NORDIC WORKING PAPERS

Checklist – Exposure Scenarios in REACH

A Nordic Group Project 2016

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Checklist for scrutiny of exposure scenarios in REACH

Nordic Exposure Group Project 2016

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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 Räisänen ¹ Anna-Maija Hämäläinen ¹	Finnish Safety and Chemicals Agency, Finland
Margareta Warholm ¹	Swedish Chemicals Agency, Sweden
Marianne van der Hagen ¹ Eva Haug and Vibeke Lindberg	Norwegian Environment Agency, Norway
Abdulqadir Suleiman ¹	Labour Inspection Authority, Norway
Víðir Kristjánsson ¹	Administration of Occupational, Safety and Health, Iceland

¹ members of NEGh

The checklist was extended in 2016 to cover also the environment. Additional members of the steering group were:

Sjur Andersen, Norwegian Environment Agency
Stellan Fisher, Swedish Chemicals Agency
Marianne Moilanen, Finnish Safety and Chemicals Agency
Jukka Mehtonen, Finnish Environment Institute

INTRODUCTION

This document is intended to be used as checklist in the REACH exposure evaluation (MS authorities and ECHA) such as compliance and consistency checks in the substance evaluation and dossier evaluation processes. It is a helpful tool to learn more about the format and content of exposure scenarios (ESs), including use descriptor system. It will also help to explore to what extent ECHA's guidance has been exploited in the building of ESs. Using the checklist during exposure evaluation assists to obtain experience of quality / challenges in ESs and it also helps to identify strengths and weaknesses in building of ESs (e.g. the usability and effectiveness of risk management measures).

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 document is to be regarded as a "living document", which will be updated when necessary, based on the experience gained. This checklist covers also environmental issues compared to the version published in 2013 which was focusing mainly on human health issues (workers and consumers).

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 hazardous or are assessed to be 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 develop a checklist for authorities to be used eg. in the substance evaluation process.
- To make the checklist available to ECHA and authorities and other relevant stakeholders.

Checklist for scrutiny of exposure scenarios in REACH

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

1. GENERAL OVERVIEW	
Check the overall quality of the dossier at first impression.	
Check that ESs are available for all uses presented.	
Check how the toxicological/environmentally relevant endpoints for which no data are available are handled/justified.	
Check if all populations, environmental compartments and 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. GENERAL OVERVIEW OF EXPOSURE SCENARIOS	
Check the overall content of exposure scenarios.	
Check that the uses are clearly described and detailed enough.	
Check the tonnage level, wide dispersive use (= widespread [used at many sites, by many users] + potential for release/exposure).	
Check that the Operational Conditions (OCs) are appropriate and realistic and are coherent to the Process Category (PROC) and Environmental Release Categories (ERCs).	
Check if the combination of PROCs/Chemical Products categories(PCs)/ERCs and hazard endpoints may indicate the potential for raised exposure and increased risk:	
<ul style="list-style-type: none"> Health: e.g. respiratory sensitizer and spraying 	
<ul style="list-style-type: none"> Environment: e.g. suspected endocrine disruptor (ED) properties or PBT/vPvB properties and outdoor use/open processes with high or intended releases. 	
Check that quantified exposure levels for all relevant routes and populations are given:	
<ul style="list-style-type: none"> inhalation 	
<ul style="list-style-type: none"> dermal 	
<ul style="list-style-type: none"> oral 	
<ul style="list-style-type: none"> workers (industrial and professional) 	
<ul style="list-style-type: none"> general population (consumers and men via environment) 	
Check estimated inhalation exposure level, also released from articles	
Check estimated dermal exposure level:	
<ul style="list-style-type: none"> substance contained in a mixture 	
<ul style="list-style-type: none"> substance migrating from an article 	
Check estimated oral exposure level:	
<ul style="list-style-type: none"> substance in a mixture or in an article unintentionally swallowed 	
<ul style="list-style-type: none"> substance from an article (e.g. migrating, particulate release) 	
Check that predicted environmental concentrations (PEC values) are assigned for each environment compartments (water, sediment, soil, air, STP).	
Check if daily intake of humans via the environment at local and regional scales are given.	

