ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

# Guidance on the preparation of an Annex XV dossier for the identification of substances of very high concern

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February 2014

**LEGAL NOTE**

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

**Guidance on the preparation of an Annex XV dossier for the identification of substances of very high concern**

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# Preface

This Guidance Document describes how the authorities (Member States Competent Authorities or the European Chemicals Agency) can prepare a dossier in accordance with Annex XV to identify a substance of very high concern under REACH. It is part of a series of guidance documents that aim to help all stakeholders with their preparation for fulfilling their obligations under the REACH Regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/guidance-documents/guidance-on-reach).

The legal references for the document are Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation)[1] and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, on classification, labelling and packaging of substances and mixtures[2].

[1] Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006).
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p.1).

# Document History

| Version | Changes | Date |
|---|---|---|
| Version 1.0 | First edition (original unnumbered version). | June 2007 |
| Version 2.0 | Second edition. The second edition of this document involved a complete overhaul of the text resulting in a reduction in the amount of detailed guidance given within this document itself. Instead, references are now given within the document to where specific instructions on how to prepare an Annex XV SVHC dossier can be found, including where to access the template for use in generating the Annex XV SVHC report.<br>The revision was necessary in order to take into account actual experience gained by the Member State Competent Authorities and ECHA in the preparation of dossiers and real working practices and to take account of the amendment of Annex XIII of REACH (according to Commission Regulation (EU) No 253/2011 of 15 March 2011, OJ L 69 7 16.3.2011). Most of the content of the previous version of the guidance had been written before REACH came into force and therefore before real experience was available on implementing the processes it described.<br>In addition, the title of the document has been amended slightly to "Guidance **on** the preparation of an Annex XV *dossier* ***for*** *the identification of substances* of very high concern" to better align it with the text of Annex XV itself. | February 2014 |

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# 1. Introduction

This document provides technical guidance to the Member States and the European Chemicals Agency on the preparation of a dossier in accordance with Annex XV to REACH. It gives guidance on how to propose and justify the identification of substances of very high concern ('SVHCs') in accordance with the procedure set out in Article 59 of the REACH Regulation (hereinafter referred to as an 'Annex XV SVHC dossier'). In this document the term 'Authority' is used to refer to the Agency (i.e. ECHA) or any Member State competent authority developing an Annex XV SVHC dossier. Where the term SVHC is used in this guidance, it refers to all substances covered by Article 57 of REACH.

# 2. Legal framework

The authorisation procedure aims to ensure that the risks from SVHCs are properly controlled and that these substances are progressively replaced by suitable alternatives where these are economically and technically viable, whilst at the same time ensuring the good functioning of the EU internal market. A description of the procedure to include substances in the authorisation process is available in the Regulations section of ECHA's website at: http://echa.europa.eu/web/guest/regulations/reach/authorisation.

SVHCs which may be included in Annex XIV to REACH, and for which thereby the authorisation requirement will be established, are substances with the following properties:

| Legal reference | Hazard class | Identification criteria |
|---|---|---|
| Article 57 (a) REACH | Carcinogenicity category 1 A/B | Section 3.6 of Annex I to the Regulation (EC) No 1272/2008 (CLP Regulation) |
| Article 57 (b) REACH | Germ cell mutagenicity category 1 A/B | Section 3.5 of Annex I to the CLP Regulation |
| Article 57 (c) REACH | Reproductive toxicity category 1 A/B, adverse effects on sexual function and fertility or on development | Section 3.7 of Annex I to the CLP Regulation |
| Article 57 (d) REACH | Persistent, bioaccumulative and toxic (PBT) | Annex XIII to the REACH Regulation (as amended[3]) |
| Article 57 (e) REACH | Very persistent and very bioaccumulative (vPvB) | Annex XIII to the REACH Regulation (as amended[3]) |
| Article 57 (f) REACH | Equivalent level of concern to those of other substances listed in point (a) to (e) of Article 57 of REACH[4] | *Substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of Article 57 points (d) or (e) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in Article 57 points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59 of REACH.* |

[3] Commission Regulation (EU) No 253/2011 of 15 March 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) as regards Annex XIII (OJ L 69/7, 16.3.2011)
[4] Hereinafter referred to as 'substances of equivalent level of concern'

# 3. Preparation of an Annex XV dossier for the identification of substances of very high concern (Article 57 of REACH)

## 3.1 Before starting to prepare a dossier

Before initiating work on an Annex XV SVHC dossier, the Authority should check whether another Member State or the Agency is already preparing such a dossier on the same substance or whether the substance is currently subject to another process under REACH (*e.g.* restriction, substance evaluation *etc.*). This can be done by checking the Registry of Intentions (RoI)[5]. Furthermore, it should be checked whether the substance is listed in the Community Rolling Action Plan (CoRAP) for substance evaluation.

