KEMI
Swedish Chemicals Agency

Ministerie van Infrastructuur en Waterstaat

Chairman's report

Stockholm, November 2020

2nd Workshop on a pragmatic approach to address the risk from combined exposure to non-intentional mixtures of chemicals – REACH as an example

27-28 October 2020

Virtual Workshop

Chairman's report[1] of the second workshop on a pragmatic approach to address the risk from combined exposure to non-intentional mixtures of chemicals - REACH as an example - virtual meeting, 27-28 October 2020

Background

This second workshop was hosted by the Swedish Chemicals Agency (KEMI) and the Dutch Ministry of Infrastructure and Water Management (Competent Authority on REACH), as a virtual meeting held on 27-28 October. The workshop was attended by around 50 representatives of Member States authorities, industry, NGO's, ECHA, EFSA and the European Commission (DG ENV).

The workshop aimed at building on the outcomes of the first workshop[2] that have been presented in CARACAL. Comments thereof from Member States and stakeholders were received and integrated into a synthesis paper[3]. The workshop provided a forum for discussion on how to introduce a Mixture Assessment Factor (MAF) in REACH. This aim was highlighted in the recently published EU's Chemicals Strategy for Sustainability[4] in which the European Commission details that it will "Assess how best and introduce (a) mixture assessment factor(s) in Annex I of REACH", for the chemical safety assessment of substances. Presentations on the EU Chemicals Strategy and the Commission Staff Working Document on combination effects provided the political framing for the discussions. Furthermore, a scientific case study on the sizing of the MAF and a preliminary analysis of impact on REACH registrations by ECHA as well as results of the pre-workshop questionnaire directed towards the questions at hand and provided an information base for discussions. The discussions focused on principles of deriving a generic MAF and whether there should be a unified, generic MAF for human health and environment; to what extent science could inform about the magnitude of the MAF; and the categories of REACH substances that should be covered. The workshop also touched upon the issue of where the factor should be applied although a more detailed discussion on this issue did not take place due to time limitations. As a general conclusion, the participants continued to support a MAF as a risk management tool for reducing the overall toxic pressure of chemicals in unintentional mixtures.

Policy context - protecting against toxic unintentional mixtures

The European Union is committed to create a climate neutral and circular economy that does not negatively impact on human health and the environment. At the same time, the EU needs to become the most competitive economy in the world and spearhead innovation. All these goals are conditional for each other's realisation (fulfilment), and thus interdependent. This implies that industry needs to lead in producing and using chemicals that are safe and sustainable by design. In the recently published Chemical Strategy for Sustainability, the European Commission details that it will "Assess how best and introduce (a) mixture assessment factor (s) in Annex I of REACH, for the chemical safety assessment of substances".

[1] Prepared in collaboration with Margaret Wouters (RIVM) and Elina Drakvik (Karolinska Institutet).

[2] https://www.chemischestoffengoedgeregeld.nl/sites/default/files/20200330-report%20WS%20Combitox.pdf

[3] Synthesis paper for CARACAL provided by KEMI and the Netherlands: "*Comments on a pragmatic procedure to regulate the risks of exposure to coincidental combinations of chemicals, in the EU*", CA/MS/47/2020

[4] Chemicals strategy. The EU's chemicals strategy for sustainability towards a toxic free environment, 14 October 2020. It is a part of the EU's zero pollution ambition, which is a key commitment of the European Green Deal.

The EU Commission has the intention to amend the REACH Regulation (or relevant Annexes) in a targeted manner. There is a need to introduce or strengthen provisions to take account of unintentional mixtures in relevant pieces of legislation. In the current situation, where knowledge and available toxicity and exposure information on unintentional mixtures and mixtures components is, and will remain for a long time ahead, fragmented and insufficient, there is a need to apply practical and workable approaches. The application of a MAF seems to be the most pertinent for industrial chemicals under REACH, but it may be applicable also to other regulatory areas, although such plans are not topical at present. In addition, there is a need to continue filling the gaps on knowledge on exposures and toxicities and to improve coordination between regulatory sectors to tackle mixtures across different regulatory areas.

The workshop discussion

The workshop discussion was structured along the following questions that were based on the questions that were sent prior to the workshop to all the participants in the form of a questionnaire, concerning:

- Whether there should be one generic MAF used in the risk assessments for both human health and the environment or different MAFs for different compartments.
- Where to apply a MAF, at the PNEC/DNEL or when determining the RCR?
- Possible consequences and uncertainties of introducing a MAF.
- Justification for potential exemptions.

Based on the presentations and the lively discussions via the web-ex, the following arguments were collected and clustered together:

Arguments **in support of** the proposed approach to adopt one single mixture assessment (MAF) for both human health and the environment under the REACH regulation were:

- One single MAF is a simple, pragmatic, effective and feasible way forward to control the risks from the combined exposure to mixtures of chemicals.
- It is impossible to know all possible unintentional mixtures man and the environment are exposed to.
- For chemicals with RCRs <<1, this MAF will make no difference, whereas it may for chemicals with RCRs close to 1 and with less possibilities to refine e.g. the exposure estimates (model-ling).
- “Science” will indicate a large range of possible MAFs, but which should be used?
- Authorities will be paralysed if they have to engage in discussing MAFs used in 4600 registrations, possibly each containing 5-10 or more different MAF scenarios.

