The relevance of REACH Guidance Documents for dossier evaluation under the Biocidal Products Directive 98/8/EC

This document was endorsed at the 35th meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (16-18 December 2009).

1. Introduction

For the implementation of REACH several guidance documents have been developed and are published by the ECHA (see http://guidance.echa.europa.eu/guidance_en.htm). These guidance documents developed for REACH can be used also for the evaluation of biocidal active substances under certain circumstances. This document is meant to provide guidance on the relevance of these REACH guidance documents for the peer review process of active substances.

The following principles can be applied considering the guidance developed under REACH:

- Guidance specifically developed for biocides (TNsGs, ESDs, decisions at the TM or CA meeting) overrules comparable REACH guidance.

- The EU Technical Guidance Document on Risk Assessment (TGD[1]) is, in principle, still valid for the assessment of active substances under 98/8/EC.

- The following REACH guidance documents are directly applicable to biocides:
  - Guidance on how to comply with the provisions of the new Regulation on Classification, Packaging and Labelling of substances and mixtures,
  - Guidance for identification and naming of substances in REACH,
  - Guidance on PBT and vPvB assessment (part C of the Concise Guidance and R11 of the In Depth guidance of Guidance on Information Requirements and Chemical Safety Assessment), and
  - Guidance on IUCLID.

- The following REACH guidance documents describe procedures which are relevant for biocides:
  - Guidance for the preparation of an Annex VI dossier on harmonised classification and labelling: relevant for submitting a proposal to ECHA on harmonised classification and labelling.
  - Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern: relevant for submitting a proposal on the identification of a substance as PBT or vPvB.

- Several parts of REACH guidance may reflect the current scientific and technical knowledge, while this is not the case for the TGD (2003). Therefore, the REACH guidance can be taken into account also for the evaluation of biocides, where relevant.

- Relevant REACH guidance could be taken into account only for the evaluation of biocides, which are not too advanced already. This applies in particular to dossiers from the 3rd and 4th priority list. The REACH guidance can also be relevant for dossiers for which otherwise guidance is missing.

[1] Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances ; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (http://ecb.jrc.ec.europa.eu/tgd/)

2. Guidance on the different processes under REACH

The Technical Meeting evaluated which of the REACH guidance documents are relevant for the biocide evaluation and which are not. Some of the REACH guidance has no relevance for biocides at all, other guidance is entirely new, has no analogy in the biocides area but still needs to be considered and some guidance needs to be considered in parts. A short evaluation of all available REACH guidance documents regarding their relevance for the biocides evaluation can be found in the table below:

No	Guidance Document	Relevance	Remarks
Guidance mainly for Industry Use			
1	Guidance on registration	No	This document describes when and how to register a chemical substance under REACH-Legislation. This guidance/procedure does not apply to biocides.
2	Guidance on pre-registration	No	This document describes how to identify the substances that can be pre-registered under REACH Legislation. This guidance/procedure does not apply to biocides.
3	Guidance on data sharing	No	This guidance describes among others the formation of SIEFs under REACH to share data among: • manufacturers and importers of pre-registered phase-in substances, • phase-in substances registered without pre-registration, • holders of information on phase-in substances that are used as plant protection products and biocides Downstream Users and other stakeholders (Data Holders) who have relevant information. Some principles of data sharing described in the guidance may be useful for biocides.
4	Guidance for monomers and polymers	No	This guidance does not apply to biocides but could be eventually helpful with necessary adoptions.

5	Guidance for intermediates	No	Specific provisions for the registration of intermediates under REACH. These provisions do not apply to biocides.
6	Guidance on Scientific Research and Development (SR8D) and Product and Process Oriented Research and Development (PPORD)	No	This guidance does not apply to biocides but could be eventually of interest.
7	Guidance on Classification and Labelling notification	No	This document describes when and how to notify a classification and labelling for a substance under REACH. This notification is a specific procedure under REACH and is not relevant for biocides.
8	Guidance on requirements for substances in articles	No	This document assists producers and importers of articles in identifying whether they have obligations under REACH, in particular in relation to registration and notification and in relation to article supply chain communication.
9	Guidance for Downstream Users	No	Describes the roles and obligations of downstream users of chemicals under REACH Legislation. This guidance/procedure does not apply to biocides.
10	Guidance on the preparation of an application for authorisation	No	Describes how to prepare an application for authorisation of chemicals under REACH and provides guidance on analysis of the alternatives and substitution plan. This guidance/procedure does not apply to biocides.
11	Guidance on Socio-Economic Analysis – Authorisation	No	Provides information related to socio-economic impacts during the handling of the application of authorisation under the REACH Legislation. This guidance/procedure does not apply to biocides.
Guidance mainly for Authorities Use			
12	Guidance on Dossier and Substance Evaluation	No	Describes the evaluation tasks to be performed by the Authorities: evaluation of testing proposals (testing proposals submitted for tests contained in Annexes IX and X) and compliance check by the Agency and substance evaluation by the MSCA. This guidance/procedure does not apply to biocides.