Make sure that all stages of the life cycle have been considered - if relevant (including service life and waste stage).			
For substances incorporated into/onto articles, the service life in the article needs to be covered in the use description and in the exposure assessment. When assessing the article service life, particular considerations on the time pattern of release need to be made.			
For substance registered for an intermediate use: Ensure that exposure of humans and the environment is controlled.			
If the substance is claimed to be manufactured and/or used under strictly controlled conditions, make sure that it is well documented whether or not all substance is consumed in the process.			
3. PHYS-CHEM and FATE 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)?			
Indication of volatility for human exposure assessment (see table below):			
<ul style="list-style-type: none">highly volatile - vapour pressure > 25 kPa,			
<ul style="list-style-type: none">low-volatile - vapour pressure < 0.5 kPa;			
<ul style="list-style-type: none">volatile - vapour pressure > 0.01 Pa,			
<ul style="list-style-type: none">non-volatile - vapour pressure < 0.01 Pa			
Dustiness			
<ul style="list-style-type: none">Low/Medium/High (see table below)			
Particle size			
<ul style="list-style-type: none">inhalable (100 µm),			
<ul style="list-style-type: none">respirable (4 µm)			
pH			
Relative density			
Definition of volatility bands			
Volatility band	Normal temperature (T ~ 20 °C)	Any operating temperature (OT) (°C)	Vapur pressure (kPa at OT)
Low	boiling point > 150 °C	boiling point ≥ 5 x OT + 50	< 0.5
Medium	boiling point 50 - 150 °C	other cases	0.5 – 25
High	boiling point < 50 °C	boiling point ≤ 2 x OT + 10	> 25

Definition of dustiness bands

High	Fine, light powders. When used, dust clouds can be seen form and remain airborne for several minutes. For example: cement, titanium dioxide, photocopier toner
Medium	Crystalline, granular solids. When used, dust is seen, but it settles down quickly. Dust is seen on the surface after use. For example: soap powder, sugar granules
Low	Pellet-like, non friable solids. Little evidence of any dust observed during use. For example: PVC pellets, waxes

Has the substance a tendency to be persistent and/or distribute in the environment?

At least following information should be available in the dossier:

Vapour pressure

- volatile chemical - Henry's law constant (H) > 250 Pa.m³.mol⁻¹ (R.16 guidance).

Water solubility

- poorly water soluble substance - water solubility below 1 mg/L (or below the detection limit of the analytical method of the test substance) (R.7b guidance).

Molecular weight

- a molecular weight > 1100 g/mol indicates the aquatic bioconcentration factor (BCF) is < 2000 (possibly not bioaccumulative, B).
- a molecular weight > 700 g/mol indicates the BCF is < 5000 (possibly not very bioaccumulative, vB) (R.11 guidance).

Octanol-water partition coefficient

- if log Kow > 4.5 substance has a potential to bioconcentrate, but Log Kow > 10 indicates low bioaccumulation potential (R.11 guidance).

Melting point

Biodegradability

Hydrolysis:

- the degradation half-lives obtained in a hydrolysis test have to be compared to persistence criteria of Annex XIII (i.e. a substance fulfils the P(vP) criterion if T_{1/2} > 40 (60) days).
- for substances where hydrolytic DT₅₀ is less than 12 hours (hydrolytically unstable substance), environmental effects are likely to be attributed to the hydrolysis products rather than to the parent substance itself.

Information on degradation products if toxic/persistent

For inorganic substances and metals some of the properties are not relevant and specific guidance should be used

- Inorganic substances e.g. abiotic degradation, solid-water partition-coefficient, water-biota part. co. maybe relevant

Metals:

http://echa.europa.eu/documents/10162/13632/information_requirements_r7_13_2_en.pdf

