

Status: Point in time view as at 12/10/2008.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, ANNEX XIII. (See end of Document for details)

[^{XI}ANNEX XIII

CRITERIA FOR THE IDENTIFICATION OF PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES

Editorial Information

XI Substituted by 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 (Official Journal of the European Union L 396 of 30 December 2006).

This Annex lays down the criteria for the identification of:

- (i) persistent, bioaccumulative and toxic substances (PBT-substances), and
- (ii) very persistent and very bioaccumulative substances (vPvB-substances).

A substance is identified as a PBT substance if it fulfils the criteria in Sections 1.1, 1.2 and 1.3.

A substance is identified as a vPvB substance if it fulfils the criteria in Sections 2.1 and 2.2.

This annex shall not apply to inorganic substances, but shall apply to organo-metals.

1. PBT-SUBSTANCES

A substance that fulfils all three of the criteria of the sections below is a PBT substance.

1.1. Persistence

A substance fulfils the persistence criterion (P-) when:

- the half-life in marine water is higher than 60 days, or
- the half-life in fresh- or estuarine water is higher than 40 days, or
- the half-life in marine sediment is higher than 180 days, or
- the half-life in fresh- or estuarine water sediment is higher than 120 days, or
- the half-life in soil is higher than 120 days.

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant.

1.2. Bioaccumulation

A substance fulfils the bioaccumulation criterion (B-) when:

- the bioconcentration factor (BCF) is higher than 2 000.

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

1.3. Toxicity

A substance fulfils the toxicity criterion (T-) when:

- the long-term no-observed effect concentration (Noec) for marine or freshwater organisms is less than 0,01 mg/l, or

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- the substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or
- there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

2. vPvB-SUBSTANCES

A substance that fulfils the criteria of the sections below is a vPvB substance.

2.1. Persistence

A substance fulfils the very persistence criterion (vP-) when:

- the half-life in marine, fresh- or estuarine water is higher than 60 days, or
- the half-life in marine, fresh- or estuarine water sediment is higher than 180 days, or
- the half-life in soil is higher than 180.

2.2. Bioaccumulation

A substance fulfils the very bioaccumulative criterion (vB-) when:

- the bioconcentration factor is greater than 5 000.]

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