

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provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (repealed)

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ANNEX II

METHODS FOR THE EVALUATION OF HEALTH HAZARDS OF PREPARATIONS IN ACCORDANCE WITH ARTICLE 6

PART A

Procedure for evaluation of health hazards

The evaluation proceeds stepwise as follows:

1. The following preparations are to be classified as very toxic:
 - 1.1. owing to their acute lethal effects and assigned the symbol 'T⁺', the indication of danger 'very toxic' and the risk phrases R26, R27 or R28;
 - 1.1.1. preparations containing one or more substances classified as very toxic that produce such effects, 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 at point 1 in Part B of this Annex (Table I and I A) 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;

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 \(Text with EEA relevance\).](#)

- 1.1.2. preparations containing more than one substance classified as very toxic in lower individual concentrations than the limits specified under 1.1.1(a) or (b) if:

$$\Sigma(P_{T+}L_{T+}) \geq 1$$

where:

- P_{T+} = is the percentage by weight or by volume of each very toxic substance in the preparation,
- L_{T+} = is the very toxic limit specified for each very toxic substance, expressed as a percentage by weight or by volume;

- 1.2. owing to their non-lethal irreversible effects after a single exposure and assigned the symbol 'T+', the indication of danger 'very toxic' and the risk phrase R39/route of exposure.

Preparations containing at least one dangerous substance that produces such effects 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 at point 2 in Part B of this Annex (Table II and II A) 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. The following preparations shall be classified as toxic:

2.1. owing to their acute lethal effects and assigned the symbol 'T', the indication of danger 'toxic' and the risk phrases R23, R24 or R25;

2.1.1. preparations containing one or more substances classified as very toxic or toxic that produce such effects 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 at point 1 in Part B of this Annex (Table I and I A) 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;

2.1.2. preparations containing more than one substance classified as very toxic or toxic in lower individual concentrations than the limits specified under 2.1.1(a) or (b) if:

$$E(P_{T+}L_T + P_T L_T) \geq 1$$

Where:

P_{T+} = is the percentage by weight or by volume of each very toxic substance in the preparation,

P_T = is the percentage by weight or by volume of each toxic substance in the preparation,

L_T = is the respective toxic limit specified for each very toxic or toxic substance, expressed as a percentage by weight or by volume;

2.2. owing to their non-lethal irreversible effects after a single exposure and assigned the symbol 'T', the indication of danger 'toxic' and the risk phrase R39/route of exposure.

Preparations containing at least one dangerous substance classified as very toxic or toxic that produce such effects 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 at point 2 in Part B of this Annex (Table II and II A) 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;

2.3. owing to their long-term effects and assigned the symbol 'T', the indication of danger 'toxic' and the risk phrase R48/route of exposure.

Preparations containing at least one dangerous substance that produces such effects 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 at point 3 in Part B of this Annex (Table III and III A) 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.

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3. The following preparations shall be classified as harmful:
- 3.1. owing to their acute lethal effects and assigned the symbol 'X_n' and the indication of danger 'harmful' and the risk phrases R20, R21 or R22;
- 3.1.1. preparations containing one or more substances classified as very toxic, toxic or harmful and that produce such effects 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 at point 1 in Part B of this Annex (Table I and I A) 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.
- 3.1.2. preparations containing more than one substance classified as very toxic, toxic or harmful in lower individual concentrations than the limits specified under 3.1.1(a) or (b) if:

$$\Sigma(P_{T+}L_{Xn} + P_T L_{Xn} + P_{Xn}L_{Xn}) \geq 1$$

Where:

- P_{T+} = is the percentage by weight or by volume of each very toxic substance in the preparation,
- P_T = is the percentage by weight or by volume of each toxic substance in the preparation,
- P_{X_n} = is the percentage by weight or by volume of each harmful substance in the preparation,
- L_{X_n} = is the respective harmful limit specified for each very toxic, toxic or harmful substance, expressed as percentage by weight or by volume;

- 3.2. owing to their acute effects to the lungs if swallowed and assigned the symbol 'X_n', and the indication of danger 'harmful' and the risk phrase R65.

Preparations classified as harmful according to the criteria specified in paragraph 3.2.3 of Annex VI to Directive 67/548/EEC. In applying the conventional method according to the above paragraph 3.1 no account shall be taken of the classification of a substance as R65;

- 3.3. owing to their non-lethal irreversible effects after a single exposure and assigned the symbol 'X_n', the indication of danger 'harmful' and the risk phrase [F2R68]/route of exposure.

Preparations containing at least one dangerous substance classified as very toxic, toxic or harmful that produces such effects 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 at point 2 in Part B of this Annex (Table II and II A) 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;

Textual Amendments

- F2** Substituted by [Commission Directive 2001/60/EC of 7 August 2001](#) adapting to technical progress [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 \(Text with EEA relevance\).](#)

- 3.4. owing to their long-term effects and assigned the symbol 'X_n', the indication of danger 'harmful' and the risk phrase R48/route of exposure.

