4.16 Procedure for classification into SOMS concern categories

Introduction

To arrive at a classification into a category of concern, two steps must be taken. First, the hazard class must be established for a substance. This is done for both environment-related properties (persistence, bioaccumulation, (eco)toxicity) and for effects on humans (toxicity, carcinogenicity, mutagenicity, reprotoxicity and hormone disruption). The procedure for this is described in Part 1. In the next step, the concern category must be established on the basis of the classification into hazard classes. In Part 2 it is described which procedure must be followed for establishing the concern category.

1 Criteria for classifying substances according to hazardous properties

1.1 The environment

The classification of substances into hazard classes for the properties Persistence (P), tendency to Bioaccumulation (B) and (Eco)toxicity (T), the so-called BPT profile. For hazard characteristics P, B and T, criteria based on direct quantitative data as well as screening criteria have been established. Here it must be emphasised that direct data should always prevail over screening data when both are available. The criteria are represented in Table 1.

Justification of the criteria

The criteria for the highest hazard classes (P1, T1 and B1; see also Table 1) are chosen in such a way that the decision-making rules for classifying substances into the category 'Very High Concern' correspond to the criteria as laid down in the Interim Strategy for Management of BPT and VPVB Substances (document ENV/D/432048/01) of the EU, which includes both limits for BPT substances and for very persistent, very bioaccumulative substances (the so-called VPVB substances). These criteria are also in line with the criteria for POPS[1)] as established in the UN Stockholm Convention with respect to international action against certain Persistent Organic Pollutants. The criteria and decision-making rules for the category 'High Concern' are identical to the criteria that apply for the initial selection of substances in the OSPAR[2)] DYNAMEC dynamic selection and prioritisation mechanism for hazardous substances.

For the category 'Concern', the criteria and decision-making rules have been chosen in such a way that they correspond with the EU classification and labelling criteria[3)] for 'very toxic for water organisms' and 'toxic for water organisms; can cause long-term damage in waters'. All substances that do not fall into one of the above-mentioned categories are placed in the category 'Low Concern', provided the minimum data requirements have been met. Substances designated as High Production Volume Chemicals (HPVCs) within the framework of Regulation (EEC) 793/93, the Existing Substances Regulation, are also classed on the basis of the data, but are thereafter regarded as a separate category.

Table 1 Criteria for classifying substances according to hazardous properties on the basis of hazards posed for the environment and indirect hazards for humans

Property	Hazard level	Hard criteria	
		Direct	
Persistence **P**	P1	'Not inherently biodegradable' and no fast a-biotic degradation	
	P2	'Inherently biodegradable': slow	
	P3	'Inherently biodegradable': adaptive or incomplete	
	P4	'Readily biodegradable' or otherwise rapidly degradable	
		Direct	**Screening**
Bioaccu-mulation **B**	B1a	BCF ≥ 5000	log K_{ow} ≥ 5
	B1b	BCF ≥ 2000	
	B2	BCF ≥ 500	log K_{ow} ≥ 4
	B3	BCF ≥ 100	log K_{ow} ≥ 3
	B4	BCF < 100	log K_{ow} < 3
(Eco)toxicity **T**	T1	NOEC ≤ 0.01 mg/L or CMRH	LC_{50} ≤ 0.1 mg/L
	T2	NOEC ≤ 0.1 mg/L	LC_{50} ≤ 1 mg/L
	T3	NOEC ≤ 1 mg/L	LC_{50} ≤ 10 mg/L
	T4	NOEC > 1 mg/L	LC_{50} > 10 mg/L

1.2 Humans

The classification of substances into hazard classes with respect to hazards for humans occurs on the basis of the following characteristics: Toxicity (G), Carcinogenicity (C), Mutagenicity (M), Reprotoxicity (R) and Hormone Disruption (H). Together these characteristic (GCMRH) can be designated as 'hazardous for humans'. It has to be said, however, that with respect to the hazard property of hormonal disruption, criteria and test protocols have yet to be determined in an international context. Hence, the inclusion of the property H in the criteria for the characteristic 'hazardous for humans' (the properties GCMRH) is formal only. Once the criteria and guidelines have been established for hormonal disruption, they will be included in the scheme for the criteria for 'hazardous for humans'.

1 Persistent Organic Pollutants.
2 Oslo-Paris Convention for the Protection of the Marine Environment of the North-East Atlantic.
3 Directive 92/32/EEC.

Justification of the criteria

For the hazard characteristics 'hazardous for humans', the criteria are based on the qualitative data that also form the basis of the R-phrases within the framework of the EU obligations for classifying and labelling substances. These European R-phrases and the assignment criteria are part of the Global Harmonisation System (GHS) (as far as they are developed) for worldwide harmonisation of the classification and labelling obligation for substances. The proposed system can, therefore, also be used for the application of the GHS. The selected descriptions specify what the limits are that determine the classification into the hazard classes; the requirements are explicitly not intended to apply only to substances that are already labelled. The classification of substances into hazard classes is largely based on the criteria that have been established in Annex VI EU Directive 67/548/EEC and on the prioritisation strategy within the framework of EURAM.

Criteria

The proposed criteria are listed in Table 2.

