Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (repealed)

ANNEX III

METHODS FOR THE EVALUATION OF THE ENVIRONMENTAL HAZARDS OF PREPARATIONS IN ACCORDANCE WITH ARTICLE 7

Introduction

The systematic assessment of all the dangerous properties for the environment is expressed by means of concentration limits, expressed as a weight/weight percentage except for gaseous preparations where they are expressed as a volume/volume percentage and in conjunction with the classification of a substance.

Part A gives the calculation procedure according to Article 7(1)(a) and gives the R phrases to be assigned to the classification of the preparation.

Part B gives the concentration limits to be used when applying the conventional method and relevant symbols and R phrases for classification.

In accordance with Article 7(1)(a) the environmental hazards of a preparation shall be assessed by the conventional method described in parts A and B of this Annex, using individual concentration limits.

(a) Where the dangerous substances listed in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** are assigned concentration limits necessary for the application of the method of assessment described in Part A of this Annex, these concentration limits must be used.

(b) Where the dangerous substances do not appear in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A of this Annex, the concentration limits shall be assigned in accordance with the specification in Part B of this Annex.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Part C gives the test methods for the evaluation of the hazards for the aquatic environment.

PART A

Procedure for the evaluation of environmental hazards

(a) Aquatic environment

I. Conventional method for the evaluation of hazards to the aquatic environment

The conventional method for the evaluation of hazards to the aquatic environment **[**X1takes into account all the hazards that a preparation may entail**]** for this medium according to the following specifications.

Editorial Information

X1 Substituted by Corrigendum to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (Official Journal of the European Communities L 200 of 30 July 1999).

The following preparations are to be classified as dangerous for the environment:

1. and assigned the symbol 'N', the indication of danger 'dangerous for the environment' and the risk phrases R50 and R53 (R50-53):

1.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned phrases R50-53 in individual concentrations equal to or greater than:

(a) either the concentration specified in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** or appear in it without concentration limits;

1.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 in lower individual concentrations than the limits specified under I.1.1(a) or (b) if:

$$\Sigma(P_{N,\,R50-53}\,L_{N,\,R50-53}) \geq 1$$

where:

$P_{N,\,R50-53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50-53 in the preparation,

$L_{N,\,R50-53}$ = is the limit R50-53 for each substance dangerous for the environment to which is assigned the phrases R50-53, expressed as percentage by weight

2. and assigned the symbol 'N', the indication of danger 'dangerous for the environment' and the risk phrases R51 and R53 (R51-53) unless the preparation is already classified according to I.1 above;

2.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrases R50-53 or R51-53 in individual concentrations equal to or greater than:

(a) either the concentration specified in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** or appear in it without concentration limits;

2.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R50-53 or R51-53 in lower individual concentrations than the limits specified under I.2. (a) or (b) if:

$$\Sigma((P_{N,\,R50-53}\,L_{N,\,R51-53}) + (P_{N,\,R51-53}\,L_{N,\,R51-53})) \geq 1$$

where:

$P_{N, R50—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50-53 in the preparation,

$P_{N, R51—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R51-53 in the preparation,

$L_{N, R51—53}$ = is the respective limit R51-53 for each substance dangerous for the environment to which is assigned phrases R50-53 or R51-53, expressed as percentage by weight

3. and assigned the risk phrases R52 and R53 (R52-53) unless the preparation is already classified according to I.1 or I.2 above;

3.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrases R50-53 or R51-53 or R52-53 in individual concentrations equal to or greater than:

(a) either the concentration specified in **[**[F1]Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in **[**[F1]Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** or appear in it without concentration limits;

3.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R51-53 or R50-53 or R52-53 in lower individual concentrations than the limits specified under I.3.1(a) or (b) if:

$$\Sigma((P_{N, R50—53}/L_{R52—53})+(P_{N, R51—53}/L_{R52—53})+(P_{R52—53}/L_{R52—53}))\geq 1$$

where:

$P_{N, R50—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50-53 in the preparation,

$P_{N, R51—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R51-53 in the preparation,

$P_{R52—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R52-53 in the preparation,

$L_{R52—53}$ = is the respective limit R52-53 for each substance dangerous for the environment to which is assigned phrases R50-53 or R51-53 or R52-53, expressed as percentage by weight;

4. and assigned the symbol ‘N’, the indication of danger ‘dangerous for the environment’ and the risk phrase R50 unless the preparation is already classified according to I.1 above:

4.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R50 in individual concentrations equal to or greater than:

(a) either the concentration specified in **[**[F1]Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 2) where the substance or substances do not appear in **[**[F1]Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** or appear in it without concentration limits;

4.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R50 in lower individual concentrations than the limits specified under I.4.1(a) or (b) if:

$$\Sigma(P_{N,\,R50}\,L_{N,\,R50}) \geq 1$$

where:

$P_{N,\,R50}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R50 in the preparation,

$L_{N,\,R50}$ = is the limit R50 for each substance dangerous for the environment to which is assigned phrase R50, expressed as percentage by weight.

