Downstream Users of Chemicals Co-ordination group

DUCC Feedback on CA/74/2020: Assessment of More Than One Constituent Substances

DUCC wishes to provide feedback on the proposal for the Assessment of More Than One Constituent Substances (MOCS) from the perspective of downstream formulators of chemicals.

Potential impact not assessed:

Whilst it is acknowledged that CA/74/2020 is a preliminary document, it is troubling that ECHA has not provided any data on the potential scope of this proposal. ECHA has stated that "*For the purpose of this paper [CA/74/2020], UVCBs and other substances with more than one component (i.e. monoconstituent substances with impurity(ies), and multiconstituent substances) are herein referred to as "more than one constituent substances (MOCS)*". Yet in Footnote 4 ECHA states: "*For the purposes of this document, we treat impurities and constituents as equivalent, and consider the implications for mono-, multi-constituents substances and UVCBs. As a consequence, when we refer to constituent in the document it is meant constituent or impurity.*". This contrasts with ECHA guidance on substance identification[1] which distinguishes an impurity ("*An unintended constituent present in a substance as manufactured. It may originate from the starting materials or be the result of secondary or incomplete reactions during the manufacture process. While it is present in the final substance it was not intentionally added.*") as a discrete, separate and undesired type of constituent ("*Any single species present in a substance that can be characterised by its unique chemical identity.*"). It is not credible or appropriate for ECHA to propose deviation from its own, well established guidance in this manner, particularly without thoroughly assessing and communicating the impact of this deviation. Applying the above logic suggests that effectively all chemical substances within the scope of REACH would be regarded as a MOCS and therefore subject to this proposal. The only exception would effectively be substances with a purity of greater than 99.9 %.

Given that ECHA reports elsewhere[2] that 23,274 substances have been registered according to REACH. It is essential to an informed discussion on this proposal that ECHA provide a comprehensive breakdown on the number of substances that are actually within scope of this proposal. Specifically, ECHA should report:

- The discrete number of UVCB, multi-constituent, mono-constituent and "mono-constituents with impurities" that have been registered according to REACH.
- A discrete breakdown of the registered tonnage band for each of these categories.
- The discrete number of substances within each of the above categories that are classified as Carcinogenicity, Mutagenicity and/or Reproductive Toxicity.
- The discrete number of substances which contain a constituent (or impurity) which is classified as Carcinogenicity, Mutagenicity and/or Reproductive Toxicity.
- The discrete number of mono-constituent substances that are registered with a minimum purity limit of 99 % for the main constituent.

Example data tables are provided in Appendix 1, to help ECHA's response to these concerns.

[1] European Chemicals Agency "*Guidance for identification and naming of substances under REACH and CLP*" (May 2017, Version 2.1).

[2] European Chemicals Agency (2020) REACH Registration statistics (Data as of: 06 December 2020) (Accessed: 15 December 2020)

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Preliminary impact on Downstream Formulators:

Following review of CA/74/2020 DUCC notes that:

- CMR Category 1 MOCS: ECHA reports in section 4.1.1. that in certain circumstances "*there may not be a need to generate information on the substance also related to certain other CMR properties*" and consequently (in section 4.1.2.) "*test information for specific CMR properties may not be available using the whole MOCS as test material*". The specific consequence for downstream formulators, as reported by ECHA, is that "*there may not be sufficient information on the MOCS for risk management of the mixture and the potential hazard of the mixture may be underestimated*".
- CMR Category 2 MOCS: ECHA reports when "*it is evident that testing of other constituents could result in a stricter classification, and so further information is required for the MOCS for the CMR property for which the substance is already classified*".

For downstream users of chemicals, both classification information and endpoint test data made available in the supply chain are used to:

- inform the classification and labelling of the products these substances are used in
- conduct the risk assessments that determine suitable product use
- and ultimately define safe storage, use and disposal requirements.

Therefore, it is essential that these substances are classified and labelled using relevant, reliable, and robust scientific data, prior to this information being communicated down the supply chain. Preliminary assessment of CA/74/2020 suggests:

- CMR Category 1 MOCS: A reduction in the amount of scientific data communicated in the supply chain for CMR endpoints.
- CMR Category 2 MOCS: What is currently proposed increases uncertainty in supply chain communication. Downstream users of chemicals would be less able to independently confirm what endpoint data should be made available by a supplier and the correlation between substance classification and any supporting data reported by a supplier. In essence, how should a formulator respond if a supplier classifies a MOCS a CMR Category 2 based on composition but existing scientific test data is consistent with no hazard classification?
- CMR MOCS (both cases): This proposal calls into question, but fails to address, the relevance of existing data. How should (or should not) existing data that has been previously communicated by suppliers be used by downstream formulators?

In relation to these points, ECHA's publicly disseminated registration statistics[3] suggest that approximately 11,500 substances are registered in tonnage bands above 10 tonnes per annum. At these tonnage bands data on CMR properties is a standard information requirement according to REACH. Whilst not all these substances will be MOCS or will have CMR data available, in the absence of statistics from ECHA it is assumed that most of these substances will need to be reclassified. Consequentially, the impact of thousands of substances being reclassified on downstream users of chemicals can be expected to be disruptively large.

[3] European Chemicals Agency (2020) REACH Registration statistics (Data as of: 06 December 2020) (Accessed: 15 December 2020)

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Based on CA/74/2020, It seems that little or no consideration has been given to the practical consequences of this proposal. DUCC respectfully requests that ECHA assesses how many substances are in scope of this proposal and that this assessment is shared with all stakeholders before further discussion of this proposal.

Brussels, 07 January 2021

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

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

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Appendix 1 – Data Request on the Scope of CA/74/2020

Table 1 – Breakdown of REACH registered MOCS

	1 – 10 tonnes/year	10 – 100 tonnes/year	100 – 1,000 tonnes/year	> 1,000 tonnes/year
UVCB				
Multi-constituent				
Mono constituent (with impurities)				
Mono constituent (without impurities)				
Total				

Table 2 – Breakdown of CMR classification for UVCB MOCS

MOCS	**1 – 10 tonnes/year**	**10 – 100 tonnes/year**	**100 – 1,000 tonnes/year**	**> 1,000 tonnes/year**
Classified as C, M or R.				
Classified for two CMR endpoints.				
Classified for three CMR endpoints.				
Total				

Table 3 – Breakdown of CMR classification for multi-constituent MOCS

MOCS	**1 – 10 tonnes/year**	**10 – 100 tonnes/year**	**100 – 1,000 tonnes/year**	**> 1,000 tonnes/year**
Classified as C, M or R.				
Classified for two CMR endpoints.				
Classified for three CMR endpoints.				
Total				

Table 4 – Breakdown of CMR classification for mono-constituent MOCS

MOCS	**1 – 10 tonnes/year**	**10 – 100 tonnes/year**	**100 – 1,000 tonnes/year**	**> 1,000 tonnes/year**
Classified as C, M or R.				
Classified for two CMR endpoints.				
Classified for three CMR endpoints.				
Total				

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Table 5 – Breakdown of CMR classification for non-MOCS (i.e. mono-constituents without impurities)

MOCS	1 – 10 tonnes/year	10 – 100 tonnes/year	100 – 1,000 tonnes/year	> 1,000 tonnes/year
Classified as C, M or R.				
Classified for two CMR endpoints.				
Classified for three CMR endpoints.				
Total				