



Downstream Users of Chemicals Co-ordination group

DUCC comments on the 33rd meeting of CARACAL, 15 January 2020

Interchangeable Component Group (ICG) Workability Solution

DUCC welcomes the ICG as a general workability solution. However, considering the proposal from the National Poisons Information Centre of Ireland (post CARACAL-32) and how it has been captured in the latest draft legal text, DUCC members are concerned about the workability of these latest ICG requirements in practise. DUCC believes the Irish proposal can be the basis of a fair and workable way forward. However, modification to the most recent draft legal text is required to meet the needs of clinicians (as highlighted by the Irish poison centre), whilst accommodating external factors imposed on Industry by the wider chemical control framework, contemporary science and supply chain practicalities.

It is noted that the current draft text (prior to the meeting of 15th January) goes further, making mechanism of acute toxic effect a mandatory data requirement of the ICG. The following unintended consequences are foreseen:

- For substances: REACH mandates a tiered approach to toxicity data generation. Therefore, substances registered at lower tonnage bands have inherently less toxicological data than those at higher tonnage bands. Thus, it can reasonably be expected that data on mechanism of acute toxic effect will not be universally available.
- For mixtures: Expert opinion within DUCC reports there is no validated non-animal test method that can generate data on a mixture's mechanism of acute toxic effect. As such, generation of new animal data is the only scientifically viable option, which is in direct contradiction to the intent of the REACH Regulation and does not respect the intent of the CLP Regulation (see Recital 25, Recital 27).
- For mid-level supply chain actors: Mid-level supply chain actors, both large and SME, typically rely on upstream suppliers to provide information on the substances and mixtures they use. Under the conditions proposed, the ability to use the ICG will be taken out of the control of many mid-level supply chain actors. Whilst some large companies may have the commercial scale to demand their supplier's mechanism of action data (assuming it is available), this is not an option for most, particularly SME's. Making mechanism of acute toxic effect a mandatory requirement, would:
 - Limit the use the possibility to use the ICG
 - Increase the administrative burden of Annex VIII via non-availability of the ICG
 - Disproportionately disadvantage SMEs (scale, resources & technical expertise)

These unintended consequences reduce the scope for innovation by reducing ingredient choice, disadvantage mid-level supply chain actors and penalise SMEs, in turn distorting the single market. These unintended consequences are significant and manifestly regressive for industry.



Downstream Users of Chemicals Co-ordination group

Considering the limited time available, DUCC proposes a modification to Sub-section 3.2.4.2. of Part B:

3.2.4.2. Conditions for components to be mutually interchangeable

A submission may include one or more ICGs representing a number of mutually interchangeable components where:

- a) For all mutually interchangeable components in each ICG,*
- the technical function is identical, and*
 - the classification for health and physical hazards (hazard class and category) is identical.*

Where applicable and if available, the mechanism of action for acute toxicity effects shall be indicated.

- b) For all possible combinations of the resulting final mixture based on the mutually interchangeable components, the hazards identification and additional information referred to in Part B Section 2. are identical.*

By way of derogation from 3.2.4.2. (a), for mutually interchangeable components classified only for skin corrosion, skin irritation, eye damage, eye irritation, aspiration toxicity, or respiratory or skin sensitisation, or a combination thereof, it suffices that only their classification for health and physical hazards (hazard class and category) is identical, provided that the pH of all mutually interchangeable components classified for skin corrosion, skin irritation, eye damage, or eye irritation are of a pH range that is either acidic or neutral or alkaline.

It is highlighted that:

- The proposed conditionality is necessary to ensure workability in the short-term and that mechanism of action data feeds into the notification system in the medium-to-long term with the advancement of science.
- No substantive rationale (scientific or otherwise) has been presented for the proposed limitation to the number of interchangeable components in a group when ingredients are classified for skin or respiratory sensitisation. In the opinion of DUCC not justifiable to impose an applicability limit without a sound and clearly communicated basis. Furthermore, an applicability limit based on chronic health classification would appear to provide little added value in support of emergency health response.

DUCC believes that the modification proposed above builds on the intention proposed by the National Poisons Information Centre of Ireland and balances the information desired by poison control centres, against the previously highlighted limitations faced by industry, In turn leading to a robust and sustainable solution for Poison Centres/Appointed Bodies and Industry.



Downstream Users of Chemicals Co-ordination group

Creation of a List of ICG Names

DUCC supports the naming of ICG groups and the creation of a list of ICG group names. This list and contained names must support the needs of medical professionals during emergency response without being excessively inflexible. Therefore, any list of predetermined ICG names in the Poison Centre Notification (PCN) format should be supplemented by a free text option to achieve these aims. It is suggested that stakeholders collaborate to derive a non-exhaustive list of useful ICG names.

IT Tool Update and Roll Out

DUCC highlights the pressing need for ECHA to release a revised PCN format (capturing changes due to the second amendment to CLP Annex VIII). Whilst it is acknowledged that this is a demanding task, Industry's need is business critical. Following PCN release, and before use, Industry then needs to:

- Test the format/software
- Update bespoke software solutions (critical for S2S users)
- Integrate the revised PCN into internal workflows
- Train staff

These actions are essential to operationalise a revised PCN and must occur with enough time to commence submission of notifications before 01 January 2021. It is vital that Commission Services and ECHA ensure that the revised PCN format is released before the end of Q3 2020.

Sector-Focused Workability Solutions

DUCC welcomes the twin track approach adopted to improve the workability of CLP Annex VIII, namely:

- a general workability solution (the ICG)
- sector-focused workability solutions (e.g. standard formulas, bespoke mixtures)

The diversity of the chemical sector and its supply chains means a universal workability solution is desirable but not practicable. Therefore, considered use of sector-focused solutions is appropriate, as is the option to apply previously agreed solutions to other sectors to avoid currently unforeseen workability issues arising in the future.

Whilst it is acknowledged that CARACAL-34 is intended to be the last workability discussion on Annex VIII, DUCC cautions against concluding these discussions in perpetuity. Public and political sentiment (e.g. environmental concerns) will drive innovation in the chemical sector for years to come. Innovation will manifest as both novel products and new approaches to placing product on the market. It is therefore essential that further workability discussions, according to the twin track approach, are a possibility. With the passage of time, Annex VIII must continue to support emergency health response to chemical exposure in an administratively effective way, whilst not acting as barrier to innovation, sustainability or market access.



Downstream Users of Chemicals Co-ordination group

31 January 2020

About DUCC

DUCC is a joint platform of **11 European associations** whose member companies use chemicals to **formulate mixtures** (as finished or intermediary products) for professional and industrial users, as well as for consumers.

DUCC focuses on the downstream users' needs, rights, duties and specificities under **REACH** and **CLP**.

DUCC's membership represents several important industry sectors, ranging from cosmetics and detergents to aerosols, paints, inks, toners, pressroom chemicals, adhesives and sealants, construction chemicals, fragrances, lubricants and chemical distributors industries. Altogether, their membership comprises more than **9.000 companies** across the respective sectors in Europe, the vast majority being SMEs. The calculated turnover of these companies is more than **215 billion euros** in Europe.

For more information on DUCC: www.ducc.eu

Jan Robinson – DUCC Chair, j.robinson@cepe.org

Divina Gómez – DUCC vice-Chair, d.gomez@feica.eu

DUCC's public ID number in the **Transparency Register of the European Commission** is: **70941697936-72**