Approaches and tools to better support consumer exposure assessment under REACH

EXECUTIVE SUMMARY
Date: 30 October 2018
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1 Short introduction

This document is an executive summary of the final report of the project: ‘Approaches and tools to better support consumer exposure assessment under REACH’. In this summary, the main observations, results and conclusions of the project are presented. For detailed information on the project, i.e. different steps in the project, exhaustive conclusions and recommendations of the project, see the final report, which serves as a background document.

This executive summary is made up of 6 questions.

1. What is the background of the project?
2. What are the main results from the stakeholder consultation?
3. What are the main problems experienced within the REACH consumer exposure assessment communication?
4. What are the proposed solutions?
5. What are the learnings regarding methodology in the study?
6. What is the follow up for the current project?
What is the background of the project?

The chemical safety assessment (CSA) under REACH includes the generation of information on safe use of hazardous substances in consumer products (both mixtures and articles). Importers and manufacturers (registrants under REACH) of hazardous chemical substances are expected to carry out an exposure assessment and determine the conditions of safe use. Such conditions are to be achieved to a large extent by product design (taking into account the habits and practices of consumers), rather than by risk management instructions to users. The conditions of use are - via the extended Safety Data Sheet (SDS) - to be communicated to the producers of consumer products, in particular formulators of products for consumer use.

Based on the experience from the first registration deadlines, information exchange amongst exposure experts of EU Member States (MS) and experience from the evaluation process, it is clear that many registrants have not yet found the right way to generate and/or communicate transparent, consistent and useful information regarding conditions of safe use for consumer products.

Formulators have a central and critical role in this communication process. They shall pass on the following information in the supply chain:

- **downstream**: conditions of safe use of chemicals as provided by the registrant and
- **upstream**: information on a specific use as provided by the downstream end-use formulator.

Optimal flow of information enables end-use formulators to place safe (consumer) products on the market with correct information on the labels.

In this project, proposals were developed and evaluated for improving the current (input information of) consumer exposure estimation tools under REACH to improve the communication in the supply chain. This should result in an increase of the transparency of the assessment, the consistency across registrants (of the same substance used in the same product) and across sectors, and the usefulness of the exposure scenarios for end-use formulators of consumer mixtures (articles are not the focus of the project).

The main steps to achieve the overall goal of this project were translated into the following tasks:

1. **Problem analysis**: Identify the experienced shortcomings in the supply chain communication to draft a concept solution strategy.

2. **Development of a solution strategy**: Develop proposals for improving the current tool(s) in order to be more suitable for generating and communicating information on safe use for consumers under REACH.

3. **Reality check**: Determine for a number of selected product types the set of information to be communicated to formulators and explore with a number of formulators which of these information elements they would perceive as being helpful for product design.
What were the main results from the stakeholder consultation?

A very important element of the current project was the consultation of stakeholders, which has been used as the basis for the problem analysis. End-use formulators from the following sectors have been consulted via a workshop and a questionnaire.

- Adhesives/sealants
- Coatings and paints
- Washing and cleaning
- Polishes and wax blends
- Cosmetics, personal care
- Lubricants, greases

**Workshop**

In the workshop, 15 participants covering formulators of coatings, adhesives, detergents and cleaning products, construction chemicals and cosmetics (larger companies and sector organisations) represented industry.

Akzo Nobel, on behalf of the European Council of the Paint, Printing Ink and Artists' Colours Industry (CEPE), and the Dutch industry association for detergents, maintenance products and disinfectants (NVZ) provided the key inputs to characterise the current situation, which was confirmed by the other organisations/companies represented, in particular:

- For raw materials purchased as mixtures, exposure scenarios do not reach the end-use formulators.
- Where suppliers provide exposure scenarios, about half of them do not match the practice of the formulator (product type not covered or condition of use not covered).
- Large formulators are able to make their own quantitative exposure assessments, however smaller formulators (which make about half of the market) are not.

All industry participants expressed that they see sector use-maps (including SCEDs) and the harmonisation of formats through Chesar\(^1\) as a major element for improving the situation, provided registrants would use them.

**Questionnaire**

In the interpretation of the results of the stakeholder consultation, one essential question is *what the end-use formulator will do with the ES information received*.

- Check his own product (and its anticipated conditions of use) against the ES received, without carrying out an own expo assessment
- Re-do the assessment of the supplier to understand the ES and possibly to modify it.
- Make his own quantitative exposure assessment, independent of the information received from the supplier.