4.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R50 not meeting the criteria under I.4.1 or I.4.2 and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 if:

$$\Sigma((P_{N,\,R50}\,L_{N,\,R50}) + (P_{N,\,R50-53}\,L_{N,\,R50})) \geq 1$$

where:

$P_{N,\,R50}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R50 in the preparation,

$P_{N,\,R50—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50-53 in the preparation,

$L_{N,\,R50}$ = is the perspective limit R50 for each substance dangerous for the environment to which is assigned phrases R50 or R50-53, expressed as percentage by weight;

5. and assigned the risk phrase R52 unless the preparation is already classified according to I.1, I.2, I.3, or I.4 above:

5.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R52 in individual concentrations equal to or greater than:

(a) either the concentration specified in **[**[F1]Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 3) where the substance or substances do not appear in **[**[F1]Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** or appear in it without concentration limits;

5.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R52 in lower individual concentrations than the limits specified under I.5.1 (a) or (b) if:

$$\Sigma(P_{R52}\,L_{R52}) \geq 1$$

where:

P_{R52} = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R52 in the preparation,

L_{R52} = is the limit R52 for each substance dangerous for the environment to which is assigned phrase R52, expressed as percentage by weight;

6. and assigned the risk phrase R53 unless the preparation is already classified according to I.1, I.2, or I.3 above:

6.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R53 in individual concentrations equal to or greater than:

(a) either the concentration specified in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 4) where the substance or substances do not appear in **[**F1Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** or appear in it without concentration limits;

6.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R 53 in lower individual concentrations than the limits specified under I.6.1(a) or (b) if:

$$\Sigma(P_{R53}\,L_{R53}) \geq 1$$

where:

P_{R53} = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R53 in the preparation,

L_{R53} = is the limit R53 for each substance dangerous for the environment to which is assigned phrase R53, expressed as percentage by weight;

6.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R53 not meeting the criteria under I.6.2 and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 or R51-53 or R52-53 if:

$$\Sigma((P_{R53}\,L_{R53}) + (P_{N,\,R50—53}\,L_{R53}) + (P_{N,\,R51—53}\,L_{R53}) + (P_{R52—53}\,L_{R53})) \geq 1$$

where:

P_{R53} = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R53 in the preparation,

$P_{N,\,R50—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R50-53 in the preparation,

$P_{N,\,R51—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R51-53 in the preparation,

$P_{R52—53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R52-53 in the preparation,

L_{R53} = is the respective limit R53 for each substance dangerous for the environment to which is assigned phrase R53 or R50-53 or R51-53 or R52-53, expressed as percentage by weight.

(b) Non-aquatic environment

(1) OZONE LAYER

I. Conventional method for the evaluation of preparations dangerous for the ozone layer
The following preparations are to classified as dangerous for the environment:

1. and assigned the symbol ‘N’, the indication of danger ‘dangerous for the environment’ and the risk phrase R59;

1.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned the symbol ‘N’ and the risk phrase R59 in individual concentrations equal to or greater than:

(a) either the concentration specified in **[**[F1]Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 5) where the substance or substances do not appear in **[**[F1]Part 3 of Annex VI to Regulation (EC) No 1272/2008**]** or appear in it without concentration limits**[**[F2].**]**

Textual Amendments

F2 Substituted by Commission Directive 2006/8/EC of 23 January 2006 amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (Text with EEA relevance).

[F3]2. . . . . .

Textual Amendments

F3 Deleted by Commission Directive 2006/8/EC of 23 January 2006 amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (Text with EEA relevance).

[F3]2.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned R59 in individual concentrations equal to or greater than:

. . . . . .

(2) TERRESTRIAL ENVIRONMENT

I. Evaluation of preparations dangerous for the terrestrial environment

Classification of preparations using the risk phrases below will follow after the detailed criteria for use of the phrases have been incorporated in Annex VI to Directive 67/548/EEC.

R54	Toxic to flora
R55	Toxic to fauna
R56	Toxic to soil organisms
R57	Toxic to bees
R58	May cause long-term adverse effects in the environment.

