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DIRECTORATE-GENERAL INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Chemicals and Consumer Industries

REACH
Chemicals

ENVIRONMENT DIRECTORATE-GENERAL
Circular Economy and Green Growth
Sustainable Chemicals

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34th Meeting of Competent Authorities for REACH and CLP (CARACAL)

Open session

31 March - 1 April 2020

Room: ..

Centre Albert Borschette

Rue Froissart 36

1040 Brussels, Belgium

Concerns: Paper by the Dutch and Swedish Competent Authorities outlining a practical approach that can be applied to manage the risks of exposure to unintended combinations of chemicals in the EU.

Agenda Point: 10.2

Action Requested: Competent Authorities and observers are invited to comment on the document and the discussion points put forward. Written comments should be sent by 8 May 2020 to:
ronald.flipphi@minienw.nl,
jochem.vander.waals@minienw.nl,
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Discussion paper for CARACAL provided by KEMI and the Netherlands

Towards a pragmatic procedure to regulate the risks of exposure to unintended combinations of chemicals in the EU

Caracal members (and observers) are invited to send their comments on this paper to: ronald.flipphi@minienw.nl, jochem.vander.waals@minienw.nl, gregory.moore@kemi.se, preferably before 8 May.

Summary

For several decades, science and policy have expressed concern for the risk exerted by the cumulative exposure of humans and the environment to chemicals. Now, a practical approach has been developed that can be applied to manage the risks of exposure to unintended combinations of chemicals.

Background

The workshop on “Towards a pragmatic procedure to regulate the risks of exposure to unintended combinations of chemicals in the EU” was hosted by KEMI (Sweden) and the Netherlands, in Leiden (NL) on 5 - 6 March 2020. The aim of the workshop was to build a common understanding of possible pragmatic approaches to address the risk from combined exposure to unintentional mixtures of substances.¹ Given its central position in the legislative network for chemicals the REACH regulation was used to analyse and understand the practicable implications of such approaches, identify issues and recommend priorities and steps forward.²

The workshop

Policy makers and risk assessors from several Member States (Austria, Belgium, Denmark, Finland, France, Germany, Latvia, Netherlands, Spain and Sweden), Norway and the United Kingdom attended the workshop. From the European Commission and its agencies, DG ENV, DG RTD and ECHA participated. CEFIC, Eurometaux, and Innovation and Chemical Industries in Sweden (IKEM) represented industry. Environment and health NGOs that took part were ChemTrust and EEB. Representatives from Italy and JRC had to cancel due to the corona epidemic.

¹ In this workshop the working definition was used: **unintentional mixtures**: the sum of aggregated and combined exposures to substances, such as surface water contaminations or the total of exogenous chemicals present in an urine sample. This term includes both coincidental mixtures and environmental mixtures.

² The scoping paper, presentations and flash report of this workshop will be made available at this web address: <https://www.chemischestoffengoedgeregeld.nl/content/workshop-pragmatic-approach-address-risk-combined-exposure-non-intentional-mixtures>

General approach: Mixture Assessment Factor

The European Commission in 2012 identified the need for comprehensive and integrated assessment of cumulative effects of different chemicals via different routes of exposure. The Conclusions of the Environment Council of 26 June 2019 called upon the Commission to present options to introduce requirements in the relevant pieces of EU chemicals legislation to ensure that the combination effects of chemicals (cocktail effects) and the combined exposure of humans and the environment from all relevant sources are properly and consistently addressed in the risk assessment and risk management processes. This approach is relevant for chemicals legislation in general, and it seems logical to start with applying the approach to REACH as the overarching legislation. Combined exposure was also highlighted as one of the priority issues in the Green Deal where the Commission stated in the section on a zero pollution ambition for a toxic-free environment that the regulatory framework will need to rapidly reflect scientific evidence on the risk posed by combination effects of different chemicals.

Detailed risk assessment of combined exposure (simultaneous or sequential exposure to multiple substances via single or multiple pathways/routes) under REACH would require extended information requirements. The registrant for one substance does not have the necessary information however and therefore cannot assess the risks of all possible mixtures his substance can be part of. To avoid this conundrum, a pragmatic approach was presented. This could be implemented by applying a Mixture Assessment Factor (also called Mixture Attribution Factor) under REACH Annex I, as part of the mandatory DNEL or PNEC derivation for substances to account for the fact that any registered substance under REACH may eventually contribute to the combined daily exposure of humans and the environment. Alternatively, the factor could also be applied to the Risk Characterisation Ratio (RCR). Introducing a MAF as a generic/default factor across all substances will decrease the overall exposure of humans and the environment and hence reduce the likelihood that negative impacts occur.

Possible advantages and disadvantages of applying the factor to the RCR or to the DNEL and PNEC were discussed, mainly relating to transparent communication and workability for all actors in the value chain (e.g. down-stream users and other legislations making use of information provided under REACH). It was concluded that the workability of the different options needs to be further analysed. How such a factor could be used for non-threshold substances (e.g., by RAC in a restriction dossier) was a question that was posed but not further discussed.

Consequences of working with a MAF

Participants mentioned several magnitudes for a Mixture Assessment Factor such as 3, 10 and 100, but these have not been assessed or discussed during the workshop. ECHA presented an indicative assessment of implications of introducing a MAF of 10 for a limited group of 24 randomly selected substances registered under REACH. This first preliminary assessment suggests that when applying a factor, more risk management measures or testing would be needed for some of the substances. Other substances may not require any additional measures. Since these are only preliminary results based on a limited set of substances, ECHA will further study possible impacts on the registration dossiers.

Results of discussion at the workshop

All participants recognised that exposure to several substances, each below the limit that is considered safe, may result in an unintended risk, and that this is supported by many scientific

publications. The participants also agreed that the Green Deal, Zero-Pollution Ambition and Sustainable Chemicals Strategy require that a pragmatic approach to consider exposure to unintentional mixtures needs to be applied when determining safe use. There was general support for the principle of applying a Mixture Assessment Factor. No other approaches to deal with the risk from combined exposure to unintentional mixtures of substances were identified. Some participants mentioned that certain groups of substances, e.g. certain metals and other minerals might need special considerations to account for their natural background concentrations. Exactly how such groups of chemicals should be considered was not discussed. Furthermore, participants agreed that sufficient time is needed to phase-in a Mixture Assessment Factor. A difference of view exists on the preferred point of application of a Mixture Assessment Factor: DNEL and PNEC, or RCR. The impact on the supply chain may be different, but their effect on exposure is mathematically identical. Proponents of the DNEL and PNEC considered that new values would be meaningful to downstream users, while those advocating the RCR stressed that this would be the right point of application from a scientific point of view. It is important to continue a discussion in a broader circle of Commission services and EU agencies. The solution that the EU will choose should be in line with the intention of European Green Deal to move towards “one substance, one assessment”.

Discussion points

- Does CARACAL support in general the outcome of the workshop and in particular that the introduction of a pragmatic approach to address the risk from combined exposure to chemicals is urgently needed?
- Does CARACAL consider the application of a Mixture Assessment Factor under REACH a feasible and efficient method to address the risk from combined unintentional exposure to chemicals?
- According to CARACAL, what procedure should be followed in determining the actual approach for introducing the Mixture Assessment Factor?
- According to CARACAL, what procedure should be followed in determining the magnitude of the Mixture Assessment Factor?