

## ANNEX XIII

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

This Annex lays down the criteria for the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) as well as the information that must be considered for the purpose of assessing the P, B, and T properties of a substance.

For the identification of PBT substances and vPvB substances a weight-of-evidence determination using expert judgement shall be applied, by comparing all relevant and available information listed in Section 3.2 with the criteria set out in Section 1. This shall be applied in particular where the criteria set out in Section 1 cannot be applied directly to the available information.

The approach to classification of mixtures to ensure that available information can be applied as much as possible to protect human health and the environment may involve the application of expert judgment in some areas. The expert judgement may also be necessary in interpretation of the data for classification of the hazardous substances, especially where the determination of the weight of evidence is necessary.

A weight-of-evidence determination means that all available information bearing on the identification of a PBT or a vPvB substance is considered together, such as the results of monitoring and modelling, suitable in vitro tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well documented case reports and observations. The quality and consistency of the data shall be given appropriate weight. The available results regardless of their individual conclusions shall be assembled together in a single weight-of-evidence determination.

The information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions.

The identification shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products.

This Annex shall apply to all organic substances, including organo-metals.

#### **1. CRITERIA FOR THE IDENTIFICATION OF PBT AND vPvB SUBSTANCES**

##### **0.1. PBT Substances**

A substance that fulfils the persistence, bioaccumulation and toxicity criteria of Sections 1.1.1, 1.1.2 and 1.1.3 shall be considered to be a PBT substance.

###### **1.1.1. Persistence**

A substance fulfils the persistence criterion (P) in any of the following situations:

- (a) the degradation half-life in marine water is higher than 60 days;
- (b) the degradation half-life in fresh or estuarine water is higher than 40 days;
- (c) the degradation half-life in marine sediment is higher than 180 days;
- (ç) the degradation half-life in fresh or estuarine water sediment is higher than 120 days;
- (d) the degradation half-life in soil is higher than 120 days.

#### 1.1.1. Bioaccumulation

A substance fulfils the bioaccumulation criterion (B) when the bioconcentration factor in aquatic species is higher than 2000.

#### 1.1.2. Toxicity

A substance fulfils the toxicity criterion (T) in any of the following situations:

- (a) the long-term no-observed effect concentration (NOEC) or EC10 for marine or freshwater organisms is less than 0,01 mg/l;
- (b) the substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B, or 2) according to By-law on Classification, Labelling and Packaging of Substances and Mixtures;
- (c) there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to By-law on Classification, Labelling and Packaging of Substances and Mixtures.

#### 1.2. vPvB Substances

A substance that fulfils the persistence and bioaccumulation criteria of Sections 1.2.1 and 1.2.2 shall be considered to be a vPvB substance.

##### 1.2.1. Persistence

A substance fulfils the ‘very persistent’ criterion (vP) in any of the following situations:

- (a) the degradation half-life in marine, fresh or estuarine water is higher than 60 days;
- (b) the degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days;
- (c) the degradation half-life in soil is higher than 180 days.

##### 1.2.2. Bioaccumulation

A substance fulfils the ‘very bioaccumulative’ criterion (vB) when the bioconcentration factor in aquatic species is higher than 5 000.

## **2. SCREENING AND ASSESSMENT OF P, vP, B, vB and T PROPERTIES**

### **2.1. Registration**

For the identification of PBT and vPvB substances in the registration dossier, the registrant shall consider the information as described in Annex I and in Section 3 of this Annex.

If the technical dossier contains for one or more endpoints only information as required in Annexes VII and VIII, the registrant shall consider information relevant for screening for P, B, or T properties in accordance with Section 3.1 of this Annex. If the result from the screening tests or other information indicate that the substance may have PBT or vPvB properties, the registrant shall generate relevant additional information as set out in Section 3.2 of this Annex. In case the generation of relevant additional information would require information listed in Annexes IX or X, the registrant shall submit a testing proposal. Where the process and use conditions of the substance meet the conditions as specified in Section 3.2(b) or (c) of Annex XI the additional information may be omitted, and subsequently the substance is considered as if it is a PBT or vPvB in the registration dossier. No additional information needs to be generated for the assessment of PBT/vPvB properties if there is no indication of P or B properties following the result from the screening test or other information.

