

113-Key Technical Issues

- Pre-REACH position on classification and risk assessment of metals
- Some REACH definitions
- Registration including classification and labelling
- Globally Harmonised System
- Assessment of alloys
- REACH Implementation projects.
- Some unresolved problems

113-Key Technical Issues

Classified elements

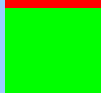
Li	Be											B	C	N				
	Mg											Al	Si	P	S			Ar
Ca	Sc	Ti	V	Cr	Mn	Fe	Co	Ni	Cu	Zn	Ga	Ge	As	Se				
Sr	Y	Zr	Nb	Mo	Tc	Ru	Rh	Pd	Ag	Cd	In	Sn	Sb					
Ba	Lu	Hf	Ta	W	Re	Os	Ir	Pt	Au	Hg	Tl	Pb	Bi					

Lanthanides

La Ce Pr Nd Pm Sm Eu Gd Tb Dy Ho Er Tm Yb



Classified in Annex 1 of Directive 67/548/EEC



Not classified in Annex 1 of Directive 67/548/EEC

113-Key Technical Issues

Risk Assessed Elements

Li	Be										B	C	N	O			
	Mg										Al	Si	P	S		Ar	
Ca	Sc	Ti	V	Cr	Mn	Fe	Co	Ni	Cu	Zn	Ga	Ge	As				
Sr	Y	Zr	Nb	Mo	Tc	Ru	Rh	Pd	Ag	Cd	In	Sn	Sb				
Ba	Lu	Hf	Ta	W	Re	Os	Ir	Pt	Au	Hg	Tl	Pb	Bi				
Lanthanides	La	Ce	Pr	Nd	Pm	Sm	Eu	Gd	Tb	Dy	Ho	Er	Tm	Yb			

Metals subjected to risk assessment under



Existing Substances Regulation 793/93

(voluntarily or resulting from priority lists)

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113-Key Technical Issues

Some Key Definitions: (REACH contains 39 in all)

- 1 Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process.....
- 2 Preparation: means a mixture or solution composed of two or more substances;
- 39 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.
3. 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;

113-Key Technical Issues

Some Key Definitions: (REACH contains 39 in all)

19) Phase-in substance: means a substance which meets at least one of the following criteria:

(a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
..... (Substances deemed to be on the market on 18 September 1981)

8) Manufacturer: means any natural or legal person established within the Community who manufactures a substance within the Community;

10) Importer: means any natural or legal person established within the Community who is responsible for import;

113-Key Technical Issues

Some Key Definitions: (REACH contains 39 in all)

- 12) Downstream user:** means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.....
- 25) Identified use:** means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;
- 35) Exposure scenario:** means the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.

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113-Key Technical Issues

Article 10

Information to be submitted for general registration purposes

A registration required by Article 6 or by Article 7(1) or (5) shall include all the following information:

- (a) a technical dossier including:
 - (i) the identity of the manufacturer (s) or importer (s).....
 - (ii) the identity of the substance.....
 - (iii) information on the manufacture and use(s) of the substance.....
 - (iv) the classification and labelling of the substance.....
 - (v) guidance on safe use of the substance.....
 - (ix) proposals for testing.....etc.
- (b) a chemical safety report when required.....etc.

113-Key Technical Issues-Classification and Labelling

Article 112

Obligation to notify the Agency

1.

(c) the hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC;

(d) the hazard label for the substance(s), resulting from the application of Article 23 (c) to (f), of Directive 67/548/EEC;

(e) specific concentration limits, where applicable, resulting from the application of Article 4(4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.

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113-Key Technical Issues-Global Harmonisation

Recital 97. To promote broad international consensus the Agency should take account of existing and emerging international standards in the regulation of chemicals such as the Globally Harmonised System (GHS) of classification and labelling of chemicals.

