Stockholm University

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Comments on the report "Future Chemical Risk Management: Accounting for combination effects and assessing chemicals in groups" (SOU 2019:45)

Below, we summarize the opinions of faculty members at the Department of Environmental Science at Stockholm University on the report "Future Chemical Risk Management: Accounting for combination effects and assessing chemicals in groups" (SOU 2019:45). We note that Prof. Christina Rudén, the Inquiry Chair who authored the report, is a colleague in our Department. None of the persons involved in preparing these opinions have been involved in any part of the process of producing the report.

The following members of the Contaminant Chemistry Unit, Department of Environmental Science at Stockholm University, contributed to preparing this reply and endorse its contents: Professor Matthew MacLeod, Professor Cynthia de Wit, Professor Ian Cousins, Professor Michael McLachlan, Associate Professor Anna Sobek and Associate Professor Jon Benskin.

Summary

We are positive to the report and support all 11 recommendations that are made for confronting chemical risk management of mixtures of chemicals. Sweden has long played a role as an international leader in driving chemicals policy and legislation. Sweden has also been an important driver in EU chemicals policy including the development of REACH. This report represents another important opportunity for Sweden to strengthen and continue its international leading role in chemicals policy and management. We do have some specific comments on certain aspects of the report.

Specific comments

1) Application of read-across methods. The report recommends the use of chemical grouping and read across to fill data gaps. This is a logical suggestion, but application of read-across can be problematic. Applying read-across in a scientifically defensible

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way requires understanding a) what endpoint/effect you are trying to capture/exclude, and b) what structural feature of the molecule is responsible for that endpoint/effect. Without considering these questions, grouping/read across can lead to incorrect estimations of the endpoint/effect, which will in turn lead to poor management decisions. Developing the knowledge for scientifically justified application of read-across can be time consuming, but is necessary.

As well as being used in a precautionary way, grouping/read-across could also be used as a basis to conclude that a whole group of substances are safe based on limited testing. In this scenario, the application of grouping/read-across creates perverse incentives, since it is industry who are largely responsible for paying for large-scale testing that could thus be avoided. We know that very small differences in structure can change the elimination kinetics, stability and toxicity of chemicals enormously.

2) Improving information on use and emissions of chemicals. We fully support the recommendation to establish a database on use and emissions of chemicals, but the suggested actions to achieve this goal may need some modifications to really make a difference. One important hurdle towards more transparency in chemical use, production and emissions is that industry can quite easily classify (and keep secret) such information, and report very broad ranges. The same goes for chemical content in products, articles and materials. To be stronger, we suggest that the recommendation includes that Sweden, in collaboration with other member states, needs to work on legislation that requires more transparency about chemical use and content in materials, products and articles. A potentially useful example of a system where all suppliers are required to report the chemical composition of their materials and components is the car industry (briefly discussed in Bolinius et al., 2018, https://doi.org/10.1039/C8EM00270C).

3) Risk assessment versus hazard assessment. The report mentions work from the European Union-funded SOLUTIONS project which estimated exposure to thousands of chemicals (van Gils et al., 2019, https://link.springer.com/article/10.1186/s12302-019-0248-3). One of us was a co-author of this study and a SOLUTIONS partner. We emphasize that the exposure assessment described in this paper was highly (one might even say hopelessly) uncertain. And, this work only describes the estimation of concentrations in exposure media in European surface waters. Equally(or maybe even more) uncertain is estimating exposure levels of each component of the mixture of chemicals that form the internal dose to an organism. In order to do this one must know the elimination and metabolism kinetics.

Given the huge uncertainties involved, starting with production volumes of all chemicals in society and estimating internal doses of the mixtures in multiple organisms with spatial and temporal accuracy, we suggest that it is also necessary to consider hazard-based regulatory strategies that are based only on intrinsic properties of the individual chemicals. The European Green Deal (https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en) currently being formulated by the European Commission will introduce new strategies for safe management of chemicals in society. These strategies include a greater focus on green chemistry with the aim that new chemicals should be "safe and sustainable" by design. Designing and regulating away problematic intrinsic properties of chemicals is a parallel strategy for tackling mixture toxicity.

4). The future role of non-target analysis in discovery and risk assessment of chemical contaminants. The report recommends the application of non-target analysis using high resolution mass spectroscopy (HRMS) techniques in screening for environmental contaminants, which we fully support. But, the report may even understate its potential! We believe that non-target HRMS analysis is rapidly evolving into a powerful tool to support chemical exposure hazard identification and risk assessment. Although it is currently difficult and time-consuming to assign unequivocal structures to chemicals detected in full-scan HRMS without standards, the technologies for that task are rapidly evolving. And, there are several promising approaches in development for quantifying levels of chemicals from full-scan HRMS data without the use of standards.

Hence, foreseeable advances in structure assignment and quantification of chemicals using full-scan HRMS analysis could provide the capability to identify currently unknown contaminants in the environment and quantify their concentration to support risk assessment. Development of these technologies should be supported and data to fully exploit them should already be being collected and archived. One specific action that should be taken is that the traditional targeted analytical methods that are currently used in Swedish environmental monitoring programs should be upgraded as soon as possible to include simultaneous collection of full-scan HRMS data that is archived for future retrospective analysis.

Sincerely,

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