Table 2 Criteria for classifying substances according to hazardous properties on the basis of hazards posed for humans

Property	Hazard level	Criteria
Toxicity for humans **G**	1	Danger of serious damage to health by prolonged exposure to very low quantities (R48/23, R48/24, R48/25)
		Very toxic or serious irreversible effects through inhalation (R26, R39/26), in contact with skin (R27, R39/27) or if swallowed (R28, R39/28)
	2	Toxic or serious irreversible effects through inhalation (R23, R39/23), in contact with skin (R24, R39/24) or if swallowed (R25, R39/25)
		May cause sensitisation by skin contact (R43)
		May cause sensitisation by inhalation (R42)
		Causes (severe) burns (R34, R35)
		Contact with water creates (very) toxic gas (R29, R31, R32)
		Vapours may cause drowsiness or dizziness (R67)
	3	Danger of serious damage to health by prolonged exposure to low quantities (R48/20, R48/21. R48/22)
		Harmful or possible risk of irreversible effects through inhalation (R20, R68/20), in contact with skin (R21, R68/21) or if swallowed (R22, R68/22)
		Risk of serious damage to eyes (R41)
		Harmful: may cause lung damage if swallowed (R65)
	4	Irritating to eyes (R36), respiratory system (R37) or skin (R38)
		Repeated exposure may cause skin dryness or cracking (R66)
		Not classified
Carcino-genicity **C**	1	Carcenogenic (R45, R49; cat. 1& 2)
	2	Limited evidence of a carcinogenic effect (R40; cat. 3)
	4	Not classified
Mutagenicity **M**	1	May cause heritable genetic damage (R46) mutagenicity possible (R40)
	4	Not classified
Reprotoxicity **R**	1	May impair fertility or may cause harm to unborn child (R60, R61)
	2	Possible risk of impaired fertility (R62, R63)
		May cause harm to breastfed babies (R64)
	4	Not classified
Hormone disruption **H**	2[4)]	P.M.
	4	Not classified

2 Decision-making rules for classification into categories of concern

2.1 The environment

To determine the category of concern with respect to the environmental hazardous characteristics, use will be made of decision-making rules based on combinations of properties. In order to present the decision-making rules in a well-ordered way, they have been placed in a hierarchical matrix. This classification matrix for categories of concern on the basis of combinations of hazardous characteristics for the environment is given in the table below.

Table 3 Decision-making rules for classification of substances into categories of concern in relation to the environment

Combination of	Properties	P,B, T			
Hazard class	**Hazard class**	**T1**	**T2**	**T3**	**T3**
P1	B1a	VHC	VHC	VHC	VHC
	B1b	VHC	VHC	HC	C
	B2	HC	HC	C	LC
	B3	HC	C	C	LC
	B4	HC	C	C	LC
P2	B1	HC	HC	C	C
	B2	HC	HC	C	LC
	B3	C	C	C	LC
	B4	C	C	C	LC
P3	B1	HC	C	C	LC
	B2	C	C	C	LC
	B3	C	C	C	LC
	B4	C	C	C	LC
P4	B1	HC	C	C	LC
	B2	C	C	C	LC
	B3	C	C	C	LC
	B4	C	C	LC	LC

VHC = Very High Concern
HC = High Concern
C = Concern
LC = Low Concern

2.2 Humans

For classifying substances into categories of concern with regard to the hazards for humans, it has been decided to use combinations of hazard classes. For each hazard characteristic, the different classes are directly linked to a category of concern. The decision-making rules with respect to the hazards for humans, therefore, result in several individual categories of concern to which the substance belongs per hazard characteristic. In order to establish the definitive category of concern with regard to the hazards for humans, the decision-making rule is such that the highest individual category is determinative. The categories of concern associated with the hazard classes can be found in Table 4.

4 For hormonal disruption the highest possible hazard class is H2, the motivation being that, within the European Directive for the classification and labeling of substances, a substance that has been demonstrated to posses hormone-disruptive properties can be classed in the most severe cases as a suspected reprotoxic substance; hence, within the framework of the SOMS criteria and decision-making rules, these substances are classed in hazard class R2.

Table 4 Decision-making rules for classifying substances into categories of concern with regard to the hazards for humans

Hazard property	Hazard class	Category of concern
G	G1	VHC
	G2	HC
	G3	C
	G4	LC
C	C1	VHC
	C2	HC
	C4	LC
M	M1	VHC
	M4	LC
R	R1	VHC
	R2	HC
	R4	LC
H	H1	HC
	H4	LC

VHC = Very High Concern
HC = High Concern
C = Concern
LC = Low Concern

2.3 Combination of 'Environmental concern' and 'Human concern'

The ultimate classification of a substance into a definitive category of concern occurs by comparing the category of concern for the environment with the category of concern for humans. Here the decision-making rule is such that the highest individual category determines the definitive category of concern. This is to say, for example, a substance that scores 'Low Concern' for the environment and 'High Concern' for humans is classified into the category 'High Concern' and a substance that scores 'Low Concern' for humans and 'Very High Concern' for the environment is placed in the category 'Very High Concern'. This also means that a substance for which essential data are lacking for one of the two components (category of concern for the environment and category of concern for humans) is ultimately placed in the category 'No Data', in other words, 'Very High Concern'.

Furthermore, a distinction will be made in the area of measures between the individual categories of concern for the environment and those for humans in which a substance is classed. For the above-mentioned substance, which has been classed in the category 'Very High Concern' on the basis of hazard characteristics for the environment and in the category 'Low Concern' on the basis of hazard characteristics for humans, the environmental measures associated with the category 'Very High Concern' and the human measures associated with the category 'Low Concern' are imposed. This does, however, mean that where these measures overlap the strictest measures should prevail.

More information, including the particulars necessary for classifying substances according to hazard class, can be found in the 'Progress Report, Implementation Strategy on Management of Substances', Ministry of Housing, Spatial Planning and the Environment, The Hague, December 2001. Mid-2003 a manual will also be published concerning this subject.