In total 30 companies of different size and from different sectors have participated in the survey. Reactions on the questionnaire suggest that the majority of raw materials are supplied with an SDS. Most respondents indicate that only a small percentage of SDSs are adequately describing the exposure scenarios for the consumer end-use. All companies have systems in place to ensure that their products are safe to use for consumers. However, there are differences in the assessment methods applied and to which extent the assessment is carried out in-house or by service providers. Larger companies responded that most or all of assessments are done in-house while smaller companies indicated an equal weighting between in-house and outsourced. No pattern across product groups can be reliably identified.

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\(^1\) Chemical Safety Assessment and Reporting tool of the European Chemicals Agency
In terms of how safety of mixtures is assessed, almost all respondents are ‘avoiding hazardous ingredients as far as technically possible’, although slightly more frequently for the larger companies than for the smaller ones. ‘Classification and labelling of the mixture based on information on its ingredients’ forms the basis of most safety assessments. ‘Documentation that the composition, use and use conditions of products matches the exposure scenarios received’ (i.e. exposure scenario conformity check) is used by the vast majority of large companies, but by less than half of the medium and small companies.

‘Exposure estimation and risk characterisation’ for (hazardous) ingredients is applied by about 2/3 of respondents of large and medium companies, but only about 20% apply it frequently (for over 50% of the hazardous ingredients). For remaining fraction of larger companies quantitative exposure estimation is carried out rarely (for less than 5% of the hazardous ingredients).

The tools mentioned for the quantitative exposure assessment are the Targeted Risk Assessment Tool by ECETOC (ECETOC TRA) and ConsExpo\(^2\). ECETOC TRA is the only tool indicated by medium companies. Large companies use a number of different tools; though mainly ConsExpo. None of the small companies indicated the use of quantitative exposure assessment tools themselves. It should be noted that many of the smaller companies indicate that they out-source assessments where needed.

More than 50% of large and medium sized companies are of the opinion that in both the core body of the SDS and in the exposure scenarios, information is missing which would be needed to carry out a safety assessment by the end-use formulators.

Note: There seems to be a bias towards large companies and medium companies in the current study. This may be caused by the design and approach of the stakeholder activities, with an active participation in the workshop, but also the questionnaire. Small(er) companies seem to be reluctant to respond because of the potential lack of knowledge of the REACH regulation and consumer exposure assessments and tools.

\(^{2}\) Computer program made by RIVM that enables estimation and assessment of exposure to substances from consumer products
What are the main problems observed within the REACH consumer exposure assessment communication?

Within this project, we identified shortcomings in the REACH consumer exposure assessment communication. In general, the observed shortcomings could be divided in three main categories:

1) Communication down the supply chain
ESs do not reach the end-use formulators. Main problem in the supply chain communication is the communication of ESs from registrants via formulators and distributors to end-use formulators. Especially in the case of purchase of raw materials in the form of mixtures, the end-use formulator does not receive the ES.

2) Content of exposure scenarios
The conditions of use in the ES do not match with the use in practice. There are difficulties to process information in ESs.
In the case an ES has been provided, there are difficulties at the end-use formulators level to process information in ESs because the information is not easy to find. Furthermore, a reasonable amount of ESs do not match or cover the use in practice (i.e. the product type or condition of use is not covered) or the ESs are too generic to be useful or verifiable. In addition, different suppliers deliver different exposure scenarios for the same substance and use. As a result, end-use formulators receive inconsistent information by separate exposure scenarios.

3) Limitations in the tools for consumer exposure assessment
Exposure assessment within REACH is complicated. There are tools which allow to do exposure assessments, but the tools have limitations and cannot be used without expertise.
The two tools that are mostly used for the exposure estimation under REACH, the ECETOC TRA consumer tool and ConsExpo, each have their own strengths and limitations. The ECETOC TRA consumer tool has been developed to support a high throughput top-down chemical safety assessment (CSA). It refers to generic product types, needs a few input parameters only, includes conservative default values, and uses very basic models to estimate the exposure. Use description and the input parameters for consumers exposure assessment (SCEDs) are made available by some sector organisations for their typical uses to help the registrant with realistic input parameters for the consumer exposure estimation with ECETOC TRA. ConsExpo has mainly been developed to estimate exposure to chemicals from specific consumer products. Some of the models in ConsExpo, especially the higher tier (more complex) ones, require a high number of input parameters and the exposure assessments are more realistic. ConsExpo fact sheets provide input information and default parameters per certain product category for carrying out exposure assessments.
What are the proposed solutions?

