ATC POSITION PAPER
On the use of the ED_{10} Approach
to set Specific Concentration Limits (SCL) for Reproductive Toxicants

ATC believes that the European Commission should clarify that, according to the Guidelines on the Application of the CLP Criteria (section 3.7.2.5), the Risk Assessment Committee cannot use ED_{10} method if adequate, reliable and conclusive data are available.

Science-based decision making is a key principle in the EU.

Using default values to set Specific Concentration Limits (SCL) for Reproductive Toxicants rather than existing adequate data does not comply with the above EU principle and with well-established international norms.

Our Ask

When assessing a SCL proposal, we believe that:

a) RAC should first assess whether existing data are adequate, reliable, and conclusive and drawing relevant conclusions from such analysis, including whether the data support the SCL as proposed
b) If the data are considered inadequate or indicate that the proposed SCL should be modified, a weight-of-evidence approach should be used to make a determination, considering all relevant available data
c) RAC should justify and document from a scientific point of view the assessment of such data.

Such policy would encourage the generation of high quality data, determining potential chemical hazards more accurately.

It would also provide a higher scientific precision which lacks in the default assumption of the ED_{10} methodology. By its own nature, ED_{10} method delivers generic conclusions derived from a standardized approach where substances are classified into large potency groups for simplification purposes.

1. Reasons for a change

Industry welcomes the CLP goal of protecting public health and environment and share the ratio of applying the ED_{10} approach on substances with limited dataset.

However, we consider essential the use of adequate, reliable and conclusive data, when available, in order to:

- Ensuring that the classification of the substance under consideration is accurate and the threshold is proportional to the substance's potential hazards
- Confirming the value of generating high quality data for use in chemical hazard characterization and creating incentives for the generation of such data
- Protecting human health and the environment without classifying chemical substances inaccurately thus unduly restricting their use.

2. Current status

The ECHA Guidance on the Application of the CLP Criteria establishes a procedure for setting an SCL for reproductive toxicants (section 3.7.2.5). It provides that the available data from animal and human studies be evaluated to establish the "reproductive toxicity dose descriptor" (ED_{10}). Following the possible application of modifying factors, the substance is then placed in the final potency group that will allow the assignment of a Specific or Generic Concentration Limit.

Section 3.7.2.5.1 of the ECHA Guidance also specifies that "*It is noted that there may be alternative approaches to assess potency, such as basing it on the BMD Methodology (Bench Mark Dose). However such alternative methods are not elaborated in this current guidance, although this does not exclude their use. If alternative approaches are used, they have to be clearly justified from a scientific and regulatory point of view and they must be able to provide robust scientific proposals and justifications*."

It is evident that The Guidance Document sets provisions for the use of alternative methods if they are clearly "justified from a scientific and regulatory point of view" - that is when adequate, reliable, and conclusive data exist.

In spite of such provisions, during its initial use of the ECHA Guidance, RAC seems to be applying the ED_{10} methodology in most cases, even when adequate data exists. This is contrary to international scientific principles and may inhibit the accurate determination of chemical hazard, therefore going against the intended scope of CLP Regulation.

For all the reasons stated above:

ATC believes the European Commission should formally clarify that, according to the Guidelines on the Application of the CLP Criteria, the Risk Assessment Committee should first use adequate, reliable and conclusive data when available and provide a scientific justification if not.