Intentional mixtures under REACH and CLP

Regarding the treatment of mixtures under REACH, the full set of requirements is complex but can be summarised as follows. The Chemical Safety Assessment required for substances produced in quantities greater than 10t per year for substances must cover all identified uses during the substance's life. Where the substance is present in mixtures at levels above the cut-off values set out in CLP[1], then uses in these mixtures must also be included in the Chemical Safety Assessment for the substance and information communicated to downstream users via an extended Safety Data Sheet.

Under REACH, downstream users (including formulators) using the substance in mixtures above the cut-off values identified above must assess whether their uses are covered by the exposure scenarios provided in the eSDS supplied to them and whether the conditions of their own uses of the substance are consistent with those in the eSDS. If they are not, action is required to have the use covered by CSA, implement conditions of use described in the emissions scenario or find a substitute. Again, information in the form of SDS must be passed further down the supply chain.

Uses of mixtures containing substances manufactured or imported in quantities of >10t per year per MI and with properties and concentrations greater than the cut-off values established in CLP[1] are required to be consistent with the operating conditions, risk management measures and exposure scenarios developed through CSA.

If relevant place note here about the amount of unintentional mixtures that are unregulated because of smaller amounts per manufacturer or importer, but with multiple manufacturers and/or importers

Intentional mixtures under CLP

In addition to the above, CLP has specific provisions for assessing the classification of mixtures. The hazard classifications are the same as those for substances under CLP and a classification is made by the formulator based on knowledge of all of the substances and mixtures contained in the mixture for which a classification is to be made. If an ingredient in a mixture is itself a mixture, then information on the substances contained in that mixture must be obtained. Once again, the process is complicated but can be summarised as follows:

- *Classification of physical hazards* - the majority of physical hazards can be determined through testing based using methods set out in Part 2 of Annex I of CLP but it is also possible to determine the classification through a calculation where sufficient data is available;
- *Classification of health and environmental hazards* - there are three main ways by which mixtures are classified for human health or environmental hazards:
    - classification can be derived using data on the mixture itself, by applying the substance criteria of Annex I of CLP, for all hazards except carcinogenicity,

[1] For example, substances with classifications such as Acute Tox. 1-3, Aquatic Acute 1 or Aquatic Chronic 1 contained in mixtures at concentrations above 0.1% or substances with classifications of Acute Tox. 4, Skin Corr./Irrit., Aquatic Chronic 2-4 or Eye Dam./Irrit. contained in mixtures above 1%.

mutagenicity and reprotoxicity, and bioaccumulation and biodegradation properties within the evaluation of “hazardous to the aquatic environment”;

- bridging principles and weight of evidence determination may be used where relevant information on the mixture itself is not available but sufficient data on similar tested mixtures and individual hazardous ingredients exist;
- where test data on the mixture or similar mixtures is not available and bridging principles cannot be applied classification may be based on calculation or on concentration thresholds for the classified substances present in the mixture. Classification of most hazard classes can be based on concentration threshold of which there are two forms: generic cut-off values[2] and generic concentration limits[3]. Specific concentration limits (SCL) or specific cut-off values may be established for individual substances are included in Annex VI of CLP and in the C&L Inventory.

More information on the classification of mixtures can be found in the ECHA Guidance on the Application of the CLP Criteria.

[2] The minimum concentrations for a substance to be taken into account for classification purposes. Where a classified substance is present in a concentration above the generic cut-off value it contributes to the mixture classification even if it does not directly trigger classification of the mixture.

[3] The minimum concentrations for a substance which triggers the classification of a mixture if exceeded by the individual concentration or the sum of concentrations of relevant substances.