH exposure scenarios

March 2014

Foreword

The project was funded by the Nordic Council of Ministries through the Nordic Chemicals Group. The project was launched by the Nordic Exposure Group NEGh). The practical work was carried out by the NEGh group together with experts (CAs) working with REACH evaluations (Table 1). Substance evaluation dossiers from the first evaluation round were utilized.

The members of the steering group are introduced below:

Table 1. Steering group

Member	Agency / Country
Lena Höglund ¹	Danish Environmental Protection Agency, Denmark
Jouni Räsänen ¹ Anna-Maija Hämäläinen ¹	Safety and Chemicals Agency, Finland
Margareta Warholm ¹	Swedish Chemicals Agency
Marianne van der Hagen ¹ Eva Haugand Vibeke Lindberg	Norwegian Environment Agency, Norway
Abdulqadir Suleiman ¹	Labour Inspection Authority, Norway
Víðir Kristjánsson ¹	Administration of Occupational, Safety and Health, Iceland

¹ member of NEGh

INTRODUCTION

This document is intended to be used as guidance in the REACH exposure evaluation (MS authorities and ECHA) such as completeness and consistency checks in the substance evaluation and dossier evaluation processes. The checklist is not necessarily complete; there may also be other relevant issues to be taken into account during substance evaluation and dossier compliance checks. This checklist will be updated when necessary, based on the experience gained. The document is focusing mainly on human health issues (workers and consumers), but it may also be utilized, for general issues, in the environmental exposure checks.

The exposure scenario is a new concept in the REACH regulation and is one of the key elements in REACH for ensuring a high level of protection of human health and environment. REACH defines exposure scenarios as a set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends others to control exposures of humans and the environment. Exposure scenario has to be established for substances which are manufactured or imported in quantities over 10 tons per year and which are classified as dangerous or as PBT/vPvB. In addition, exposure scenario is needed also in cases where exposure information is used as a basis for waiving certain animal tests specified in REACH.

The first REACH exposure scenarios were developed by registrants during the 1st registration phase in 2010. So far, some experience of exposure scenarios has been gained from dossier compliance checks (ES in CSR), substance evaluations (ES in CSR) as well as from the downstream user sites, when they receive extended safety data sheets (eSDS). The experience gained indicates clearly that there is room for improvement both in the exposure scenarios in the chemical safety reports and in the annexes of the SDSs.

Guidance documents, various IT tools and ES formats have been developed by ECHA and industrial associations such as CEFIC. However, these may be considered rather complicated, and thus not always helpful enough.

The specific aims of this project were:

- To learn more about the format and content of ESs, including the use descriptor system.
- To check to what extent ECHA's guidance has been exploited in the building of ESs.
- To obtain experience of the quality /challenges in ESs.
- To identify strengths and weaknesses in building of ESs (e.g. the usability and effectiveness of risk management measures).
- To develop instructions or recommendations for authorities to be used eg. in the substance evaluation process.
- To make the check list available to ECHA and authorities and other relevant stakeholders.

Checklist for scrutiny of ES in REACH

(e.g. during substance evaluation and dossier compliance checks)

1. GENERAL ISSUES
• Check that the overall quality of the dossier is acceptable at first impression. • Check how the toxicological/eco-toxicological endpoints for which no data are available are handled/justified. • Make sure that all stages of the life cycle have been considered - if relevant (including service life and waste stage). • Check if there is consistency throughout the CSR in the way the exposure assessment has been performed.
2. EXPOSURE SCENARIOS
• Check the overall content of exposure scenarios. • Check that the uses are clearly described and detailed enough. • Check that the Operational Conditions are appropriate and realistic and are coherent to the PROC. • Check if the combination of PROCs/PCs and hazard endpoints may indicate the potential for raised exposure and increased risk (e.g. respiratory sensitizer and spraying). • Check that quantified exposure values for all relevant routes and populations are given: ○ inhalation ○ dermal ○ oral ○ workers (industrial and professional) ○ consumers • Check estimated inhalation exposure level. • Check estimated dermal exposure level: ○ substance contained in a mixture ○ substance migrating from an article • Check estimated oral exposure level: ○ substance in a mixture or article unintentionally swallowed ○ substance migrating from an article • Make sure that all stages of the life cycle have been considered - if relevant (including service life and waste stage). • In order to ensure that consumers and downstream users are not exposed to a substance registered as an intermediate, make sure that all substance is consumed in the process.
3. PHYS-CHEM PROPERTIES
• Verify that phys-chem properties of relevance for exposure scenario are taken into consideration, eg. in the model calculations. ○ Has the substance a tendency to become airborne (physical state)? ○ Volatility: - highly volatile - vapour pressure > 25 kPa, - low-volatile - vapour pressure < 0.5 kPa; - volatile - vapour pressure > 0.01 Pa, - non-volatile - vapour pressure < 0.01 Pa ○ Dustiness - Low/Medium/High (see eg. Table R14-10) ○ Particle size