ECHA Guidance on information requirements and chemical safety assessment. Appendix R.7.13.2: Environmental risk assessment for metals and metal compounds.	
4. CLASSIFICATION AND LABELLING	
Check that the substance classification for human and environmental endpoints is according to CLP Annex VI or entered in C&L Inventory.	
Have the highest concerns been recognised in the classification?	
If the substance is classified for human health, check that also environmental ESs are established if any environmental hazard has been identified (although there may not be environmental C&L).	
If the substance is classified for the environment, check that ESs for human populations are established if any hazard for human health has been identified (although there may not be human health C&L).	
5. PBT	
Check that for substances fulfilling the PBT or vPvB criteria an emission characterisation and qualitative risk characterisation has been conducted. The outcome will be the identification and implementation of RMMs which minimise the emissions to the environment. Note! There are available two CSR templates (provided on ECHAs web page), one for PBT substance and one for non-PBT substance.	
Check that if a substance has a bioaccumulation potential and also has potential to cause toxic effects if accumulated in higher organisms, a detailed assessment of secondary poisoning has been conducted (see following notes).	
Note! The most important and widely accepted indication of bioaccumulation potential is a high value of the n-octanol/water partition coefficient (<i>Kow</i>). However, some properties of a substance may preclude high accumulation levels even though the substance has a high log <i>Kow</i> or has a structural similarity to other substances likely to bioaccumulate. Alternatively there are properties, which may indicate a higher bioaccumulation potential than that suggested by a substance's low log <i>Kow</i> value. When a substance (R.16 guidance):	
<ul style="list-style-type: none"> • has a log <i>Kow</i> ≥ 3 and a molecular weight below 700 g/mol; or 	
<ul style="list-style-type: none"> • is highly adsorptive; or 	
<ul style="list-style-type: none"> • belongs to a class of substances known to have a potential to accumulate in living organisms; or 	
<ul style="list-style-type: none"> • there are indications from structural features; and 	
<ul style="list-style-type: none"> • there is no mitigating property such as of hydrolysis (half-life less than 12 hours) or biodegradability (substance is readily biodegradable) <p>there is an indication of bioaccumulation potential.</p>	
Note! An assessment of indirect exposure of humans via the environment is generally only conducted if (R.16 Guidance):	
<ul style="list-style-type: none"> • the tonnage >1 000 t/y or 	
<ul style="list-style-type: none"> • the tonnage >100 t/Y and the substance is classified 	
<ul style="list-style-type: none"> • as STOT RE 1; or 	
<ul style="list-style-type: none"> • as a carcinogen or mutagen (any category); or 	
<ul style="list-style-type: none"> • as toxic to reproduction (categories 1A or 1B). 	

