

Preparations in EU Chemical Policy

Brief overview of past and present

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Workshop on Special Preparations

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Before REACH – Legislation for Classification and Labelling

- Dangerous Substances Directive (67/548/EC): concerned with hazard classification of substances
- Dangerous Preparations Directive (88/379/EC): concerned with hazard classification of preparations
- United Nations Global Harmonised System (UN GHS): concerned with hazard classification of substances and mixtures

Before REACH – Situation for Alloys in EU

- In the EU, alloys are regarded as preparations and therefore subject to the Dangerous Preparations Directive (hazard classification of preparations)
- Preparations are assumed to be simple mixtures where the constituents retain their own intrinsic properties (e.g. a mixture of salt and sand)
- **But, alloys do not conform to this definition**
as the properties of substances in alloys are modified and some alloys could be regarded to exhibit their own intrinsic properties

Before REACH – Situation for Alloys in EU

- EIMAG 1996 Workshop with as purpose to address alloys in the Dangerous Preparations Directive (DPD)
- Outcome: recital 10 of new DPD (1999/45/EC), recognising “alloys” exhibit their own intrinsic properties and may need their own hazard classification system
- DPD can challenge only non CMR end points
- The Commission failed to address recital 10 of the DPD and instead began to work on REACH

REACH Regulation (1907/2006/EC)

- REACH is concerned with the assessment of *substances* on their own, in *preparations* and in *articles*
- Definitions in REACH
- ✂ *Substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

REACH Regulation (1907/2006/EC)

- ✂ *Preparation*: means a mixture or solution composed of two or more substances;
- ✂ *Article*: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

Alloys in REACH (1907/2006/EC)

If alloys are neither substances nor preparations as defined

What constitutes an alloy in REACH?

- Alloys can be regarded as mixtures (on an atomic scale) that exhibit distinct and different properties from their constituents (i.e. not simple mixtures)
- **This leads to the concept of alloys as**

Special Preparations

What constitutes an « Alloy » in REACH?

- 1) *Definition of Alloy*: means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means;
- 2) *Annex 1, paragraph 0.11*: when assessing the risk of the use of one or more substances incorporated into a special preparation (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account.

What constitutes an « Alloy » in REACH?

- 3) *Recital 31*: the Commission, in close cooperation with industry, Member States and other relevant stakeholders, should develop guidance to fulfil the requirements under this Regulation related to preparations (in particular with regard to safety data sheets incorporating exposure scenarios) including assessment of substances incorporated into special preparations — such as metals incorporated in alloys. In doing so, the Commission should take full account of the work that will have been carried out within the framework of the RIPs and should include the necessary guidance on this matter in the overall REACH guidance package. This guidance should be available before the application of this Regulation.

What constitutes an « Alloy » in REACH?

In response to Recital 31, the Commission asked EIMAG (European Industry Metallic Alloys Group) to organise a

Workshop on an Assessment Methodology for Preparations and Special Preparations

This workshop took place on 10th & 11th October 2006 and resulted in the Guidance for assessment of Special Preparations

What constitutes an « Alloy » in REACH?

- The workshop concentrated on the assessment of Special Preparations and discussed the following options:
 - Simple mixtures;
 - Multi-constituent substances;
 - Exposure scenarios for substance properties modified by incorporation in a chemical matrix;
 - Proposals for the assessment of special preparations.
- The outcome is proposed to feed into RIP-3.2 (CSA) and RIP-3.3 (Testing requirements)

Future of alloys (under EU GHS)

- Alloys (preparations) will become mixtures
- The EU GHS will have the same definition for alloy as the UN GHS and REACH
- For the EU GHS the Commission will retain the testing limitations for CMR end-points
- The derogation for not labelling alloys in the massive form is retained

Thank you for your attention

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