113-Key Technical Issues

Globally Harmonised System (GHS)

- Voluntary System for Classification and Labelling of Chemicals initiated by UN in 1990
- GHS good for alloys because it allows for testing out for all end points on a case by case basis.
- EU proposed a Regulation based on GHS and in 2006 invited consultation via the Internet
- Eurofer and Eurometaux responded for metals industries.
- Consultation is now being assessed and a modified Regulation is expected.

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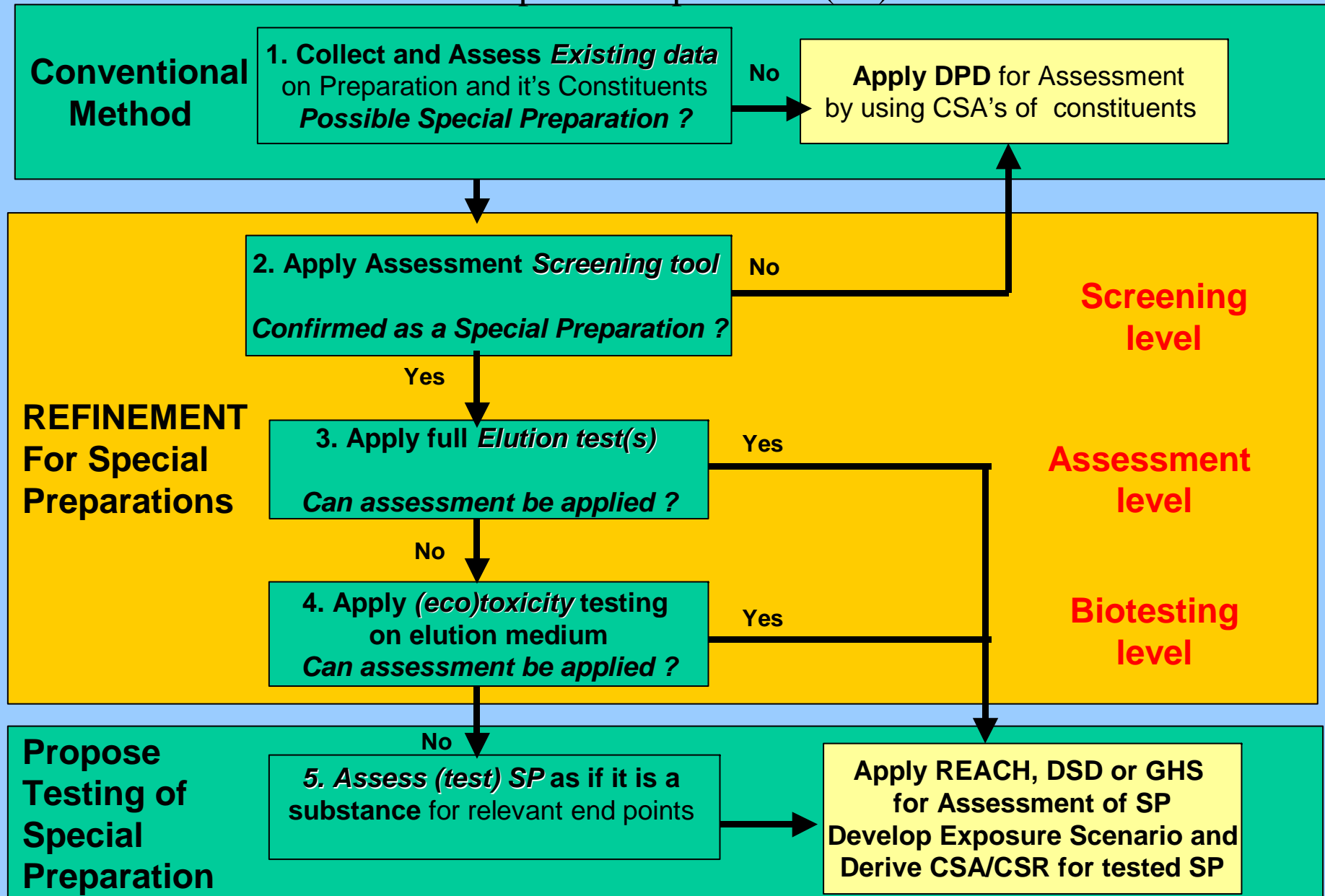
113-Key Technical Issues-Alloys

