Session Proposal for SETAC 2015 in Barcelona

Session title: Improving risk assessment approaches for substances with complex composition

OR another title proposal:

Improving approaches for difficult non-standard risk assessment of chemicals

Session description/ motivation:

The fundamental principles of risk assessment of chemicals are well established and there is detailed guidance on how to conduct a risk assessment for a 'simple' case. Many cases are not straightforward, however, and therefore risk assessors often have to use expert judgement to adapt the standard methodologies. Common types of 'difficult' risk assessment cases are:

- substances with complex composition:
  - multi-constituent substances
  - UVCBs (Substances of Unknown or Variable composition, Complex reaction products or Biological materials) e.g by-products, petroleum chemicals, reaction products)
  - mono-constituent substances where impurities play a role in the assessment
- substances that undergo transformation, during use or by transformation in the environment
- naturally-occurring entities,background in the environment, endogenously or as an essential nutrient

REACH Guidance sets a very important principle when dealing with complex substances. The preamble in R7.13 states that it is necessary to develop a specific testing strategy to ensure that the composition of the sample to be tested in the laboratory reflects fully the composition of the likely human or environmental exposure. This is not always straight-forward especially when a substance has a highly variable composition.

What key assessment steps are to be considered for substances of complex composition? What are the uncertainties associated with such assessment?

Risks may be substantially over or under estimated if, for example, the whole substance exposure used in experimental studies is different to the expected human/ environmental exposure due to the different behaviour of individual constituents during use or following environmental release. When to look at data from the whole substance and when to look at date from the constituents of the substance?

There are limitations in the available scientific knowledge e.g. understanding how substances behave in the environment and their toxicology, limitations in the availability and reliability of methods to translate scientific understanding into tools for risk assessment and limitations in how authorities have been able to apply and develop scientific knowledge into regulatory guidance.

How can exposure to a reactive substance and to its transformation products be addressed when the quantities of both change during use and/or after release into the wider environment? Uncertainties in the exposure assessment for the substance and its transformation products may give rise to substantial uncertainties in the prediction of risk, particularly where the substance and its transformation products have very different effects.

How can the risk of increased exposure of a substance that is naturally present in the human body and/or environment be addressed?

For this session we would like to attract case studies from industry, academia and regulators on how to develop the risk assessment methodologies, based on the current risk assessment practice and the latest thinking in regulatory science (notably on mixture effects). It should be possible to define high level approaches as elements to address or consider based on established good regulatory practice.

Keywords: risk assessment, substances with complex composition, uncertainties, substances undergoing transformation, naturally-occurring entities

Chairs: Charmaine Ajao, Peter Fisk, Hugo Waeterschoot