Read-across classification

The Cobalt Development Institute (CDI) is an international trade association of a wholly non-profit making character which has been in existence for over 50-years. The CDI is an association of producers, users and traders of cobalt. The CDI has the following objectives:

(1) Promoting the responsible and sustainable use of cobalt in all forms.

(2) Consulting organisations, agencies and governments for research or investigations in all matters concerning cobalt.

(3) Providing members with topical information on all cobalt matters including health & safety and environmental legislation plus regulatory affairs possibly affecting their interests.

(4) Promoting co-operation between members and providing a forum for the exchange of information concerning the resources, production and uses of cobalt.

Membership of the CDI includes 32 member companies from 16 countries including all the major cobalt producers.

The Board of the CDI has also established three Cobalt REACH Consortia to implement REACH on behalf of the cobalt industry. A separate wholly-owned subsidiary of the CDI, the Cobalt REACH Consortium (CoRC) acts as the Secretariat to the Consortia.

REACH has many ambitions and compelling aims to protect EU citizens and workers from exposure to chemicals, and these are supported by Industry. Over the past years since adoption of the REACH regulation, the cobalt industry has taken its responsibility to comply with the financial, technical, scientific and administrative burden. By 1 December 2010 the registration of cobalt and other relevant cobalt substances (18 in total) had been completed and registration dossiers for a further 8 cobalt substances have been prepared for submission by May 2013.
We are currently continuing with our efforts to ensure that we contribute to the evaluation process. The Cobalt Consortium has already expended over Euro 7million and work continues for the remaining substances covered by the Consortium.

The purpose of the statement below is to clarify the rationale for the classification of a specific cobalt compound, Co octoate, which has been recently questioned through an article in the February 2013 Chemical Watch Magazine (http://chemicalwatch.com/13876/dsm-raises-concerns-about-cobalt-salt-classification).
The EU Classification and Labelling requirements for classified cobalt substances are published on the CDI website: http://www.thecdi.com/cdi/images/documents/Cobalt%20Endpoint%20Table%20v5.pdf.

The preparation of REACH registration files for 28 different Co substances implies the strong need for read-across approaches in order to be able to assess toxicity and

classify all substances while limiting the number of *in vivo* studies in compliance with EU legislation (Art. 13 of regulation (EC) 1907/2006). Together with the need for credible *in vitro* approaches, the CDI has access to many *in vitro*- as well as existing *in vivo* studies (e.g., from individual member companies). This has allowed the CDI to develop considerable expertise in the development and implementation of grouping and read across, as well as (to our knowledge) the largest available database of bioelution studies on Co substances, including Co carboxylates and inorganic salts. This database shows marked differences in bioaccessibility both between the groups (Co carboxylates versus inorganic salts), as well as within each group.

The assumption that there is similar bioaccessibility between cobalt carboxylates and inorganic cobalt salts is therefore incorrect based on CDI data. Equally incorrect is the assumption that read across between the two groups is therefore also generally agreed. On the contrary, the cobalt industry has recognised that in order to develop and agree a read-across strategy, more *in vitro* studies were required, and new data have been collected including a new, solid database of bioelution properties.

Because it has been demonstrated that Co inorganic salts and -carboxylates have very different properties (toxicity, solubility, bioaccessibility), simple read-across between the groups was concluded not to be possible. Instead, the application of read-across for classification must follow a logical and scientific approach on a case-by-case basis, and needs to take into account all available information, such as *in vivo* data and toxicokinetics, in addition to bioelution results.

The classification of Co octoate for reproductive toxicity (Repr. 2) is based on read-across from an inorganic Co salt (Co dichloride). In this particular case, the requirement for assigning the more restrictive category 1B classification has not been met (i.e. shall only be based on clear evidence of adverse effects on fertility in the absence of other toxic effects (Regulation (EC) 1272/2008, Annex I, Section 3.7.2.1.1). Also, both *in vitro* bioaccessibility as well as *in vivo* toxicity data (acute LD50 studies) provide an indication for lower bioavailability of Co octoate than the Cat 1B cobalt salts.

Furthermore, to expand the toxicology database, the co-registrants (manufacturers) have submitted to ECHA relevant testing proposals for analogous cobalt substances, for three repeated-dose and reproductive toxicity studies. If approved, these studies will be carried out and provide a more robust database for read-across decision-making in the context of chronic oral endpoints.

Exposure scenarios have been developed to show safe use of Co octoate, and DUs should be notifying its suppliers (or the Consortium) if they cannot meet the conditions described in the scenarios.

If you have further questions or comments on this matter, please contact the REACH Consortium, at REACHinfo@thecdi.com.