6. MANUFACTURE AND USES	
Use descriptors:	
<ul style="list-style-type: none"> Check that there is consistency between description of manufacture and use in relation to PROCs, PCs and ERCs chosen. 	
<ul style="list-style-type: none"> Check that the terminology from R.12 guidance is followed. 	
<ul style="list-style-type: none"> Check if the use of short titles is consistent with the ES. 	
Identify all uses: Professional/Industrial /Consumer.	
Check that description of where the substance is used is available, eg. indoors with general ventilation / LEV (effectiveness).	
Check description of operational conditions: e.g. location of use (indoor/outdoor), continuous or batch processing, open/closed process, dry process/water contact possible, manual/automatic dosing, qualitative information on which types of waste occur from equipment cleaning, processing and RMM and how they are handled/disposed of.	
Consider the level of containment (Low/Medium/High).	
Check that the use of Specific consumer exposure determinants (SCEDs) is justified.	
Check that the use of Specific environmental Release Categories (SpERCs) is justified.	
Check that the use of Specific worker exposure determinants (SWEDs) is justified.	
Be aware of downstream sector specific use maps including SCEDs, SpERCs and SWEDs	
Check substance use rate; amount of substance used per day, fraction of EU tonnage used in region, fraction of regional tonnage used locally.	
Are the number of emission days per year reasonable?	
Check that exposure estimates for all indentified uses are available.	
Consider exposures at elevated temperature if relevant (correspond to the data in Section 3).	
Check that local and regional release rates are given for each use and appropriate release factors linked to OC/RMMs (assumed to be in place) with sound justification have been used.	
Check that tonnage for each identified use is given and they are compatible with the total amount (compare to the information is provided in the IUCLID section 3.5).	
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:	
<ul style="list-style-type: none"> 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.	
7. DERIVED NO EFFECT LEVELS (DNELs) AND PREDICTED NO EFFECT CONCENTRATIONS (PNECs)	
Make sure that the DNELs/PNECs are developed for relevant routes/species 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 and R.10, if not, make sure there is a proper justification for not using defaults (substance specific information needed).																									
Make sure that in the case DNEL or PNEC cannot be derived but hazard has been identified or cannot be excluded, a qualitative risk characterisation has been carried out.																									
Note that for substances fulfilling the PBT or vPvB criteria a reliable prediction of long-term exposure is not possible. An emission characterisation and risk characterisation must be conducted.																									
8. EXPOSURE MEASUREMENT DATA																									
Check that the measurements are reliable, representative and statistically powerful enough. See eg. EN standard 689 (CEN 1995) ECHA R.14 (R14.2 or 6), R.15, and R.16 (Appendix 16-7.) guidance.																									
Indicative number of measurements needed to determine confidently that the true RCT is below 1.																									
<table><tr><td colspan="2"></td><td>RCR 0.5 < 1</td><td>RCR 0.1 – 0.5</td><td>RCR < 0.1</td></tr><tr><td colspan="2"></td><td>N*</td><td>N</td><td>N</td></tr><tr><td rowspan="3">Variation and uncertainty in the data</td><td>Low</td><td>~20-30</td><td>12-20</td><td>6 - 12</td></tr><tr><td>Moderate</td><td>~30-50</td><td>~20-30</td><td>12 - 20</td></tr><tr><td>High</td><td>> 50</td><td>~30 - 50</td><td>~20 - 30</td></tr></table>				RCR 0.5 < 1	RCR 0.1 – 0.5	RCR < 0.1			N*	N	N	Variation and uncertainty in the data	Low	~20-30	12-20	6 - 12	Moderate	~30-50	~20-30	12 - 20	High	> 50	~30 - 50	~20 - 30	
		RCR 0.5 < 1	RCR 0.1 – 0.5	RCR < 0.1																					
		N*	N	N																					
Variation and uncertainty in the data	Low	~20-30	12-20	6 - 12																					
	Moderate	~30-50	~20-30	12 - 20																					
	High	> 50	~30 - 50	~20 - 30																					
N = number of samples RCR = Risk Characterisation Ratio * Variation and/or uncertainty can be caused by on the one hand true variation in exposure (as indicated by a measure of variation) and on the other hand by lack of knowledge about how representative the data are for the situation to be assessed. High: a high geometric standard deviation (GSD) in the measured data (e.g. > 3.5) or the representatives of the data is suspected to be significantly uncertain for the situation to be assessed. Moderate: a moderate GSD (e.g. 2 – 3.5) and/or the representativeness of the data is questionable. Low: a low GSD (e.g. < 2) and the data can be considered representative for the situation to be assessed.																									
9. EXPOSURE ESTIMATION TOOLS (MODELS)																									
Can the assessments be reproduced (all model input parameters and assumptions need to be available and transparent).																									
Check that linear modification has not been performed with Easy TRA tool, as this tool does not support that (in the worst case it can reduce exposure predictions by an order of magnitude).																									
Check that the exposure model used is appropriate to the scenario.																									
Check the version of the model.																									
Check that the default values or deviations used in the CSR are justified.																									
<ul style="list-style-type: none">defaults from exposure models																									
<ul style="list-style-type: none">defaults from REACH Guidance																									

