

A Novel Approach For The Assessment Of Workplace Health Risks Under The EU Chemicals Policy

C. MONEY*, F. FLOCH, S. JACOBI, S. LANZ, M. PENMAN, C. RODRIGUEZ, C. DE ROOIJ, G. VEENSTRA

ExxonMobil, Machelen, B-1831, Belgium; Rhodia, Lyon, F-69457, France; Degussa, Hanau-Wolfgang, D-63457, Germany; BASF, Ludwigshafen, D-67056, Germany; ExxonMobil, B-1831, Machelen, Belgium; Procter & Gamble, Strombeek-Bever, B-1853, Belgium; Solvay, B-1120, Bruxelles, Belgium; Shell Chemicals, SE1 7NA, London, UK

Background

The European Union is introducing a new approach for the control of supplied chemicals. Within the proposals contained within the White Paper for a new chemicals policy, chemical suppliers will be required to submit a "chemical safety report" that demonstrates that the human and environmental risks presented from the use of substance can be readily managed across the life cycle of substance. The chemical safety report demands a suitable assessment of risks, including the effectiveness of likely risk management measures. It is envisaged that the contents of the report will also serve to ensure that users of chemicals, particularly small and medium sized enterprises, are better able to manage such risks.

In response to the scientific and practical challenges presented by the White Paper, ECETOC has developed a tiered approach for developing such safety reports and which targets efforts at those risk of higher concern. The ECETOC approach is based upon a series of Tiers. The first level (Tier-0) establishes whether substances as a whole are of "low concern". The second level (Tier-1) aims to identify exposure scenarios that represent a potential concern and which would warrant more detailed investigation at the third (Tier-2) level. The intent is to introduce an approach that is simple, transparent and delivers consistent outputs across a range of circumstances. The level of sophistication and scientific rigour are driven by the likely risks arising from the identified uses of a substance. This not only enables resources to be focused at those uses that appear to be of highest concern, but also targets a more rigorous evaluation of risk at them in order to reduce uncertainties.

The ECETOC approach builds on existing concepts used in the determination and management of workplace health risks e.g. the UK COSHH Essentials approach, the OEL's recommended by the

* Corresponding author

EU's Scientific Committee on OEL's. But, uniquely, it applies them to areas of regulation that have not previously embraced such concepts. By adopting an approach such as this, the output of the ECETOC process has the potential to align with the prevailing expectations of existing pieces of workplace and environmental legislation.

In assessing the nature of workplace risks, from a defined list of generic exposure scenarios, the ECETOC approach identifies how a substance may be used. These scenarios represent tasks or unit activities that are common throughout the chemical-using industry and reflect the core determinants necessary to reliably predict workplace exposure. The scenarios accommodate variations in exposure control e.g. presence or absence of exhaust ventilation and provide an indication of when dermal exposure would also present a potential risk. The information contained within the scenarios is then used to populate and run established exposure prediction models such as those contained in the EU Technical Guidance Documents under the EU Existing Chemicals Regulation.

The approach also uses concepts of hazard categorization to develop Generic Exposure Values (GEVs) for each category of hazard. Three categories of hazard have been defined within the ECETOC scheme. These align with other previously advocated schemes (e.g. UK COSHH essentials, UIC product risks). GEVs for volatile materials have been derived for each of the categories, based upon a comparison of the most stringent OELs published for a range of the most common industrial substances within that category. The GEV serves as a yardstick to judge whether a risk is likely to be associated with the category if the exposure is exceeded i.e. whether a more rigorous and detailed assessment of risk would be warranted at the Tier-2 level. GEVs have also been determined a solid materials. However, the process used determine these has been based upon the broad relationships between OELs for volatile and solid materials that have been identified within previous schemes. The basis of the hazard categorization, together with the associated generic exposure values is summarized in the Table below.

| Hazard Category | Human Health Classification | | | Generic Exposure Value | |
|--|-----------------------------|----------------------------|--|------------------------|-----------------------------|
| | Risk Phrase | Classification | Descriptor | Volatiles (ppm) | Solids (mg/m ³) |
| L O W | | U | Acute Toxicity, Irritation, Repeated Dose Toxicity | 10 | 1 |
| | R20 | H | Acute Toxicity Inhalation | | |
| | R21 | H | Acute Toxicity Dermal | | |
| | R22 | H | Acute Toxicity Oral | | |
| | R65/67 | H | Aspiration/Drowsiness | | |
| | R36 | I | Irritation Eye | | |
| | R37 | I | Irritation Respiratory System | | |
| R38/R66 | I | Irritation Skin (Repeated) | | | |
| M E D I U M | R48 | H | Prolonged Exposure | 1 | 0.1 |
| | R40 | H | Cat 3 Carcinogen | | |
| | R68 | H | Cat.3 Mutagen | | |
| | R62, R63 | H | Cat 3 Reproduction | | |
| | R23 | T | Acute Toxicity Inhalation | | |
| | R24 | T | Acute Toxicity Dermal | | |
| | R25 | T | Acute Toxicity Oral | | |
| | R39 | T | Irreversible Effects | | |
| | R43 | I | Sensitisation: Skin | | |
| | R41 | I | Severe Eye Irritation | | |
| R34, R35 | C | Corrosion | | | |
| H I G H | R42 | H | Sensitisation/Inhalation | 0.05 | 0.005 |
| | R48 | T | Prolonged Exposure | | |
| | R45/49 | T | Carcinogen Cat. 1, 2 | | |
| | R46 | T | Mutagen Cat. 1, 2 | | |
| | R60, R61 | T | Reproduction Cat 1, 2 | | |
| | R26 | VT | Acute Toxicity Inhalation | | |
| | R27 | VT | Acute Toxicity Dermal | | |
| R28 | VT | Acute Toxicity Oral | | | |

* Substances classified R45, R49, R46, R60 or R61 are of Very High Concern.

Findings

The ECETOC approach has now been validated across a range of representative industrial scenarios. These cover almost seventy situations where chemicals might be routinely encountered within industry and include examples of both good and poor working conditions. ECETOC have explored the utility of a number of exposure prediction models. But the EASE model appears to offer the most reasonable predictive power for the purposes of the ECETOC. In no instance has a false negative (defined as an inability for the ECETOC process to identify a situation considered elsewhere to be a risk) has arisen. And for a screening level process, the frequency of false positives remains acceptable and reassuring at around the 40% level for volatile materials and 30% for solids.

| | | EU Risk Outcome | |
|------------------------------------|----------|--------------------|---------------------|
| | | Concern | No Concern |
| Tier 1 Screening Outcome (solids) | Positive | 15 (True Positive) | 7 (False Positive) |
| | Negative | 0 (False Negative) | 10 (True Negative) |
| Tier 1 Screening Outcome (liquids) | Positive | 9 (True Positive) | 14 (False Positive) |
| | Negative | 0 (False Negative) | 11 (True Negative) |

Accuracy = 68%

Sensitivity = 100%

Summary

The ECETOC approach demonstrates excellent promise in terms of the accuracy and precision it offers and ECETOC will continue to extend the validation to embrace an ever increasing number of scenarios. The approach is workable, simple and understandable for all groups who will be impacted by the contents of the White Paper. It provides a transparent basis for the delivery of consistent risk assessments across the range of circumstances and, accordingly, facilitates the appropriate targeting of resource and expertise. The approach provides for a high degree of automation and, accordingly, enhances the ability of industry to deliver chemical safety reports for a large number of chemicals in a timely and ordered fashion. ECETOC is now developing an integrated web-based model capable of providing a comprehensive assessment of both workplace and consumer health risks at the Tier-1 level.