Preparations containing at least one dangerous substance classified as toxic or harmful that produces such effects 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 at point 3 in Part B of this Annex (Table III and III A) 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.

4. The following preparations are to be classified as corrosive

- 4.1. and assigned the symbol 'C', the indication of danger 'corrosive' and the risk phrase R35;

- 4.1.1. preparations containing one or more substances classified as corrosive to which is assigned the phrase R35 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 at point 4 in Part B of this Annex (Table IV and IV A) 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.

- 4.1.2. preparations containing more than one substance classified as corrosive to which is assigned phrase R35 in lower individual concentrations than the limits specified under 4.1.1(a) or (b) if:

$$\Sigma(P_{C,R35} L_{C,R35}) \geq 1$$

where:

- $P_{C,R35}$ = is the percentage by weight or by volume of each corrosive substance which is assigned phrase R35 in the preparation,
- $L_{C,R35}$ = is the corrosive limit R35 specified for each corrosive substance to which is assigned phrase R35, expressed as a percentage by weight or by volume;

- 4.2. and assigned the symbol 'C', the indication of danger 'corrosive' and the risk phrase R34;

- 4.2.1. preparations containing one or more substances classified as corrosive to which is assigned the phrase R35 or R34 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

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- (b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) 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;

- 4.2.2. preparations containing more than one of the substances classified as corrosive to which is assigned the phrase R35 or R34 in lower individual concentrations than the limits specified under 4.2.1(a) or (b) if:

$$\Sigma(P_{C, R35} L_{C, R34} + P_{C, R34} L_{C, R34}) \geq 1$$

where:

- $P_{C, R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,
 $P_{C, R34}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,
 $L_{C, R34}$ = is the respective corrosive limit R34 specified for each corrosive substance to which is assigned phrase R35 or R34, expressed as a percentage by weight or by volume.

5. The following preparations are to be classified as irritants:

- 5.1. liable to cause serious eye damage and assigned the symbol 'Xi', the indication of danger 'irritant' and the risk phrase R41;

- 5.1.1. preparations containing one or more substances classified as irritant to which is assigned phrase R41 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 at point 4 in Part B of this Annex (Table IV and IV A) 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;

- 5.1.2. preparations containing more than one of the substances classified as irritant and to which is assigned phrase R41, or classified as corrosive and to which is assigned phrase R35 or R34, in lower individual concentrations than the limits specified under 5.1.1(a) or (b) if:

$$\Sigma(P_{C, R35} L_{Xi, R41} + P_{C, R34} L_{Xi, R41} + P_{Xi, R41} L_{Xi, R41}) \geq 1$$

where:

- $P_{C, R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,
 $P_{C, R34}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,
 $P_{Xi, R41}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R41 in the preparation,
 $L_{Xi, R41}$ = is the respective irritant limit R41 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R41, expressed as percentage by weight or by volume;

- 5.2. irritant to eyes and assigned the symbol 'Xi', the indication of danger 'irritant' and the risk phrase R36;

5.2.1. preparations containing one or more substances classified as corrosive to which is assigned phrase R35 or R34 or as irritant and to which is assigned phrase R41 or R36 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 at point 4 in Part B of this Annex (Table IV and IV A) 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;

5.2.2. preparations containing more than one substance classified as irritant to which is assigned phrase R41 or R36, or as corrosive and to which is assigned phrase R35 or R34, in lower individual concentrations than the limits specified under 5.2.1(a) or (b) if:

$$\Sigma(P_{C, R35}L_{Xi, R36} + P_{C, R34}L_{Xi, R36} + P_{Xi, R41}L_{Xi, R36} + P_{Xi, R36}L_{Xi, R36}) \geq 1$$

where:

- $P_{C, R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,
- $P_{C, R34}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,
- $P_{Xi, R41}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R41 in the preparation,
- $P_{Xi, R36}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R36 in the preparation,
- $L_{Xi, R36}$ = is the respective irritant limit R36 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R41, or R36 expressed as percentage by weight or by volume;

5.3. irritant to skin and assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R38;

5.3.1. preparations containing one or more substances classified as irritant and to which is assigned phrase R38 or as corrosive and to which is assigned phrase R35 or R34 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 at point 4 in Part B of this Annex (Table IV and IV A) 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;

5.3.2. preparations containing more than one of the substances classified as irritant and to which is assigned phrase R38, or as corrosive and to which is assigned phrase R35 or R34 in lower individual concentrations than the limits specified under 5.3.1(a) or (b) if:

$$\Sigma(P_{C, R35}L_{Xi, R38} + P_{C, R34}L_{Xi, R38} + P_{Xi, R38}L_{Xi, R38}) \geq 1$$

where:

