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‘Targeted’ stakeholder consultation - Study supporting the Commission in developing a proposal for introducing the Mixtures Assessment Factor concept in REACH

Fields marked with * are mandatory.

This Questionnaire

Wood, Ramboll, IOM, and the University of Gothenburg have been contracted to assist the European Commission (DG Environment) in assessing how best to introduce one or more MAF(s) in REACH for the chemical safety assessment of substances REACH.

This questionnaire aims to support this study through consultation with expert stakeholders who can provide insights into the pros and cons of introducing the MAF concept into REACH registration.

Please note that this questionnaire runs alongside the Commission’s ‘Public Consultation’ on the targeted revision of REACH and aims to collect more detailed information and insights than will be provided through that wider consultation.

The questionnaire is part of a number of consultation activities to support the project, including two project workshops and interviews with stakeholders.

Targeted revision of REACH

REACH (Regulation (EC) No 1907/2006) aims to ensure a high level of protection of human health and the environment. This is done by the four processes of REACH, namely the registration, evaluation, authorisation and restriction of chemicals. REACH also aims to enhance innovation and competitiveness of the EU chemicals industry.

The REACH Regulation places responsibility on industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers are required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database in the European Chemicals Agency (ECHA) in Helsinki. The Regulation also calls for the progressive substitution of the most dangerous chemicals (referred to as "substances of very high concern") when suitable alternatives have been identified.

The Chemicals Strategy for Sustainability recognises the need for a targeted revision of REACH to achieve its objectives by addressing a number of problems that have been identified. To address the problems identified, a range of possible measures are being considered. One of these is the introduction of (a) Mixtures Assessment Factor(s) (MAF).

The overall objective of the initiative is to ensure that the provisions of the REACH Regulation reflect the ambitions of the Commission on innovation for safe and sustainable chemicals and a high level of protection of health and the environment, while preserving the internal market, as provided for in the Chemicals Strategy for Sustainability.

Background to the mixture assessment factor concept

As set out in the Commission's progress report on chemical mixtures, even exposures at concentrations regarded as safe (i.e. where no effects are expected) for the individual substance can result in adverse (eco)toxicological effects when several substances occur together in a mixture.

Under REACH, registrants are required to document the safety of their substances, but they are not required to take into account the possibility of co-exposure to other substances. Indeed, they are seldom in a position to do so, as they usually do not have information on how other substances are used. A mixture assessment factor (MAF) is a pragmatic approach to manage the unknown unintentional co-exposures, i.e., that a registrant does not know about the other substances which would also affect the humans and the environment that are exposed to his substance.

A MAF is the factor by which the regulatory threshold of a given substance (PNEC or DNEL) needs to be divided in order to ensure a level of protection against unintended mixture effects that is similar to the level of protection aimed for in a single substance assessment. The maximum risk quotient (PEC/PNEC or exposure/DNEL ratio) under which "safe use" of the substance can still be demonstrated in the chemical safety report taking into account unintentional mixtures is equal to 1/MAF. Different MAF values could apply to different exposed populations (e.g. the general public, the environment, occupational settings) or different types of chemicals.

The project team is developing options for science-based values of MAFs (task 1); investigating ways to incorporate a MAF into REACH (task 2); reviewing the predicted interactions between MAF(s) in REACH and other legislation (task 3); and assessing the impacts of selected policy options for introducing a MAF or MAFs into REACH (task 4).

Completing the questionnaire

The questionnaire includes requests for information, data and opinions on the possible implications of introducing a MAF into REACH.

If you do not have completely accurate information, please provide your best estimate.

If you are unable to answer any given question please just move on to the next question.

We will not include details of you or your organisation's name or responses without your explicit authorisation.

Statement on handling of confidential data for targeted consultation

As part of this project, the project team is consulting with stakeholders to help understand the potential implications that introducing a Mixture Assessment Factor in REACH would have. This "targeted" stakeholder consultation consists of this survey and also interviews and other written correspondence between Wood and stakeholders.

It is recognised that some stakeholders may wish to provide confidential data as part of this consultation exercise. We have set out below the measures that we will take in order to protect any confidential information provided to the project team in connection with this work.