- inhalable (100 µm), - respirable (4 µm) (see http://av.se/dokument/inenglish/legislations/eng1118.pdf. See p.59-60) ○ pH ○ Relative density
4. CLASSIFICATION AND LABELLING
• Verify that the substance classification for human toxicity endpoints is correct according to CLP Annex VI or entered in C&L Inventory. • Have the highest concerns associated with the substance been identified? • Check that also environmental CSA and ES are established (although there may not be environmental C&L).
5. MANUFACTURE AND USES
• Use descriptors: ○ Check that there is consistency between description of manufacture and use in relation to PROCs and PCs chosen. ○ Check that the terminology from R.12 guidance is followed. ○ Check if the use of short titles is consistent with the ES. • Identify all uses: Professional/industrial /consumer. • Description of where the substance is used, eg. indoors with general ventilation / LEV (effectiveness). • Level of containment (Low/Medium/High). • Check that the use of Specific consumer exposure determinants (SCEDS) is justified. • Check that exposure estimates for all uses are available. • Consider if substance is incorporated into a mixture or articles used by the public (e.g. consumers). • Check that sensitive subpopulations such as children are taken into account if appropriate. • Check that specific operations are taken into account. ○ example: cleaning, maintenance, sampling. • Check if the Operational Conditions (OC) are relevant for the Use Descriptors. • Check that Risk Management Measures (RMM) are consistent with OC.
6. DERIVED NO EFFECT LEVELS (DNELs)
• Make sure that the DNELs are developed for relevant routes of exposure and effect. • Make sure that if community/national occupational exposure limit values are used instead of DNEL, it is justified according to ECHA guidance (GD IR & CSA R.8 Appendix R.8.13). • Check if assessment factors are according to ECHA guidance R.8, if not, make sure there is a proper justification for not using defaults (substance specific information needed).
7. EXPOSURE MEASUREMENT DATA
• Check that the measurements are reliable, representative and statistically powerful enough. See eg. Table R14-2 in the ECHA R.14 guidance.
8. EXPOSURE ESTIMATION TOOLS (MODELS)
• Can the assessments be reproduced (all model input parameters and assumptions are available and transparent). • Check that the exposure model used is appropriate to the scenario. • Check the version of the model. • Check that the default values used in the CSR are justified. ○ defaults from exposure models.

- defaults from REACH Guidance.
- defaults from the Nordic Exposure Group's default value report.

9. CROSS-CHECK CLASSIFICATION WITH PROCS

- Check if there is potential high risk from the combination of the following PROCs in conjunction with the specified serious health hazard classifications:

Process categories:

PROC 7 industrial spraying
PROC 8a non-dedicated facilities
PROC10 roller application or brushing
PROC 11 non-industrial spraying
PROC 13 dipping and pouring
PROC 19 hand-mixing with intimate contact

Specified classifications:

H314 Causes severe skin burns and eye damage
H317 May cause an allergic skin reaction
H318 Causes serious eye damage
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
H340 May cause genetic defects
H341 Suspected of causing genetic defects
H350 May cause cancer
H351 Suspected of causing cancer
H360 May damage fertility or the unborn child
H361 Suspected of damaging fertility or then unborn child
H371 May cause damage to organs
H372 Causes damage to organs through prolonged or repeated exposure
H373 May cause damage to organs through prolonged or repeated exposure

- Check if there are any indications of exposure of the general public to substances classified as carcinogens, mutagens and toxic to reproduction in relation to REACH Annex XVII, entries 28-30.
- Check if there are any indications of exposure of the general public to substances classified as:

H314 Causes severe skin burns and eye damage
H317 May cause an allergic skin reaction
H318 Causes serious eye damage
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
H341 Suspected of causing genetic defects
H351 Suspected of causing cancer
H361 Suspected of damaging fertility or then unborn child

10. RISK MANAGEMENT MEASURES

- Is the ES compatible with the hierarchy of the RMMs (STOP-principle, i.e. Substitution, Technical measures, Organisational measures, and/or Personal measures) applied?
If not justification is needed:

ECHA R.14:

"Product related RMMs, e.g. reducing the dustiness by converting a powder into an oil-coated powder, into granules, etc. can be implemented by the producer whereas site-specific RMMs are to be implemented by the DU. The hierarchy of the

RMMs (STOP-principle, i.e. Substitution, Technical measures, Organisational measures, and/or Personal measures) is generally applied at the DU level. The technical, organisational and personal RMMs which the M/I recommend for DUs should be practical and proportionate to the anticipated risk. For details the reader is referred to the Guidance on Risk management measures and operational conditions, Chapter R.13, including the introduction to the RMM Library".

- Ventilation (General and Local Exhaust Ventilation) and their efficiencies.
- Check that PPE efficiencies are appropriate /realistic.
- Check if the PPE is really necessary.
- Check that the glove material is specified (and break-through time given)
- Check the details of the PPE to be used; duration of use; frequency of changing are given on proper usage of PPE.
- What not to do/When PPE will fail to protect due to other factors (e.g. using a mask when having a beard)
- Crosscheck PPE with C&L
- Check that the respiratory protection is appropriate and identified detailed enough (e.g. information on the proper purifying element (cartridge or canister), the adequate particulate filters and the adequate masks, or self-contained breathing apparatus).
- Protective Clothing is appropriate and identified detailed enough
- Goggles or other is appropriate and identified detailed enough
- Check that other possible technical measures are feasible

11. SCALING

- Verify that scaling advice (if given) is done according to ECHA's principles (See Guidance for downstream users, Annex 2)

12. RISK CHARACTERISATION - RCR

- Check that there is no high risk characterization ratios (RCRs) in the close vicinity of 1 (>0.9) or 1 (not above)
According to REACH Annex I, 6.4 the risk to humans and the environment can be considered to be adequately controlled if the exposure levels estimated do not exceed the appropriate DNEL/PNEC. High RCRs though, indicate a need for clarification and possible reduction of the exposure. The Registrant may therefore be requested either to refine the estimations, or to submit further justification that risk is controlled related to exposure via the relevant and /or combined routes.