

Online debate 8 June A grip on Hazardous Substances: Additional Q and A

In the online debate session, Monday 8 June, there was not enough time to answer all the questions from the participants. Some of the questions were specifically addressed to one of the speakers. On our request they sent us their answers later by email. In this table we also added the Q and A's and comments that were shared in the Slido during the debate by the participants. We have anonymised all questions and answers.

Q: What is the urgency for effect based monitoring (EBM) in the EU?

A: Mankind produces >350k chemicals (Wang et al. 2020, Environ. Science and Technology), and EBMs help avoid the need for 350k chemical dossiers (still lacking insights in the effect of (unintentional mixtures)).

Q: As far as I can see it is based on hindsight, no prediction. Is it correct to say it is a start but not the key for the future ?

A: Risk assessment should have both perspectives: prospective and retrospective. We did both in SOLUTIONS. My task here was to report on monitoring (the retrospective part). This part is key in order to check whether our prospective risk assessment is actually protective. And it is obviously not sufficiently protective. I don't think, it is just a start but it is a key element missing so far. To speak in regulatory terms: We have to much better interlink REACH and Water Framework Directive perspectives.

Q: Effect Based Assessments (EBAs)s are a great tool to have. The proof of the principle is there as clear from Solutions research. The question is of course, who should take this up to implement and enforce this on a much wider scale? EU? National level?

A: Both. On the EU level EBMs and chemical screening should be encouraged as a tool for assessing the likelihood of not achieving a good status and guidance how to apply should be given (and has been developed in a working group und WG Chemicals). The monitoring itself is done on a national level and needs to be implemented there.

Q: What about very specific but sensitive effects in specific species like the neonicotinoids in bees? Do you agree that EBA's as presented are a good start but that there is a long way to go?

A: The EBMs (Effect Based Monitoring) presented cover relatively well acute toxicity in aquatic ecosystems (with predictions to chronic risks using factors) together with some major sublethal effects independent from the compounds causing this effect. This is much more than monitoring does today when it focuses on few individual compounds. However, it is true, it does not cover all relevant effects. It is very important (and pays) to open the door for effect-based monitoring now to improve current monitoring schemes and to trigger research and innovation closing still existing gaps

Q: You mentioned mutagenic intermediates from dye production. Are trustworthy bioassays available for mutagenicity?

A: For mutagenicity we have a relatively broad battery of assays available. They provide very valuable information but have (like every method) also false positives and false negatives. I personally prefer the oldest one: the Ames test using different strains due to its diagnostic power.

Q: Material passports are a good step forward. Should fate of chemicals during and after use of the materials/products not also be included?

A: About the material passport: Be sure producers register besides their products also their emitted side-products and excipients in a European database.

Q: What is exactly the legal basis for these liabilities? There is not a general rule on a EU level...

A: I would be interested to have further discussion with you on this topic. We are working in the www.gov4nano.eu a bit on this topic.

Q: Agree that system now underestimates risks? Do you have any suggestion that if your effect-based assays show risks what to do? What risk management options do we have? Which individual chemical in the mixture should be banned/restricted?

A: Yes, we currently underestimate risks. Identifying risk drivers and their sources is key. The tools for that are available (although there is still a lack of measured toxicity data for many compounds aggravating assessment). Thus, monitoring definitely helps to identify chemicals that need to be banned. However, we must be careful not to just replace one bad chemical with another one with similar properties and hazards and wait till the new one is occurring at high enough concentrations to ban it, too. Thus, non-chemical solutions for a societal requirement and benign by design chemicals should be used for replacement.

Q: To further improve monitoring and apply lessons learned, where should we first start monitoring and applying these tools first, particular product groups, materials, sectors? Like flame retardants in electronics?

A: For the textile industry we are a foundation that is working with the industry to provide input chemistry restrictions for the manufacturing of materials and production. There are initiatives that can contribute such as ZDHC. The idea/approach can work in many other aspects of manufacturing. Besides working with footwear and apparel we are also in communication with "home goods" and the automotive industry
But I do think the strength is that we made it specific to this industry and provide them with specific guidance on the specific issues, therefore I think it is easier to explain and implement into a generic legislation.

