

Research actions identified as addressing the needs of several EU Scientific Advice Agencies

Scientific assessment methods

3. Exposure Science (lead: EFSA, possible collaborators: ECHA, EEA, EFSA, OSHA)

In regulatory risk assessment, research activities in the area exposure science aimed at assessing the internal dose would serve the needs of several EU Scientific Advice Agencies. This will require the use of validated and comparable models from different exposure routes (oral, inhalation and dermal) and addressing all possible sources of exposure (diet, consumer products, environment and occupational). In this context, sharing of the data collected from different domains could be extremely useful.

Common research priorities

Regulatory risk assessment of chemicals or biological agents and their products involves understanding and predicting exposure. Tools for exposure estimation, in a monitoring situation, and prediction, in a pre-regulatory situation, have a variable level of validation and transparency. Consensus within the regulatory community does not always exist on the acceptability of the risk predicted by comparing exposure and hazard.

In the area of human and environmental exposure assessment it is accepted that different modelling tools can generate very different outcomes and there is some scepticism that they reflect real world exposures together with uncertainty over the validity of the estimates for regulatory risk management purposes. There is currently neither clear alignment between outcomes for comparable or corresponding situations under different regulatory frameworks. To achieve a wider acceptance of the exposure tools it is important that they are up-to-date, transparent, applied correctly within their intended realm, independently validated, or at least tested, and seen to align with expectation. In addition, the uncertainties associated to these tools should be identified qualitatively and, if possible, quantitatively assessed.

The widening of the discourse beyond the safety assessment of a single substance includes the assessment of chemical mixtures or mixtures of other stressors both in humans and in the case of environmental exposure (e.g. bees).

Hence research is needed to test modelled outcomes and to augment and support the long term development of the next generation of models aimed at assessing exposure to single chemicals and mixtures. Common research is of primary importance when developing models for the assessment of exposure from all possible sources (diet, consumer products, environment and occupational). A coordinated approach for collecting, storing, accessing and assessing of data is a prerequisite in this remit.

Role and relevance for futures

Exposure assessors must be ready to further develop current models for the prediction and estimation of exposure in order to, as far as possible, determine the internal dose. The estimation of the internal exposure will require the use of models from different exposure routes (oral, inhalation and dermal) and addressing all possible sources of exposure (diet, consumer products, environment and

occupational). The level of validation, conservativeness and transparency of these models should be as much as possible comparable. The ultimate aim should be to estimate aggregate exposure considering all sources and routes; through a comprehensive knowledge on toxicokinetics and toxicodynamics. Moving away from exposure based on external dose towards internal dose will allow reducing uncertainty and animal use. To determine internal dose, implies bringing into the assessment the kinetics processes (knowledge of metabolism and accumulation patterns for compounds will be key) and use data from biomonitoring studies¹. Related areas of research and methodology development are on human and environmental biomonitoring, including reference values, and bioelution and bioaccessibility methods to estimate release.

Opportunities for collaboration between Agencies

Exposure models and data generation

Generic evidence is particularly required when conservative over-estimation and lack of precision do not serve the purpose. Evidence is also required where there are concerns about mathematical modelling in cases where exposure would appear unreliably high. To support the evidence, common research is needed on the development of standard factors that are part of the exposure models and, being often based on expert judgement, add considerable uncertainty to the results. In particular, generic data are required to address tasks for oral ingestion, inhalation and dermal exposure. The development of adequate biomonitoring studies could be used for the development and validation of mathematical exposure models. New knowledge on various aspects influencing environmental fate/behaviour/exposure of substances should be incorporated into environmental exposure estimate decision-support tools. The reliability of the available release factors for emissions to air, water, soil and waste for various uses/processes/industries (e.g. Emission Scenario Documents, ERCs, SpERCs) is particularly uncertain.

Exposure models addressing chemical mixtures have been developed and are already used in different domains but further refinements are needed in order to address the complexity of this topic.

Data sharing and clusters of knowledge

It is important to engage with national authorities and research institutes as there are difficulties in drawing valid comparisons based on national data, due to differences in data collection frameworks and data quality. It would be useful to form clusters for data and knowledge sharing, involving scientists developing methodologies used to address common challenges. In this context, a wide sharing of the data collected within monitoring surveys from different domains could be extremely useful. Within this context, more active use of and linking of existing data warehouses to the IPCHeM platform would enhance the availability of scientific evidence for exposure assessment of chemicals. IPCHEM aims to support a more coordinated approach for collecting, storing, accessing and assessing data related to the occurrence of chemicals and chemical mixtures, in relation to humans and the environment. EFSA, EEA and ECHA are already participating in this project. IPCHeM is also the platform that will host biomonitoring and related data collected within the Horizon 2020 project of Human BioMonitoring for Europe (HBM4EU).

¹ ECVAM TK 2015 strategy.

<http://publications.jrc.ec.europa.eu/repository/bitstream/JRC96418/eurl%20ecvam%20toxicokinetics%20strategy.pdf>