

Meeting 28th May 2008

SPECIAL PREPARATIONS WORKSHOP

Assessment of Special Preparations

Draft Final EIMAG Guidance

Special Preparations

Recital (31) states

“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.”

In response, industry has developed the following flow diagrams, supported by a written text, as guidance on the assessment of special preparations

Special Preparations

REACH Annex I, paragraph 0.11 states

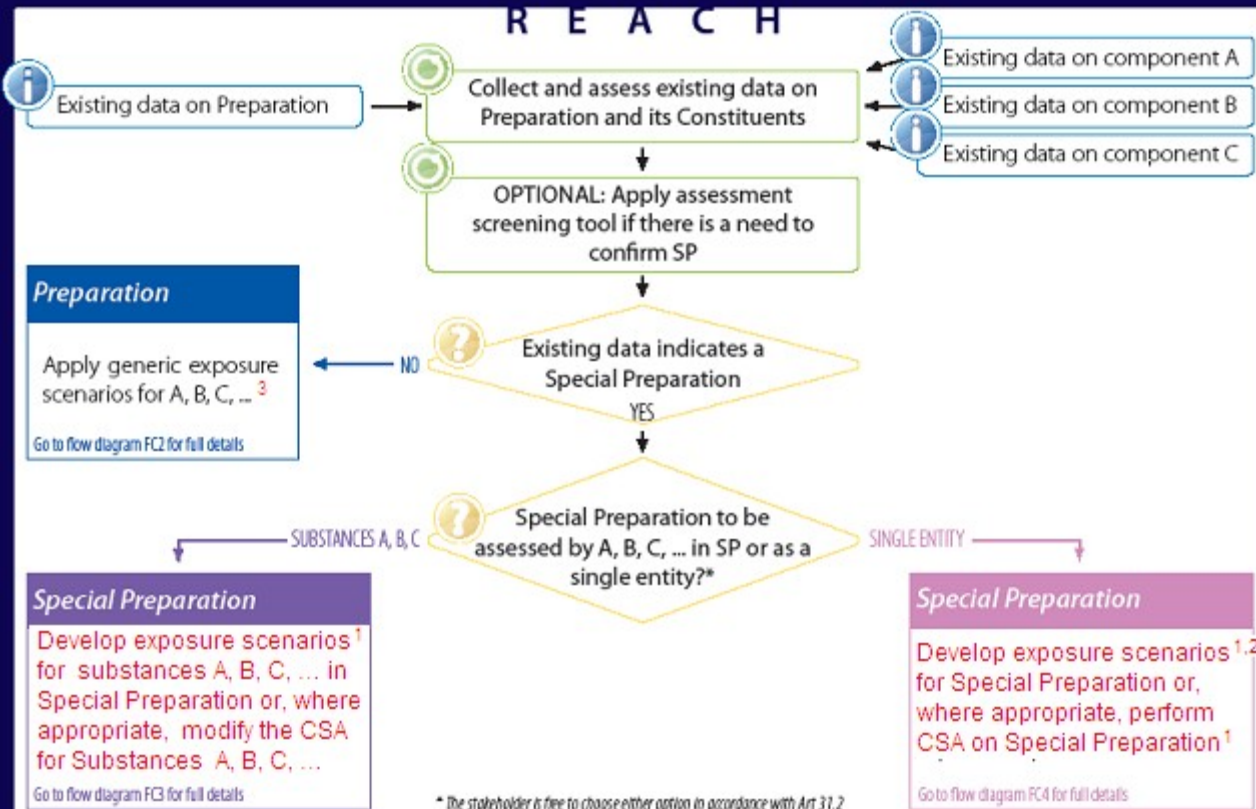
“When assessing the risk of the use of one or more substances incorporated into a special preparation (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account.”

Hence, the following working definition is proposed:-

“Special preparation means a mixture in which the intrinsic properties of one or more constituent substances, as a result of their inclusion within the chemical matrix, cannot be directly applied to the properties of the mixture.”