- $P_{C, R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,

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- $P_{C, R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,
- $P_{X_i, R38}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R38 in the preparation,
- $L_{X_i, R38}$ = is the respective irritant limit R38 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R38, expressed as percentage by weight or by volume;

5.4. irritant to respiratory system and assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R37;

5.4.1. preparations containing one or more substances classified as irritant and to which is assigned phrase R37 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 at point 4 in Part B of this Annex (Table IV and IV A) where the substance or the substances do not appear in [F¹Part 3 of Annex VI to Regulation (EC) No 1272/2008] or appear in it without concentration limits;

5.4.2. preparations containing more than one substance classified as irritant and to which is assigned phrase R37 in lower individual concentrations than the limits specified under 5.4.1(a) or (b) if:

$$\Sigma(P_{X_i, R37} L_{X_i, R37}) \geq 1$$

where:

- $P_{X_i, R37}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R37 in the preparation,
- $L_{X_i, R37}$ = is the irritant limit R37 specified for each irritant substance to which is assigned phrase R37, expressed as percentage by weight or by volume;

5.4.3. gaseous preparations containing more than one of the substances classified as irritant to which is assigned phrase R37 or as corrosive and to which is assigned phrase R35 or R34 in lower individual concentrations than the limits specified under 5.4.1(a) or (b) if:

$$\Sigma(P_{C, R35} L_{X_i, R37} + P_{C, R34} L_{X_i, R37} + P_{X_i, R37} L_{X_i, R37}) \geq 1$$

where:

- $P_{C, R35}$ = is the percentage by volume of each corrosive substance to which is assigned phrase R35 in the preparation,
- $P_{C, R34}$ = is the percentage by volume of each corrosive substance to which is assigned phrase R34 in the preparation,
- $P_{X_i, R37}$ = is the percentage by volume of each irritant substance to which is assigned phrase R37 in the preparation,
- $L_{X_i, R37}$ = is the respective irritant limit R37 specified for each gaseous corrosive substance to which is assigned phrase R35 or R34 or gaseous irritant substance to which is assigned phrase R37, expressed as percentage by weight or by volume.

6. The following preparations are to be classified as sensitising:

6.1. by skin contact and assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R43.

Preparations containing at least one substance classified as sensitising and to which is assigned phrase R43 that produces such effects 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 at point 5 in Part B of this Annex (Table V and V A) 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. by inhalation and assigned the symbol 'X_n', the indication of danger 'harmful' and the risk phrase R42.

Preparations containing at least one substance classified as sensitising to which is assigned phrase R42 that produces such effects 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 at point 5 in Part B of this Annex (Table V and V A) 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.

7. The following preparations are to be classified as carcinogenic:

- 7.1. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R45 or R49.

Preparations containing at least one substance producing such effects, classified as carcinogenic and to which is assigned phrase R45 or R49 which denotes carcinogenic substances in category 1 and category 2, 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 at point 6 in Part B of this Annex (Table VI and VI A) 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;

- 7.2. those of category 3 which are assigned the symbol 'X_n' and the phrase R40.

Preparations containing at least one substance producing such effects classified as carcinogenic and to which is assigned phrase R40 which denotes carcinogenic substances in category 3, 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 at point 6 in Part B of this Annex (Table VI and VI A) 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.

8. The following preparations are to be classified as mutagenic:

- 8.1. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R46.

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Preparations containing at least one substance producing such effects, classified as mutagenic and to which is assigned phrase R46 which denotes mutagenic substances in category 1 and category 2, 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 at point 6 in Part B of this Annex (Table VI and VI A) 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;
- 8.2. those of category 3 which are assigned the symbol 'X_n' and the phrase [F2R68].

Preparations containing at least one substance, producing such effects, classified as mutagenic and to which is assigned phrase R68] which denotes mutagenic substances in category 3, 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 at point 6 in Part B of this Annex (Table VI and VI A) 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.

9. The following preparations are to be classified as toxic for reproduction:

- 9.1. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R60 (fertility).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R60 which denotes substances toxic for reproduction of category 1 and category 2, 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 at point 6 in Part B of this Annex (Table VI and VI A) 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;

9.2. those of category 3 which are assigned the symbol 'X_n' and the phrase R62 (fertility).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R62 which denotes substances toxic for reproduction of category 3, 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 at point 6 in Part B of this Annex (Table VI and VI A) 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;

9.3. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R61 (development).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R61 which denotes substances toxic for reproduction of category 1 and category 2, 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 at point 6 in Part B of this Annex (Table VI and VI A) 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;
- 9.4. those of category 3 which are assigned the symbol 'X_n' and the phrase R63 (development).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R63 which denotes substances toxic for reproduction of category 3, 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 at point 6 in Part B of this Annex (Table VI and VI A) 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.