A potentially important Recital. (One of 117)

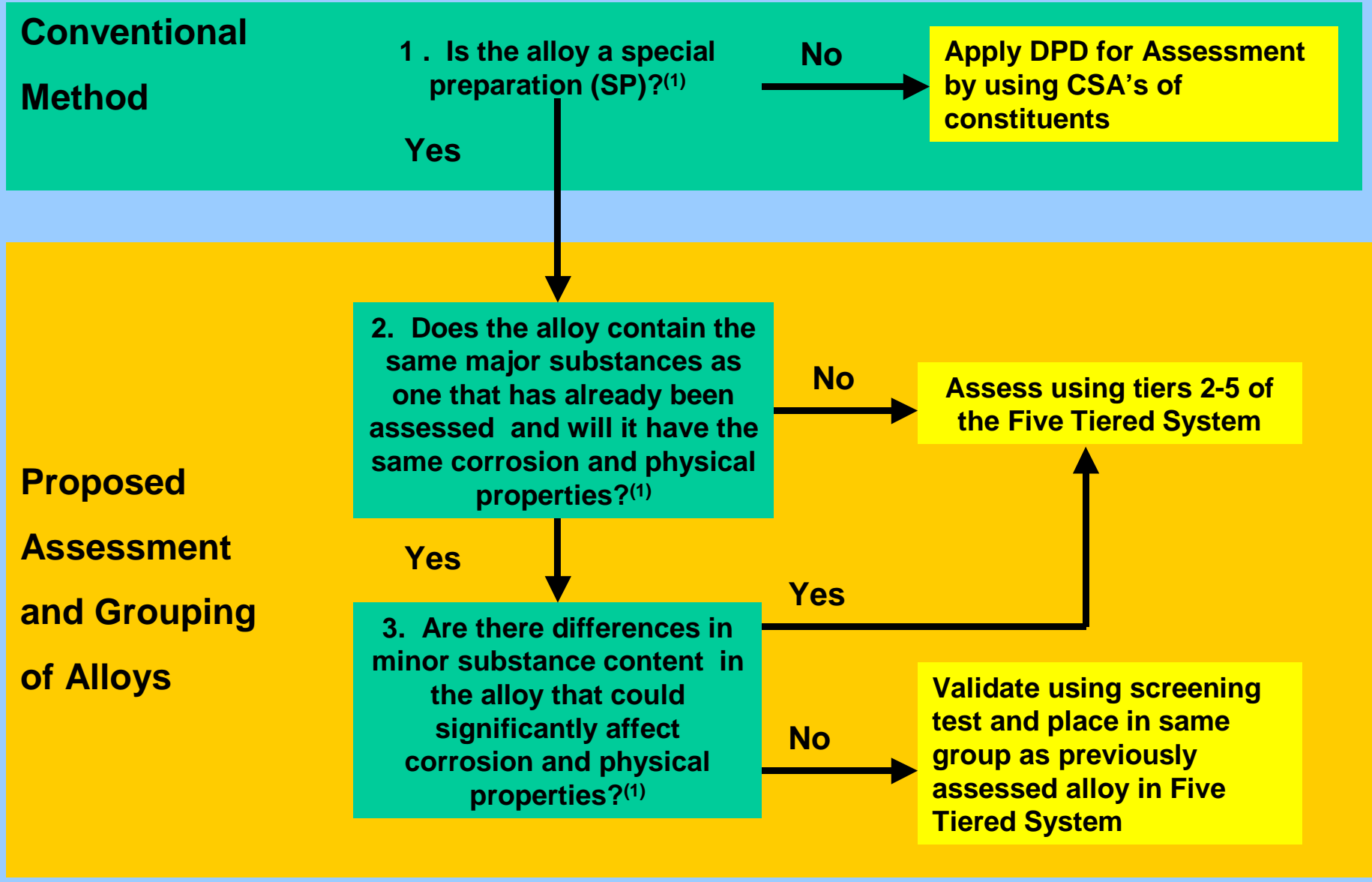
(27) The Commission, in close cooperation with industry, Member States and other relevant stakeholders, should develop guidance to fulfil the requirements under this Regulation related to preparations (in particular with regard to safety data sheets incorporating exposure scenarios) including assessment 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.