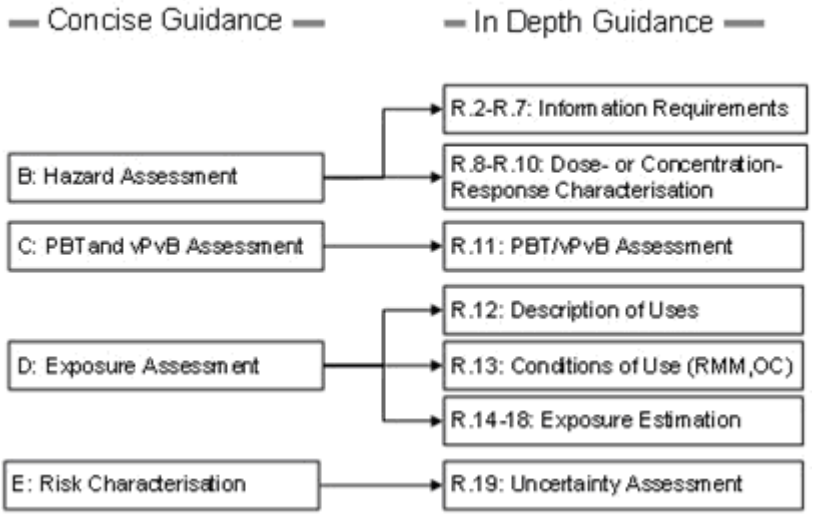
13	Guidance for the preparation of an Annex VI Dossier on Harmonised Classification and Labelling	Yes	This document describes how to prepare an Annex VI dossier for a harmonised classification and labelling proposal.
14	Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern	Yes, partially	This guidance is relevant with respect to the preparation of an Annex XV dossier containing a proposal identifying a substance as a PBT or vPvB.
15	Guidance on inclusion of substances in Annex XIV substances subject to Authorisation	No	Provides an overview on the authorisation procedure from the identification of the substances subject to authorisation until their inclusion in Annex XIV. This guidance does not apply to biocides.
16	Guidance for the preparation of an Annex XV dossier for restrictions	No	Provides an overview how to prepare an Annex XV dossier to propose and justify a restriction on the manufacturing, marketing and use under REACH. This guidance does not apply to biocides.
17	Guidance on Socio-Economic Analysis – Restrictions	Partially	According to Annex VI No. 63 of the BPD the Member State shall take into consideration the benefits of using the biocidal product. But this aspect should play a minor role in the scientific assessment. In case a socio economic analysis must be carried out, the document could be applicable.
Guidance on the different methods under REACH			
18	Guidance for identification and naming of substances under REACH	Yes	Agreed at 24th CA meeting (13-16 March 2007) Due to the fact that a prerequisite of the TNsG on Technical Equivalence is the existence of the same identity of the active substances which are regarded, the Guidance-Document is essential.
19	Guidance on how to comply with the provisions of the new Regulation on Classification. Packaging and Labelling of substances and mixtures	Yes	Provides detailed guidance on how to apply the CLP criteria for physical, health and environmental hazards.
20	Guidance on information requirements and chemical safety assessment	Yes partially	See below for a more detailed evaluation.
21	Guidance on priority setting for evaluation	No	Priority setting for evaluation (testing proposals, dossiers or substances) under REACH. This guidance/ procedure does not apply to biocides.
22	Guidance on IUCLID	Yes	

3. Evaluation of "Guidance on information requirements and chemical safety assessment"

As No 20 seems to be the most important document in this context a more detailed evaluation of the "Guidance on Information Requirements and Chemical Safety Assessment" is necessary for its use as guidance for the biocides evaluation.
This guidance consists of

- a Concise Guidance (Part A to G) and
- of a more detailed In Depth Guidance (or reference guidance containing chapters R.2 to R.20 (see figure 1)).

Figure 1: Abstract of the structure of the "Guidance on Information Requirements and Chemical Safety Assessment"



The guidance describes the data requirements under REACH and represents with respect to risk assessment an advancement of the TGD. The following chapters of the guidance are of major importance for biocides:

Concise Guidance

- Part B: Hazard Assessment
- Part C: PBT and vPvB Assessment
- Part D: Exposure Assessment, if not otherwise decided for the biocide
- Part E: Risk Characterisation, if not otherwise decided for the biocide

In Depth Guidance

- R.6: QSARs and grouping of chemicals
- R.7 a to c: Endpoint specific guidance
- R.8: Characterisation of dose [concentration] - response for human health
- R.10: Characterisation of dose [concentration]-response for environment
- R.11: PBT assessment
- R.16: Environmental exposure estimation

- R.15: Consumer exposure estimation
- R.17: Estimation of exposure from articles
- R.18: Estimation of exposure from the waste life stage
- R.19: Uncertainty analysis