Special Preparations

Flow diagram FC1: Overview of the assessment of Preparations and Special Preparations



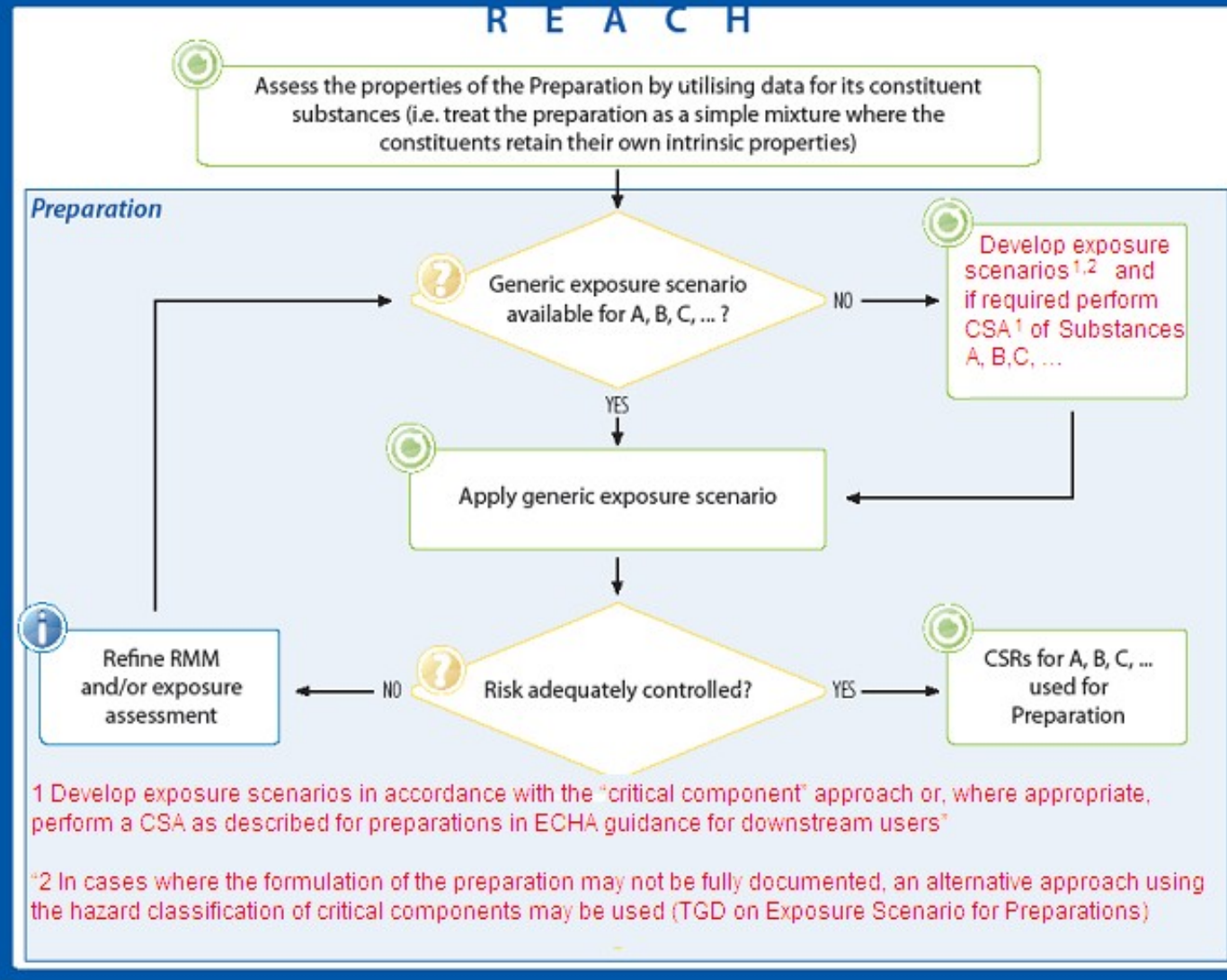
1: Develop exposure scenarios in accordance with the "critical component" approach or, where appropriate, perform a CSA as described for preparations in ECHA guidance for downstream users

2: Apply or, where appropriate, develop generic exposure scenarios to cover a range of preparations