EPMA Members Workshop 5-6 December 2006

Five Tiered Decision System for **Health and Environmental** Assessment of Special Preparations (SP)



Grouping of Alloys for Assessment



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113-Key Technical Issues

REACH Implementation Projects

RIP 1: REACH Process Description

RIP 2: REACH – IT

RIP 3: Technical Guidance and Tools for Industry

RIP 4: Technical Guidance and Tools for Authorities

RIP 5: Setting up the Pre-Agency

RIP 6: Setting up the Agency

RIP 7: Commission preparations for REACH

113-Key Technical Issues

RIP 3

RIP 3: TGD's and Tools for Industry	Start	Duration (m)	End
3.1 TGD on preparing the Technical dossier for Registration	Jan 06	6	Jul 06
3.2.-1A TGD on preparing the CSR (1A Scoping)	Dec 04	7	Jul 05
3.2.-1B TGD on preparing the CSR (1A Draft CSA)	Dec 04	7	Jul 05
3.2.-2 TGD on preparing the CSR (2 Guidance Development)	Oct 05	12	Oct 06
3.3-1 TGD on Information Requirements (1: Scoping)	Dec 04	7	Jul 05
3.3.-2 TGD on Information Requirements (2 Guidance Dev)	Oct 05	12	Oct 06
3.4. Guidance Document on Data Sharing (pre-registration)	Oct 05	9	Jul 06
3.5.1 TGD Downstream User Requirements (1: Preliminary Study)	Feb 05	9	Nov 05
3.5.2 TGD Downstream User Requirements (1: Guidance Dev)	Feb 06	10	Dec 06
3.6 Guidance on C and L under GHS	Apr 06	8	Dec 06
3.7 TGD on preparation of application for Authorisation	Apr 06	8	Dec 06
3.8 Guidance on fulfilling requirements for articles	Apr 05	9	Jan 06
3.9.-1 Guidance on carrying out an SEA (1: Preliminary Study)	Feb 05	10.5	Dec 05
3.9.-2 Guidance on carrying out an SEA (2: Guidance Development)	Mar 06	12	Mar 07
3.10 Guidance on performing the substance ID check	Dec 04	7	Jul 05

113-Key Technical Issues-Example document

START-UP GUIDANCE BASED ON THE CONCISE PRELIMINARY TECHNICAL GUIDANCE DOCUMENT

RIP3.2-2, August 2006 (205 pages)

113-Key Technical Issues

PART A: INTRODUCTION TO THE CONCISE P-TGD

- 1 GENERAL INFORMATION**
- 2 DETAILING THE CSA**
- 3 DOCUMENTATION, FORMAT AND TOOLS**

PART B: CONCISE P-TGD

- 1 HAZARD ASSESSMENT**
- 2 PBT AND VPVB ASSESSMENT**
- 3 EXPOSURE ASSESSMENT**
- 4 RISK CHARACTERIZATION**
- 5 FINAL EXPOSURE SCENARIO**
- 6 HOW TO MAKE A CSR**
- 7 HOW TO MAKE AN SDS**

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113-Key Technical Issues-Some other problems

- Nano powders are not mentioned in REACH. How should they be treated? Can they be regarded as separate substances? Can they be given separate CAS numbers and risk assessments? Etc.
- Secondary raw materials are currently regarded as waste.
- Natural diamonds appear to be exempt from REACH. Similarly carbon and graphite are exempt but diamond has a different CAS number. Will “read across” be allowed for assessment and classification? Etc.
- ??