In particular, while information that stakeholders provide will be taken into account in our analysis, which will form the basis of our reporting to the European Commission, the measures that we will take to protect the data that stakeholders provide include:

- Ensuring that the confidential information provided will not be passed on to third parties outside the project team, directly or indirectly, partially or completely.
- Ensuring that the confidential information will only be made available to those project team members that need to know about it for the purposes of the project.
- Whilst the information provided is likely to be taken into account in the outputs (reports) from the contract, the confidentiality of the data will be preserved by:
    - Making anonymous all information relevant to specific companies, chemical substances and/or facilities within our reporting.
    - Not using the information provided for any purpose other than for this project.
    - Presenting uncertainty ranges in reported data (e.g. on quantities, emissions or costs) in order to avoid disclosing market-sensitive information.
    - Presenting aggregated data covering estimates for all companies and/or company average data, rather than data specific to individual companies.
    - Excluding other confidential information that stakeholders specify should not be included in the reporting.

If you require any further information or would like to discuss specific issues of confidentiality then please contact the project team. Please note, however, that we will not be able to enter into bilateral confidentiality / non-disclosure agreements with individual stakeholders.

About you

* A1 Your name

Giulia Sebastio

* A2 Organisation name

Downstream Users of Chemicals Coordination Group (DUCC)

* A3 Email address

giulia.sebastio@aise.eu

* A4 Telephone number

0494148515

About your organisation

* B1 Please indicate what type of organisation you represent:

- (●) Industry association
- ( ) Company
- ( ) Non-governmental organisation (NGO)
- ( ) Public authority
- ( ) Trade union
- ( ) Academia
- ( ) Other (please specify)

B2 Please indicate if you are or represent:

- [x] Manufacturer of chemicals
- [x] Importer of chemicals
- [x] Downstream user or distributor of chemicals
- [ ] Other (please specify)

B3 If any, approximately how many REACH substance registrations did your company (or members you are representing for associations) submit?

B4 Please indicate the sector(s) that your company/association operates in.

- [x] SU1 - Agriculture, forestry, fishery
- [ ] SU2a - Mining, (without offshore industries)
- [ ] SU2b - Offshore industries
- [ ] SU4 - Manufacture of food products
- [ ] SU5 - Manufacture of textiles, leather, fur
- [ ] SU6a - Manufacture of wood and wood products
- [ ]
- [ ] SU13 - Manufacture of other non-metallic mineral products, e.g. plasters, cement
- [ ] SU14 - Manufacture of basic metals, including alloys
- [ ] SU15 -Manufacture of fabricated metal products, except machinery and equipment
- [ ] SU16 - Manufacture of computer, electronic and optical products, electrical equipment
- [ ] SU17 - General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment.
- [ ] SU18 - Manufacture of furniture
- [x] SU19 - Building and construction work

SU6b - Manufacture of pulp, paper and paper products

- [ ] SU7 - Printing and reproduction of recorded media
- [x] SU8 - Manufacture of bulk, large scale chemicals (including petroleum products)
- [x] SU9 - Manufacture of fine chemicals
- [ ] SU11 - Manufacture of rubber products
- [ ] SU12 - Manufacture of plastics products, including compounding and conversion
- [ ] SU20 - Health services
- [ ] SU23 - Electricity, steam, gas water supply and sewage treatment
- [x] SU24 - Scientific research and development
- [x] SU0- Other

What should a MAF apply to?

* C1 If a Mixture Assessment Factor (MAF) were introduced into REACH chemical safety assessments (under the REACH registration process), do you think there should be:

- [ ] A single MAF addressing both human health and the environment
- [ ] One MAF for human health and another MAF for the environment
- [ ] One MAF for the environment, another MAF for exposure of the general public and a different MAF for occupational exposure
- [x] Different MAFs applied to substances with different types of effects/hazards
- [x] Different MAFs applied to substances with different types of uses
- [x] Another option (please provide details in your response below)

Please provide further explanation/information on your response to the above.

The MAF should be applied to substances that, based on their characteristics, can end up in an unintended mixture and, if so, contribute to the mixture toxicity. Unintentional co-exposure has spatial and temporal dimensions. Because the likelihood of possible unintentional co-exposure to chemicals for Human Health and to the Environment is highest for substances that can bioaccumulate, and substances that are persistent, respectively, the focus of MAF should be on PBTs that are used in high tonnages and wide dispersive uses. Thus as DUCC we support a mixture of Option 4 and Option 5.

How would you (or your members) respond to a MAF?

D1 Within your chemical safety assessments (CSAs) (or those of your member companies), if a MAF of 2, 5, 10 or 100 were introduced, approximately what proportion (percentage) of your portfolio (e.g. % of substances or % substance use combinations) would require:

	MAF= 2	MAF= 5	MAF= 10	MAF= 100
Additional exposure modelling to demonstrate safe use with a MAF in place (e. g. higher tier models)?	For this table, see our qualitative comments below			
Additional exposure monitoring to demonstrate safe use?				
Additional refinement of the PNEC/DNEL to refine the hazard assessment?				
Additional risk management measures (RMMs) or operational conditions (OCs) implemented in manufacture or downstream use?				
Withdrawal of certain uses (because they could no longer be demonstrated to be safe)?				

