WE ARE THE CENTRE FOR CHEMICAL SAFETY ASSESSMENT

ECETOC report reviews information used to determine chemical exposure levels that are safe for human health

Brussels, 24 February 2021 – An ECETOC technical report has reviewed the existing information used to determine a substance's 'derived no-effect level' (DNEL), defined as the exposure level beneath which a substance does not harm human health. Establishing a DNEL is a key step in the safety assessment of a chemical under the EU's REACH legislation.

European Chemicals Agency (ECHA) has defined the process to derive DNELs based upon recognised international practices and the need to extrapolate from experimental data (usually from animal testing) to human exposure using assessment factors (AFs). While, ideally, these AFs would be based on chemical-specific information, in practice the scarcity of relevant data necessitates using 'default' AFs.

AFs are used to address the differences between laboratory data, humans, and sensitive subpopulations. They take into account differences between species, human variability, as well as the difference between the duration of a study and how long workers and consumers may be exposed to a substance in reality.

ECETOC has reviewed the science on AFs three times over the past 25 years[i] and concluded that the default approach is conservative and that the available science, albeit limited, supports the use of alternative factors in some cases.

This current review aimed to establish if the available science had changed over the past 10 years, as well as summarising industry's experience in applying the alternative AFs proposed by ECETOC in 2010.

In the case of AFs for intra- and inter-species variation, the current review did not find significant new scientific data beyond that which was available in 2010. The underlying data still supports the views expressed in the earlier ECETOC reviews. However, it has become clear that there are differences between ECHA's and ECETOC's interpretation of the data, and how to combine them into appropriate AFs. The paper recommends that the ECETOC alternative AFs are only used for REACH submissions if supported by chemical-specific justification, including transparent documentation. While the high cost of developing Chemical Specific Adjustment Factors (CSAF) limits this approach to a relatively small number of high-profile, or high-value chemicals, the CSAF case studies support the viewpoint that default AFs are in some cases overly conservative.

In the case of the AFs for study duration, it is recognised that large quantities of mammalian toxicity test data have been generated in recent years under the REACH compliance program. Recent analysis of this and other data points to the need to review the AFs and associated guidance to account for study duration to avoid divergent viewpoints and practices developing.

The full report, Assessment Factors to Derive DNELs – Critical Evaluation of the Status Quo*, can be found here.*

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NOTE TO EDITORS

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ABOUT ECETOC

ECETOC, the Centre for chemical safety assessment, is a collaborative space for leading scientists from industry, academia and governments to develop and promote practical, trusted and sustainable solutions to scientific challenges which are valuable to industry, as well as to the regulatory community and society in general.

[1] *TR 68; ECETOC, 1995; TR 86; ECETOC, 2003 and TR 110; ECETOC, 2010*