3: Refer on TGD on Exposure Scenario for Preparations

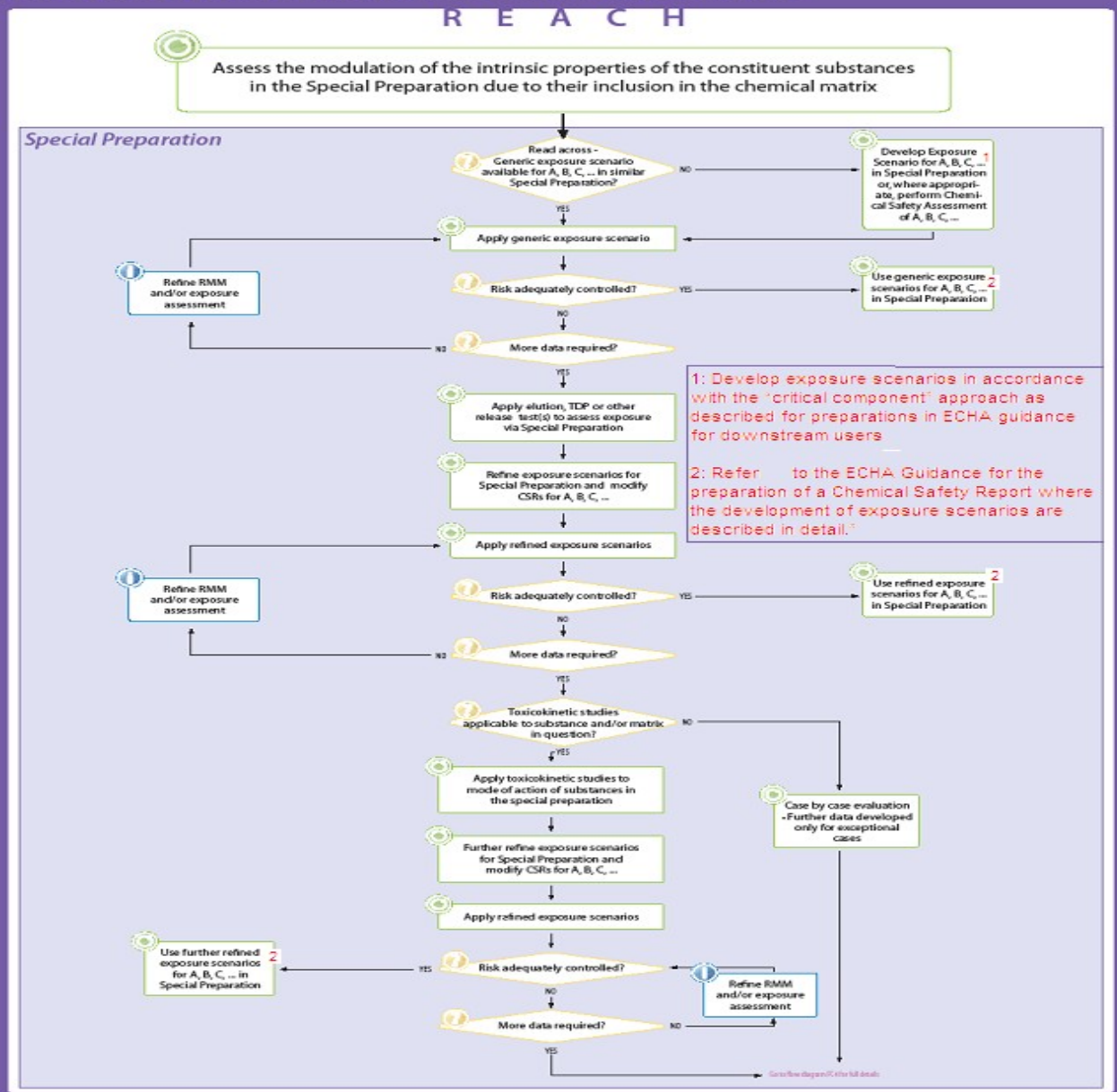
Special Preparations

Flow diagram FC2: Guidance for the Assessment of Preparations



Special Preparations

Flow diagram FC3: Guidance for the Assessment of Special Preparations



Special Preparations

Flow diagram FC4: Guidance for the Assessment of Special Preparations as a single entity