D2 Please provide details of how you derived the above estimates.

DUCC refers to the values provided by it's members.
We note that based on case studies all sectors in DUCC's membership have identified a substantial impact to their portfolios, with some sectors identifying impact as high as 100%
There would also be an impact on uses and key uses would be withdrawn.
For Downstream user sectors assessing impact can be difficult as information on RCRs is often with suppliers and full visibility on these values is not possible.
Finally, there is a perception that if RCR of substances are calculated to be >1 due to the addition of a blanket MAF a downstream user will simply be able to do a DU CSR to refine the assessment. However, for an impact of this magnitude, this will not be an action that DU companies will have the resources to take and the impact will disproportionately affect SMEs.

Costs of refining exposure assessments

E1 How much do you expect the costs to be per substance to refine exposure assessments (environmental, consumer and workers exposure assessment) to demonstrate safe use with a MAF in place? Please provide estimates (and a justification) of time and/or costs (in €) related to (a) higher tier modelling; (b) monitoring. Please indicate if the activities and/or costs are one-off or recurring, whether they are per year, etc.

Need for additional animal testing

F1 If some additional refinement of the PNEC/DNEL were required (question D1 above), for what proportion (percentage) of your portfolio of substances would additional vertebrate tests be needed?

F2 Please provide details of the specific tests likely to be needed, if known.

F3 Please provide details of the estimated costs per substance where such tests would be required.

Need for and costs of additional risk management measures (RMMs)

H1 If additional RMMs were identified above (question D1), please indicate what specific (environmental, occupational or consumer uses) RMMs you would expect to be needed and how widespread these would be (e.g. numbers of sites).

H2 Where known, please indicate the unit costs (e.g. per measure) and/or total costs of those RMMs or operational conditions (OCs) (capital and annual operating costs).

Withdrawal of some uses of substances from the market

I1 If you would expect some uses to be withdrawn (see D1 above), please provide:

	Details of (examples of) the specific substances and uses /functions and/or products that would no longer be available	Justification of why they would be withdrawn	Either the loss of profit/turnover (in €) or the percentage that they represent of your total portfolio/turnover
Example 1			
Example 2			
Example 3			

If you would like to provide any other information on potential withdrawal of substances from the market, please do so here:

Other costs to industry

J1 Aside from those costs already covered (to refine exposure assessments, for possible animal testing, to implement RMMs and associated with the withdrawal of some uses of substances), would you incur any other costs from having to revisit your CSAs to account for a MAF? If so, please explain what those costs would be and provide an estimate of their magnitude. For example, these may include: costs of resubmission of registration dossiers; SIEF administrative costs; or costs of updated eSDS amongst others.

We have identified the following impacts to downstream users:

- Need for reformulation of mixtures
- Losing valuable, sustainable substance uses
- Reduction of the ingredient portfolio available to make formulations (fewer options, leading to innovation loss). Manufacturers may decide not to supply a substance any longer, with an impact on downstream users. This will be especially true if that substance is crucial to the DU sector.
- Higher level of efforts of the creation of DU CSR – high impact for SMEs
- Forcing more CSA done at DU or even end-user DU level, who can have less expertise and resources to do them
- Increase in administrative work
- Further SDS exposure scenario fragmentation (i.e. more). Diversion (waste) of resources in recalculation exercises.
- Loss of efficacy of final products
- In some sectors, sectoral legislation is in place that obliges the registration and approval of mixtures before these are placed on the market. If there is an obligation to reformulate a large number of mixtures, due a blanket MAF approach, companies will need to re-submit product dossiers with large costs.
- DU will receive information on substances with a MAF for each substance. This will present workability issues. Downstream users do not only consider one ingredient at a time, but all the ingredients in their mixture.
- End customers to use more PPE. An related to this, increasing RMMs may cause workers to disregard the additional measures as these could be seen as disproportionate.
- High impact on solvents. A long pipeline of reformulations and search for alternatives.
- Unacceptable increased requirement for animal tests

Reduction in environmental and health risks

L1 If a MAF of [2, 5, 10, 100] were introduced, do you think this would lead to a reduction in risks/impacts on health and/or the environment and, if so, of how much. Please provide specific examples of where this would be the case e.g. based on information available from monitoring/regulation/enforcement in your country.