For the experienced shortcomings in the project (described in section 4 of this summary), the project consortium proposes the following solutions

1) **Communication down the supply chain**
The assumed root causes for the problems in the supply chain are that the actors in the supply chain are not sufficiently aware of their obligations. For instance, the obligation to provide an ES for mixtures is unclear, the supplier is not aware of his obligation to forward the ES or the ES gets otherwise lost in the supply chain. This can be solved by:

1. **Clarify the obligations** to provide ES for mixtures.
2. **Raising awareness** of the registrants, distributors and upstream formulators to smoothly pass on ESs for hazardous substances/mixtures down the chain to the level of end-use formulators.
3. **Include an enforcement action** on ES forwarding from upstream to downstream in the enforcement programs of member states.
4. **Use of IT tools**, e.g. blockchain for the transfer of information through the supply chain. The use of ESCom XML by registrants can be promoted as the ESCom XML helps distributors with the translation of ES.

2) **Content of exposure scenarios** and limitations in the exposure assessment tools
The assumed root cause that the end-use formulator cannot easily distil information relevant information from the ESs received is the high number of contributing scenarios and that the ESs cannot be checked automatically. This can be solved by:

1. Supplier to **make a pre-selection of relevant contributing scenarios** for a particular end-use formulator, to avoid receiving all contributing scenarios related to the substance.
2. The scenarios could be **made available for automatic check by downstream users** using for instance ESCom XML and by providing the ES in XML format.

The assumed root cause for the mismatch between the conditions of use in the ES and the existing practice of use lies in the registrant's lack of understanding/information on end uses of his substance. This can lead to information in the ES that is too generic for the end use formulator to be useful or verifiable. Furthermore, communication of feedback from end-use formulator to registrant is usually not successful. This can be solved by:

3. **Promoting the use of SCEDs and ConsExpo fact sheets** to improve the correctness and usefulness of ES.
4. **Analysing for which DU sectors the information in form of SCEDs and ConsExpo fact sheets is missing**. Motivation of these sectors for development of such information.
5. **Analysing which end-use formulators prefer to carry out their own DU CSR and why they don't get into dialogue with their suppliers** (upstream communication).
6. **Clarifying the added value of high quality exposure assessments** in registration dossiers to registrants.
7. **Encourage National Enforcement Authorities to check at the level of end-use formulator the conditions of use in the ES** with the knowledge of the end-use formulator on consumer habits and practises.

The assumed root causes for inconsistency in the condition of use in ES across registrants of the same substance in the same products are the following; Different registrants use different exposure assessment tools and/or corresponding information sources (SCEDs or ConsExpo factsheet);
Even when using the same tool, registrants apply different iteration strategies (in particular when the tool invites for ‘playing’ with various parameters in order to get the risk controlled).
This can be solved by:
8. **Harmonizing the conditions of use** communicated in the ES, irrespective of the tool used.
9. **Analysing where the alignment and harmonisation of exposure parameters** between ECETOC TRA and ConsExpo is possible. Identify where SCED and ConsExpo fact sheet information refer to the same product type but suggest different input values for the exposure assessment. Align overlapping SCED and ConsExpo fact sheet information.
10. **Fix default/input parameters in ConsExpo** to make exposure assessments with higher tier tool user-friendly.

3) **Limitations in tools for consumer exposure assessment**
Another assumed root cause for the difficulties to match the conditions of use in the ES with existing conditions may be the difficulties of registrants to work with the exposure tools, due to their complexity.
This can be solved by:
11. **More education on use of consumer exposure tools** and how to use SCEDs (ECETOC TRA consumer tool) and ConsExpo fact sheets by the registrant to carry out the CSA.
12. **Improvement of the guidance for the different tools** with regard to their use in REACH.

The proposed solutions are divided in the three categories as described above; however, another division is possible as many of the issues are highly interrelated. Some solutions for the tools also applicable for the improvement of the ESs (for instance number 11). The proposed solutions can be translated to actions that have to be executed by different stakeholders. In Chapter 6 of the final report (background document), a detailed overview of solutions is provided in a structured way, together with actions and (responsible) actors.