PART B

Concentration limits to be used for the evaluation of environmental hazards

I. For the aquatic environment

The concentration limits fixed in the following tables, expressed as a weight/weight percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

[[F2]TABLE 1A

Acute aquatic toxicity and long-term adverse effects

Classification of the substance	**Classification of the preparation**		
	N, R50-53	**N, R51-53**	**R52-53**
N, R50-53	see Table 1b	see Table 1b	see Table 1b
N, R51-53		$C_n \geq 25$ %	2,5 % ≤ C_n< 25 %
R52-53			$C_n \geq 25$ %

Preparations containing a substance classified with N, R50-53, the concentration limits and the resulting classification given in table 1b are applicable.

TABLE 1B

Acute aquatic toxicity and long-term adverse effects of substances very toxic to the aquatic environment

LC_{50} or EC_{50} value ('$L(E)C_{50}$') of substance classified as N, R50-53 (mg/l)	**Classification of the preparation**		
	N, R50-53	**N, R51-53**	**R52-53**
0,1 < $L(E)C_{50}$ ≤ 1	$C_n \geq 25$ %	2,5 % ≤ C_n< 25 %	0,25 % ≤ C_n< 2,5 %
0,01 < $L(E)C_{50}$ ≤ 0,1	$C_n \geq 2,5$ %	0,25 % ≤ C_n< 2,5 %	0,025 % ≤ C_n< 0,25 %
0,001 < $L(E)C_{50}$ ≤ 0,01	$C_n \geq 0,25$ %	0,025 % ≤ C_n< 0,25 %	0,0025 % ≤ C_n< 0,025 %
0,0001 < $L(E)C_{50}$ ≤ 0,001	$C_n \geq 0,025$ %	0,0025 % ≤ C_n< 0,025 %	0,00025 % ≤ C_n< 0,0025 %
0,00001 < $L(E)C_{50}$ ≤ 0,0001	$C_n \geq 0,0025$ %	0,00025 % ≤ C_n< 0,0025 %	0,000025 % ≤ C_n< 0,00025 %

For preparations containing substances with a lower LC_{50} or EC_{50} value than 0,00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).**]**

[[F2]TABLE 2

Acute aquatic toxicity

LC_{50} or EC_{50} value ('$L(E)C_{50}$') of substance classified either as N, R50 or as N, R50-53 (mg/l)	**Classification of the preparation N, R50**
0,1 < $L(E)C_{50}$ ≤ 1	$C_n \geq 25$ %
0,01 < $L(E)C_{50}$ ≤ 0,1	$C_n \geq 2,5$ %
0,001 < $L(E)C_{50}$ ≤ 0,01	$C_n \geq 0,25$ %

For preparations containing substances with a lower LC_{50} or EC_{50} value than 0,00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).**]**

$0{,}0001 < L(E)C_{50} \leq 0{,}001$	$C_n \geq 0{,}025$ %
$0{,}00001 < L(E)C_{50} \leq 0{,}0001$	$C_n \geq 0{,}0025$ %

For preparations containing substances with a lower LC_{50} or EC_{50} value than 0,00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).**]**

Table 3

Aquatic toxicity

Classification of the substance	**Classification of the preparation R52R52**
R52	$C_n \geq 25$ %

Table 4

Long-term adverse effects

Classification of the substance	**Classification of the preparation R53R53**
R53	$C_n \geq 25$ %
N, R50—53	$C_n \geq 25$ %
N, R51—53	$C_n \geq 25$ %
R52—53	$C_n \geq 25$ %

II. For the non-aquatic environment

The concentration limits fixed in the following tables, expressed as weight/weight percentage or, for gaseous preparations as a volume/volume percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

[[F2]TABLE 5

Dangerous for the ozone layer

Classification of the substance	**Classification of the preparation N, R59**
N with R59	$C_n \geq 0{,}1$ %**]**

PART C

Test methods for the evaluation of the hazards for the aquatic environment

Normally, the classification of a preparation is made on the basis of the conventional method. However, for the determination of the acute aquatic toxicity, there may be cases for which it is appropriate to carry out tests on the preparation.

The result of these tests on the preparation may only modify the classification concerning acute aquatic toxicity which would have been obtained by the application of the conventional method.

If such tests are chosen by the person responsible for the placing on the market, it must be ensured that the quality criteria of the test methods in Part C of Annex V to Directive 67/548/EEC have been complied with.

Furthermore, the tests are to be carried out on all three species in conformity with the criteria of Annex VI to Directive 67/548/EEC (algae, daphnia and fish), unless the highest hazard classification relating to acute aquatic toxicity has been assigned to the preparation after testing on one of the species or a test result was already available before this Directive entered into force.