A: We were not working on individual consumer products so far. Testing consumer products is very important. However, I suggest to combine that also with monitoring (effect based and non-target screening) of more integrated matrices (house dust, laundry wastewater, biowaste from households, urban runoff.....) in order to identify major risk drivers and follow them back to the product level.

Q: "Underestimation of Risk?" To what group of chemicals which are not already regulated does this refer?

A: Acute toxic risks to aquatic organisms are typically dominated by pesticides and biocides as well as some pharmaceuticals, particularly antibiotics. Of course, most of them are regulated and should not be found in concentrations in the aquatic environment that are not safe.
Unfortunately, the opposite is true. We need feedback loops. If monitoring tells that registered chemicals are not safe, this needs to be solved. A second answer to your question would be that in many cases we find adverse effects by effluents etc. which cannot be explained by chemicals monitored or regulated. If we take the efforts to identify the drivers of these effects we often find site-specific chemicals e.g. from local industry, which can and should be detected with a combination of effect-based monitoring and non-target screening.

Q: Risk of mixtures, is it accumulative or are there synergistic effects? And what is the potential of modeling for prediction?

A: The website of the SOLUTIONS-project (www.solutions-project.eu) provide an overview of all relevant products. Specifically look at the Policy Briefs - they summarize the cumulative risks and impacts that occur in the environment.

Q: I'm a journalist and I realize there is no one truth but I'm getting lost in the many reports and the framing by stakeholders. Is it possible to use Block chain to keep track of 'changing truth' and new insights/changing societal demands?

A: At RIVM we provide current and authorized information on risks of substances for health and the environment <https://rvs.rivm.nl/>. Also the recent initiative www.waarzitwatin.nl might be of interest!

Q: The challenges society is faced with today are not limited to environmental pressure of chemicals on man and environment. Climate change and increasing scarcity of resources require innovation and new materials...

A: Yes! So what we need more than ever is to develop integrated assessment tools that take all these different risks into account

A: Many chemicals considered very hazardous will help meeting these challenges. Intelligent chemicals policy takes this into account.

Q: If the government is not able to "know" all that is needed how could the consumer be asked to "score" their products?

A: Here the EU-Product Environmental Footprint may act as important approach: this eventually presents environmental footprints of products in a comparative way, using labels on products (well-known for energy-use of household equipment).

Q: Will safe by design startups ever be able to get a market position if they still have to compete with very high production volume chemical or should there be tax-incentives or something like that?

Q: CE logos are not working with internet selling non-compliant products. Example: watertaps from China leaching several metals. How do we cope with that?

Q: Replacing hazardous substances means we first need to know they are hazardous, even the ones we find everywhere ('always present chemicals') still have not been investigated to classify them as hazardous. How to solve this catch 22?

A: By applying the precautionary principle?

A: Replacing chemicals might be a problem instead of a solution too! For example: the longchain PFAS replaced by less-known shortchains or by GenX. Later GenX became GenY... For the product, the use of the same chemical properties is needed. To avoid regrettable substitution, we need indeed to apply updated risk assessment and risk management tools at the design phase, e.g. by avoiding persistency in the innovation of Safe and Sustainable by Design Products

A: Yes a phenomenon with a name: regrettable substitution. A solution also mentioned in the RLI report is to look at substances as a group when characteristics are similar.

Q: To keep up pace with innovation... When a company wants to put a new medicine on the market, it has to demonstrate/prove in front that the medicine is safe. Is a similar way of working not recommendable for all 'critical' products?

A: In fact the chemical legislation in the EU REACH, does that. And it is a very high standard.

A: We now still have problems with medicine residues entering into the environment via waste water treatment facilities. Safe enough?

Comment: Agree that we really need a fundamental discussion on what substances, what products and what materials are essential and which ones are not.

This paper provides a useful start:

https://chemrxiv.org/articles/The_Concept_of_Essential_Use_for_Determining_When_Uses_of_PFASs_Can_Be_Phased_Out/7965128/1

Agreed! Although I believe the list of essential substances will be much larger than a lot of people think (and hope). But that would be a good insight.

[Read more about the report and the event](#)

Council for the Environment and Infrastructure (Rli)

Bezuidenhoutseweg 30

P.O. Box 20906

2500 EX The Hague

The Netherlands

info@rli.nl

www.rli.nl