<ul style="list-style-type: none"> defaults from the Nordic Exposure Group's default value report 	
10. CROSS-CHECK CLASSIFICATION WITH PROCs/ERCs	
<p>Check if there is potential high risk from the combination of the following PROCs in conjunction with the specified serious health hazard classifications:</p> <p><i>Process categories:</i></p>	
<i>PROC 5 mixing or blending in batch processes</i>	
<i>PROC 7 industrial spraying</i>	
<i>PROC 8a non-dedicated facilities</i>	
<i>PROC10 roller application or brushing</i>	
<i>PROC 11 non-industrial spraying</i>	
<i>PROC 13 dipping and pouring</i>	
<i>PROC 19 hand-mixing with intimate contact</i>	
<i>Specified classifications:</i>	
<i>H314 Causes severe skin burns and eye damage</i>	
<i>H317 May cause an allergic skin reaction</i>	
<i>H318 Causes serious eye damage</i>	
<i>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled</i>	
<i>H340 May cause genetic defects</i>	
<i>H341 Suspected of causing genetic defects</i>	
<i>H350 May cause cancer</i>	
<i>H351 Suspected of causing cancer</i>	
<i>H360 May damage fertility or the unborn child</i>	
<i>H361 Suspected of damaging fertility or then unborn child</i>	
<i>H371 May cause damage to organs</i>	
<i>H372 Causes damage to organs through prolonged or repeated exposure</i>	
<i>H373 May cause damage to organs through prolonged or repeated exposure</i>	
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:	
<i>H314 Causes severe skin burns and eye damage</i>	
<i>H317 May cause an allergic skin reaction</i>	
<i>H318 Causes serious eye damage</i>	
<i>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled</i>	
<i>H341 Suspected of causing genetic defects</i>	
<i>H351 Suspected of causing cancer</i>	

<i>H361 Suspected of damaging fertility or then unborn child</i>	
Check if there is potential high risk from the combination of the following ERCs in conjunction with the specified environment hazard classifications:	
<i>Environmental release categories:</i>	
ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)	
ERC8d Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor)	
ERC10b Widespread use of articles with high or intended release (outdoor)	
ERC11b Widespread use of articles with high or intended release (indoor)	
ERC12b Processing of articles at industrial sites with high release	
<i>Specified classifications:</i>	
H400 Very toxic to aquatic life	
H410 Very toxic to aquatic life with long lasting effects	
H411 Toxic to aquatic life with long lasting effects	
H412 Harmful to aquatic life with long lasting effects	
H413 May cause long lasting harmful effects to aquatic life	
11. RISK MANAGEMENT MEASURES	
<p>Is the ES compatible with the hierarchy of the RMMs (STOP-principle, i.e. Substitution, Technical measures, Organisational measures, and/or Personal measures) applied?</p> <p>If not justification is needed:</p> <p>ECHA R.14: <i>"RMMs are a combination of design, engineering solutions and the administrative measures that deliver the required acceptable level of exposure. Within the CSR, RMMs are required to be described; this is usually in generic terms such as LEV or personal protective equipment. These descriptions are interpreted in the workplace within the context of Chemical Agents Directive (98/24/EC). The Directive establishes a hierarchy in the application of control measures, this means that engineering controls such as closed systems, containment and use of ventilation arrangements (local exhaust at the point of emission and/ or general building ventilation (passive or mechanical)) are always the preferred primary means to control exposure."</i></p> <p><i>"A substantial amount of occupational health and safety guidance is widely available that provides information on conditions for safe use in the workplace. Registrants are encouraged to link the RMMs in the CSR and in the ES for communication to such advice when possible. Information from downstream user sector organisation can support this (see also Section R.14.5.4)."</i></p>	
Ventilation (General and Local Exhaust Ventilation) and their efficiencies.	
Check that personal protective equipment (PPE), efficiencies are appropriate /realistic.	
Check if the PPE is really necessary.	

Check that the type of material, thickness and breakthrough times of the gloves and the duration of use for all exposure scenarios where the use of gloves is advised.	
Check the details of the PPE to be used; duration of use; frequency of changing are given on proper usage of PPE.	
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, supported by information on appropriate standards.	
Goggles or other is appropriate and identified detailed enough.	
Check that other possible technical measures are feasible.	
Check if the risk management measures limiting releases to air, water and soil has been identified; (e.g. filters, scrubbers, on-site biological or biological-chemical wastewater treatment plants or other waste water treatment technique suitable for activities of concern.).	
Connection to the municipal sewage water treatment plant yes/no.	
Check that for the substance that fulfil PBT/vPvB criteria RMMs which minimise the emissions to the environment has been identified and implemented.	
12. SCALING	
Verify that scaling advise (if given) is done according to ECHA's principles (See Guidance for downstream users, Appendix 2).	
13. RISK CHARACTERISATION - RCR	
<p>Check if there are any high risk characterization ratios (RCRs) approaching 1 (> 0.9) especially in relation to widespread use and where there is a risk of combined exposure to the substance.</p> <p><i>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.</i></p>	