

# TECHNICAL GUIDANCE DOCUMENT FOR PREPARING THE CHEMICAL SAFETY ASSESSMENT

## Chapter R.1: Introduction

**“Technical Guidance Documents in support of the New EU Chemicals Legislation (REACH) –  
V: Development of a Technical Guidance Document for preparing the Chemical Safety  
Assessment (REACH Implementation Project 3.2-2)”**

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## 1 **R.1 GENERAL INTRODUCTION**

2 This document provides guidance on how the information requirements in REACH may be met.  
3 Comprehensive guidance is provided on the collection and assessment of the available information  
4 on the intrinsic properties of the substances to be registered under REACH, on the information  
5 requirements specified by the Regulation, on the identification of data gaps and on the generation of  
6 the additional information required to comply with the Regulation. In the REACH Regulation, the  
7 information requirements are detailed in Annexes VI through X and Annex XI includes general  
8 rules on how to adapt the standard information requirements set out in Annexes VII-X<sup>1</sup>.

9 To achieve a high level of protection of human health and the environment while limiting the need  
10 for additional testing, all available data on the intrinsic properties of a substance must first be  
11 evaluated. Where available data are not adequate to meet the requirements of the REACH  
12 Regulation, additional testing may need to be generated. However, before embarking on animal  
13 testing, use of alternative methods and all other options must be considered.

14 In this context, Article 13 (1) of REACH states that *information on the intrinsic properties of*  
15 *substances may also be generated by means other than tests, provided that the conditions set out in*  
16 *Annex XI are met. In particular for human toxicity, information shall be generated whenever*  
17 *possible by means other than vertebrate animal tests, through the use of alternative methods, for*  
18 *example, in vitro methods or qualitative or quantitative structure-activity relationship models or*  
19 *from information from structurally related substances (grouping or read-across<sup>2</sup>).*

20 The information collected or generated will be used in a multiplicity of settings within REACH  
21 (e.g. for priority setting, classification and labelling, risk assessment and PBT assessment).  
22 Chemical safety assessment within REACH is fundamentally dependent on an adequate conclusion  
23 on classification and PBT/vPvB assessment since exposure assessment and risk characterisation are  
24 triggered by classification and fulfilment of PBT/vPvB criteria. Therefore data need to be adequate  
25 for both classification & labelling and for chemical safety assessment if the latter is required.

26 Currently in the EU, dangerous substances and preparations must be classified and labelled  
27 according to Directives 67/548/EEC and 1999/45/EC respectively. These Directives will be  
28 repealed in the near future and replaced with a EU Regulation for the classification and labelling of  
29 substances and mixtures that will be based on the Globally Harmonized System<sup>3</sup> (GHS; see also  
30 RIP 3.6).

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<sup>1</sup> Throughout the document, all references to the REACH text refer to Regulation (EC) No.1907/2006 published in the OJ on 30.12.2006

<sup>2</sup> In this guidance these are described as category and analogue approaches respectively

<sup>3</sup> Globally Harmonized System of Classification and Labelling of Chemicals (GHS), first revised edition, United Nations, New York and Geneva, 2005 (ST/SG/AC. 10/30/Rev. 1)