**Testing of selected solutions**
In the current project, one of the shortcomings has been selected for further elaboration; a solution strategy for this shortcoming is proposed by the project consortium and this solution has been checked by industry.

The shortcoming selected is dealing with the situation that exposure scenarios often do not match the actual practice.
The proposed solution to be tested was focused on the better use of the available information/exposure tools such as SCEDs/ECETOC TRA and ConsExpo fact sheets/tool in preparing the exposure assessment.

For this test case, different solutions to improve the ES generated with Chesar (based on ECETOC TRA as well as on ConsExpo) have been proposed and tested by two (large) companies in the detergent sector and six companies in the paint sector (two large, three medium and one small size company).

A detailed list of proposals for modification of the ESs is described in the background final report. Aim of the proposals was to develop an improved ES containing all relevant conditions of use described in a clear manner for the end-use formulator. These improvements are independent of the exposure tool used in the exposure assessment (either ConsExpo or ECETOC TRA).
The main conclusions to be drawn from the responses of the companies to the proposed improvements in the different exposure scenarios tested:

1. End-use formulators have still not fully understood what to do with the exposure scenarios received. More guidance and training may be needed.
2. End-use formulators have difficulties to identify clearly enough which of their products are covered by the ES received and which not.
3. End-use formulator have difficulties to interpret the conditions of use. More clear description of the conditions of use may be needed.
4. End-use formulators prefer a harmonised set of use-conditions described in exposure scenarios compared to the current situation, where the type of use-conditions addressed in the ES depend on the tool the registrant has used.
5. The principles for assessing infrequent uses are not fully clear, and the approaches in the tools differ from each other and from the corresponding ECHA guidance. The owners of consumer exposure tools and ECHA should discuss how to solve the difference in the estimation of infrequent uses.
6. There are no possibilities yet in Chesar and ECETOC TRA to address different tasks (use phases) with the same product leading to significantly different exposure. Inclusion of other use phases (such as mixing and loading, or post-application) in SCEDs and modification of Chesar to address different use-phases may be needed.
7. End-use formulators may need to know more details on how the registrant has carried out the exposure assessment, but not necessarily via the ES on a regular basis. Suppliers should for example provide this information only on request, in order to prevent long and complex exposure scenarios.
What are the learnings regarding methodology in the study?

- Readiness of small companies to participate was limited, and other means of involving such companies should be tried out, e.g. identification via associations and then targeted direct contact (mail and phone). As a consequence, it was not possible in the current study to sufficiently differentiate the needs and available methods/expertise (i.e. assessment capacity) of large, medium and small companies.

- The study covers only limited types of products and sectors. Therefore it is likely that observations and conclusions are not fully representative.

- Feedback from testing by companies should be associated with direct contact (via phone or face to face interview) and not only obtained via written feedback. Otherwise it is too difficult to interpret the written answers, unless the questionnaire is extremely simple.

- To make this study, as well as the conclusions drawn from it, more applicable to all end-use formulators (of different sizes and sectors), there is a need for clarifying methods for different user groups (small and larger end use formulators with or without own assessment capacities).

- In the test case, due to lack of ‘existing practices’ it is not so easy to identify how to further significantly improve the content of ESs. Many small proposals were tested but the sample size in the study has been very small and it is unclear how representative this selection was. There was only one small (paint) company participating in this study.
What is the follow up of the current project?

- In order to decide what the follow up is of this project and which actions could be further worked out in the (near) future, a workshop with different stakeholders could be organized. In this workshop, lessons learned from the current study and specific the evaluation of the standard and improved ES can be further discussed. Potential participants are for instance DG ENV, ECHA, representatives of the ECETOC TRA and ConsExpo tools, sector representatives and other stakeholders. Also other (more general) conclusions and recommendations from the current project can be discussed with the different stakeholders in such a workshop.

- To test the suggestions of improvement of the ESs also with small companies, more dialogues with small companies should be organised. This could be done for instance in the form of a workshop specific for small companies.

- Conclusions/ recommendations from other relevant (ongoing) projects should be taken into account in the further follow-up of the present project, for example:
  1. Comparison of Specific Consumer Exposure Determinants (SCEDs) with observational data from the EPHECT survey (ANSES).
  2. From registration dossier via safety data sheet to workplace risk assessment - Data availability and quality between REACH and Occupational Safety (REACH2SDS) (BAuA)
  3. Data on consumer uses and exposure in registrations (BfR)