	Significant reduction	Some reduction	No reduction
MAF=2: Reduction of risks/impacts on health	○	○	◉

MAF=5: Reduction of risks/impacts on health	○	○	◉
MAF=10: Reduction of risks/impacts on health	○	○	◉
MAF=100: Reduction of risks/impacts on health	○	○	◉
MAF=2: Reduction of risks/impacts on environment	○	○	◉
MAF=5: Reduction of risks/impacts on environment	○	○	◉
MAF=10: Reduction of risks/impacts on environment	○	○	◉
MAF=100: Reduction of risks/impacts on environment	○	○	◉

Examples/justification:

Only a targeted approach that focuses on the areas that matter will result in a reduction of risks. A blanket approach will create impacts in areas where risks are already well managed.

Potential impacts on competition and competitiveness

M1 If a MAF were introduced into the registration process under REACH, do you think there would be any impacts on competition within the EU or competitiveness of the EU as a result? If so, please provide specific details and justification.

A MAF applied only in the EU would lead to unfair competition from outside the EU where articles can be manufactured with products that would no longer be available in the EU

M2 Do you think the introduction of a MAF would affect the reputation of the EU chemicals industry and legislation worldwide, as a frontrunner in terms of protection of human health and the environment? Would this result in a competitive advantage? This could occur, for example, through EU products being considered safer than others. Please explain your answer.

No. Already currently with the requirements of REACH, no such competitive advantage is perceived

Incorporating a MAF into REACH

N1 The MAF could be incorporated into Annex I of REACH in two main ways. Which of the following approaches do you favour if a MAF is introduced into REACH?

- ○ As an additional factor used for derivation of a PNEC and/or DNEL. In this case, the value would be reduced by a factor equivalent to the value of the MAF, making the MAF a hazard assessment tool.
- ◉ As an additional factor applied to the risk characterisation ratio (RCR). In this case, safe use would be demonstrated when the RCR has a value less than 1/MAF, making the MAF a risk management tool.

N2 Please explain your answer to question N1.

Applying a MAF to the DNEL will mean EU limit values will differ from the rest of the world
Adding a MAF to PNEC and DNEL will have a carry over impact on sectors that use the PNEC and DNELs without possibility for refinement

Applying a MAF in the case of naturally-occurring substances

O1 Are your aware of any naturally occurring substance groups (e.g. metals, enzymes) that might need specific considerations (e.g. additional guidance) if a MAF is introduced? Please specify which.

- If naturally occurring substances also pose risks, there is no reason to differentiate them from man-made chemicals.
- If the substance is not hazardous or the hazard is well managed, it should be treated like man-made chemicals.
- For some substances considering background concentration may be of value
- In fact, DUCC would like to raise that asking this question, is in itself, a justification for a differentiated approach to MAF depending on the properties of specific substances.

O2 What differences compared to other substances do you think would need to apply? Please explain your answer.

MAF for non-threshold substances

P1 Different considerations might be needed to address non-threshold toxicants when applying a MAF. Are you aware of approaches that could be used/or are under development for applying a MAF for non-threshold toxicants?

- ○ Yes
- ○ No

P2 If you answered yes, please elaborate on these approaches.

P3 For cases where a dose-response relationship for non-threshold substances could feasibly be derived, how should the contribution of such substances to the risks from unintentional mixtures be taken into account within the chemical safety assessment? For example, could a derived minimal effect level (DMEL) be used instead of the DNEL in applying the MAF?

Don't see it necessary to apply for non-threshold substances, as they are assessed on very low risk concept which is quite conservative

P4 For cases where a dose-response relationship could not feasibly be derived, how should the contribution of such substances to the risks from unintentional mixtures be taken into account within the chemical safety assessment? Please elaborate on your answer.

Interaction between MAF and legislation other than REACH

Q1 If a MAF were introduced in REACH, what potential impacts do you think this may have on the following legislative areas (e.g., in terms of achieving or hindering objectives; improving or reducing coherence, double-regulation), for example, if information from REACH CSAs is used in other legislation or if substances are regulated by both REACH and other legislation:

- Environmental legislation (e.g., Water Framework Directive, Waste Framework Directive).
- Product-specific legislation (e.g., food contact materials, plant protection products, biocides, cosmetics, toys).
- Worker protection (e.g., the Chemical Agents Directive).
- Other

Please explain the nature of any potential positive and/or negative impacts anticipated.

Other information

R1 If you would like to provide any further information, please give details here, and if you would like to share any documents/attachments, please do so below.

Please upload your file(s)

Only files of the type pdf,doc,docx,odt,txt,rtf,png,jpg,jpeg,gif,bmp,xls,xlsx,ods are allowed

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