Even if the substance is not listed in any of the formal REACH or CLP processes, the Authority is encouraged to check via the Activities Coordination Tool (ACT) whether the substance is under consideration by other Member States for further regulatory risk management (RRM). If another process is under consideration or has been initiated for the same substance, it is recommended to contact the other Authorities working on the substance to ensure that work is not duplicated.

Where the SVHC identification is based on an adverse effect for which classification criteria have been defined in the CLP Regulation and the substance has not yet been classified for such adverse effect, it is strongly recommended to first use the process set out in the CLP Regulation to conclude whether these criteria are met before proposing such substance to be identified for inclusion in the candidate list. Where the identification is not based on effects for which there are classification criteria in the CLP Regulation, more information and advice on how to assess and structure the relevant information can be found within this guidance and in related documents on the support section of ECHA's web-site: http://echa.europa.eu/web/guest/support/authorisation/substances-of-very-high-concern-identification.

## 3.2 Preparing a dossier

As soon as the Authority starts work on preparing the Annex XV dossier, they should inform ECHA, so that the ACT entry for the substance can be updated promptly and the information on the intention to prepare an Annex XV SVHC dossier can be included in the RoI.

An Annex XV SVHC dossier consists of two parts:

a) The Annex XV SVHC report: This report should be attached to the technical dossier in IUCLID.

   The information provided in Part I of the report is used to make the hazard based assessment of the properties and to confirm whether the substance can be successfully identified as an SVHC.

   The information in Part II of the report is used in the next step of the authorisation process, *i.e.* the prioritisation of substances from the Candidate List to be recommended for inclusion in Annex XIV to REACH (and become subject to the authorisation requirements). The ***registration dossiers*** are the ***main source of information*** for this

[5] http://echa.europa.eu/addressing-chemicals-of-concern

part of the SVHC report. In addition, information from downstream user reports and classification and labelling notifications should be used. Furthermore, any other available relevant information can be used.

b) A technical dossier (in IUCLID format): This should include information on substance composition and can include robust study summaries imported from registration dossiers. It is recommended to copy these robust study summaries, stored as endpoint study records in IUCLID, as references (cf. referencing endpoint study records in the IUCLID manual D.4.7.10). In that way, the link with the source of the information used in the Annex XV SVHC report remains available. These reference study records can be annotated by the Authority as needed, or new (robust) study summaries can be created by the Authority when the information extracted from the registration dossiers is incorrect or should be revised substantially or when additional data is available.

The expression "Annex XV SVHC dossier" is used in this Guidance to refer to the combined package of a) the Annex XV SVHC report, plus, b) the technical (IUCLID) dossier.

The Authority should (i) collect the relevant information, (ii) assess the information, (iii) compare it to the relevant criteria, (iv) draw conclusions as to whether the criteria are met and (v) document the information, assessment and conclusions in the Annex XV SVHC report.

The *Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA)* (available at http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment) contains detailed guidance on the interpretation of studies in relation to the individual criteria. The present guidance therefore does not discuss technical issues in relation to such studies. If the basis for the identification is Article 57 of REACH (a), (b) or (c), (i.e. it is Carcinogenic/Mutagenic/Toxic for Reproduction category 1A/B (CMR)), then it is sufficient to provide in Part I of the Annex XV SVHC report a reference to the respective entry in Annex VI of the CLP Regulation. If the basis for the identification is Article 57 (d), (e) or (f), then the Annex XV SVHC dossier should provide full details on how these criteria have been met.

Authorities should use the **annotated Annex XV template** when preparing an Annex XV report, proposing the identification of a substance as an SVHC. It is available on the support section of ECHA's web-site at: http://echa.europa.eu/web/guest/support/authorisation/substances-of-very-high-concern-identification.

## 3.3 Further guidance and support

More detailed information and advice can be found in the support section of the ECHA website under "substances of very high concern identification": http://echa.europa.eu/web/guest/support/authorisation/substances-of-very-high-concern-identification, including the annotated Annex XV template for the preparation of the Annex XV report.

Procedural advice including ECHA's procedure for handling the identification of SVHCs is also provided in the aforementioned section, with the aim of ensuring that it is the latest available information on emerging and developing issues, with respect to SVHCs.

The support section also contains guidance documents on the *identification and naming of substances under REACH and CLP* and on *IR&CSA*. *Part C* and *Chapter R.11* of the *Guidance on IR&CSA* are particularly relevant for PBT/vPvB assessment, as these parts/chapters describe the scientific methods associated with the assessment. See: http://echa.europa.eu/guidance-documents/guidance-on-reach.

## 3.4 What to do when an Annex XV dossier is not appropriate

There may be cases where the Authority carries out work on an Annex XV dossier but concludes that there is no need for a dossier at this point in time. In such cases, it is important that the work that has already been undertaken is not lost, but is made available for potential future work. Thus, the Authority is encouraged to record the results of the work it has carried out via the ACT. A simple description of the work undertaken and the reasons why it was decided not to proceed may be sufficient.

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