### **2.2. Authorisation**

For dossiers for the purposes of identifying substances referred to in Article 47(ç) and Article 47(d), relevant information from the registration dossiers and other available information as described in Section 3 shall be considered.

## **3. INFORMATION RELEVANT FOR THE SCREENING AND ASSESSMENT OF P, vP, B, vB and T PROPERTIES**

### **3.1. Screening Information**

The following information shall be considered for screening for P, vP, B, vB and T properties in the cases referred to in the second paragraph of Section 2.1 and may be considered for screening for P, vP, B, vB and T properties in the context of Section 2.2.

#### **3.1.1. Indication of P and vP properties**

- (a) Results from tests on ready biodegradation in accordance with Section 9.2.1.1 of Annex VII;
- (b) Results from other screening tests (tests on inherent biodegradability);
- (c) Results obtained from biodegradation (Q)SAR models in accordance with Section 1.3 of Annex XI;
- (ç) Other information provided that its suitability and reliability can be reasonably demonstrated.

#### **3.1.2. Indication of B and vB Properties**

(a) Octanol-water partitioning coefficient experimentally determined in accordance with Section 7.8 of Annex VII or estimated by (Q)SAR models in accordance with Section 1.3 of Annex XI;

(b) Other information provided that its suitability and reliability can be reasonably demonstrated.

### 3.1.3. Indication of T properties

(a) Short-term aquatic toxicity in accordance with Section 9.1 of Annex VII and Section 9.1.3 of Annex VIII;

(b) Other information provided that its suitability and reliability can be reasonably demonstrated.

## 3.2. Assessment Information

The following information shall be considered for the assessment of P, vP, B, vB and T properties, using a weight-of-evidence approach.

### 3.2.1. Assessment of P or vP properties

(a) Results from simulation testing on degradation in surface water;

(b) Results from simulation testing on degradation in soil;

(c) Results from simulation testing on degradation in sediment;

(c) Other information, such as information from field studies or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.

### 3.2.2. B or vB properties

(a) Results from a bioconcentration or bioaccumulation study in aquatic species;

(b) Other information on the bioaccumulation potential provided that its suitability and reliability can be reasonably demonstrated, such as:

— Results from a bioaccumulation study in terrestrial species;

— Data from scientific analysis of human body fluids or tissues, such as blood, milk, or fat;

— Detection of elevated levels in biota, in particular in endangered species or in vulnerable populations, compared to levels in their surrounding environment;

— Results from a chronic toxicity study on animals;

— Assessment of the toxicokinetic behaviour of the substance;

(c) Information on the ability of the substance to biomagnify in the food chain, where possible expressed by biomagnification factors or trophic magnification factors.

### 3.2.3. Assessment of T properties

(a) Results from long-term toxicity testing on invertebrates as set out in Section 9.1.5 of Annex IX;

(b) Results from long-term toxicity testing on fish as set out in Section 9.1.6 of Annex IX;

(c) Results from growth inhibition study on aquatic plants as set out in in Section 9.1.2 of Annex VII;

ç) The substance meeting the criteria for classification as carcinogenic in Category 1A or 1B (assigned hazard phrases: H350 or H350i), germ cell mutagenic in Category 1A or 1B (assigned hazard phrase: H340), toxic for reproduction in Category 1A, 1B and/or 2 (assigned hazard phrases: H360, H360F, H360D, H360FD, H360Fd, H360fD, H361, H361f, H361d or H361fd), specific target organ toxic after repeated dose in Category 1 or 2 (assigned hazard phrase: H372 or H373), according to By-law on Classification, Labelling and Packaging of Substances and Mixtures;

d) Results from long-term or reproductive toxicity testing with birds as set out in Section 9.6.1 of Annex X;

e) Other information provided that its suitability and reliability can be reasonably demonstrated.