Arguments **not in support of** the proposed approach to adopt one single mixture assessment factor (MAF) for both human health and the environment under REACH regulation were:

- A blanket MAF would be arbitrary and not based on science.
- A MAF needs to be refined (by authorities) based on actual site-specific conditions.
- Based on monitoring, it should in each case be possible to refine the MAF.
- The MAF should be adjusted based on the characteristics of the chemical e.g. persistency.
- Focus on the few chemicals that cause a risk in mixtures.

Some industry representatives noted that industrial use of substances is a controlled process and there is no potential for unintentional co-exposure in the environment. MAF should be regarded as a management tool between substances that require further refinement, prioritising those substances of concern. Also, site specific assessment can be done to refine the exposure when data is available.

It was further discussed that REACH is addressing manufacture and use of chemicals and for those with classifiable hazards, a risk assessment is required. Hence, REACH cannot be used for remediating environmental exposure. It was pointed out that it is known that in many cases data are not available for many different uses which is a key motivation to develop a generic MAF that pragmatically addresses the problem of wide uses, little data and general exposure. Hence, negating the proposal for site, scenario or regional specific assessments. Those supporting a generic (pragmatic) approach noted that REACH is not looking for real world risk drivers, but rather that a MAF will identify those substances for which the RCR is close to 1 ("RCR-based risk drivers") and require more risk reduction measures for them, whereas substances that do not considerably contribute to the risk would not be affected. Thus, MAF is lowering the overall chemical pressure, which is a fundamental aspect of this approach.

The potential magnitude of MAF remains yet to be addressed as well as where the MAF should be introduced, i.e. either in PNECs/DNELs or in the risk characterization. It was suggested that an inventory of additional case studies might be helpful in further narrowing down the discussion on potential magnitude of the MAF. It was also noted that it would take several years before more comprehensive scientific clarity is obtained e.g. on real-world mixture exposures in Europe, possible drivers of toxicity and attaining relevant toxicity data for individual mixture components, which is why the generic approach has been brought forward as a feasible and rapidly implementable solution. It was further highlighted that introducing the MAF should not end-up solely as a paper exercise but should have impact to better protect humans and the environment of the total burden of chemicals and unknown mixtures, contributing to overall reduction in exposures.

Conclusions

Based both on the pre-workshop questionnaire and an online poll during the workshop, a majority of the participants supported that a single, generic MAF is a pragmatic, effective and feasible way forward under REACH and should be pursued. Presently, there is insufficient evidence to support the selection of different MAFs for humans and environment: hence, a single generic MAF seems to be a

workable way forward to lower the overall toxic pressure. After all, there is an interlacing of exposures: humans are part of the environment; occupational workers are also consumers; and childbearing women are also occupational workers.

An Impact Assessment will provide a solid basis for deciding the magnitude of the MAF. It was highlighted again that introducing a MAF in REACH will be a political decision on risk management. The scope and focus is on REACH while bearing in mind a broader picture across legislations in terms of consistency and coherence as well as potential consequences of where to introduce the MAF (in PNECs/DNELs or in the risk characterisation).

The EU Commission will launch a study on provisions for introducing a MAF in REACH and its results may feed into the general Impact Assessment of possible revision of REACH. The Impact Assessment is scheduled to start in 2021. The exact process (amending Annexes or more extensive legislative changes) is yet to be determined and may be subject to parallel changes or developments in the remit of REACH.

The workshop also discussed and suggested some important elements to be considered in an Impact Assessment. These include non-threshold substances, characteristics of substances (e.g. persistency), innovation, competitiveness and benefits for human health and environment. The Impact Assessment should however be kept focused and limited in scope. The consequences will need to be looked at carefully, including e.g. trying to avoid additional animal testing. It was also emphasised that introducing a MAF and actions concerning safe and sustainable by design as outlined in the Chemicals strategy are complementary to each other. Also, additional risk management measures may be needed for chemicals that are highly toxic/persistent and these are also brought up in the Chemicals strategy.

Industry participants agreed to cooperate with ECHA in the analysis of substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB substances) (and specifically on petroleum products) as well as to discuss with ECHA their initial analyses on the impacts of introducing a MAF. Civil society organisations also offered to contribute to the process and further discussions, some of which put pressure on the process to speed up the introduction of a MAF.

Next steps:

- Based on the EU Chemicals strategy “Asses how best introduce (a) mixture assessment factor(s) in Annex 1 of REACH”. The Commission is planning to publish a roadmap for public consultation (end 2020), having the results of an Impact Assessment report available by the second quarter (Q2) of 2022, and having a proposal for the revision of REACH agreed by the end of 2022.
- The analysis of impact on registrations by ECHA will be finalised by first quarter (Q1) of 2021, providing support for further specifying and refining remaining questions.
- CEFIC, Concawe, Eurometaux and Fuels of Europe will support ECHA in the analysis of metals, UVCB substances and petroleum products.

- Along with the impact study, the following groups of chemicals or uses require specific attention: metals, naturally occurring substances, intermediates, chemicals in isolated industrial environments, non-threshold substances, UVCB's and other MOCS's (more than one constituent substances), substances of less than 10 ton per annum, uses under strictly controlled conditions.
- It was suggested to establish a CARACAL subgroup on implementation of MAF in REACH to discuss the way forward.
- The aim is to discuss the progress on the issue at the next CARACAL Meeting in November, after which the next steps will be clarified. One proposal is to continue focused on-line meetings with this, or a selection of this, group to tackle the remaining questions and work in parallel and transparently, complementing the EC led preparation of an implementation approach for MAF under REACH.