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**COMMITTEE OF EXPERTS ON THE TRANSPORT OF
DANGEROUS GOODS AND ON THE GLOBALLY
HARMONIZED SYSTEM OF CLASSIFICATION
AND LABELLING OF CHEMICALS**
Sub-Committee of Experts on the Globally
Harmonized System of Classification
and Labelling of Chemicals
(Third session, 10-12 July 2002)

**GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION
AND LABELLING OF CHEMICALS (GHS)**

Proposals for modification of the draft GHS document

**Transmitted by the experts from Belgium, Canada, Finland, Germany,
Netherlands, Norway, Sweden and the United States of America**

Modifications that are identified in the attached document refer to the draft GHS-document (documents ST/SG/AC.10/C.4/2001/20, ST/SG/AC.10/C.4/2001/21, ST/SG/AC.10/C.4/2001/22, ST/SG/AC.10/C.4/2001/23, ST/SG/AC.10/C.4/2001/24, ST/SG/AC.10/C.4/2001/28).

Proposals for changes

Document ST/SG/AC.10/C.4/2001/24

Delete chapter 4 completely.

Document ST/SG/AC.10/C.4/2001/28

Delete Annex 12 completely.

Document ST/SG/AC.10/C.4/20, page 15, paragraph 18

Delete the text referring to Rotterdam Convention. Paragraph 18 should read:

" The GHS is not intended to harmonise risk assessment procedures or risk management decisions (such as establishment of a permissible exposure limit for employee exposure), which generally require some risk assessment in addition to hazard classification. In addition chemical inventory requirements in various countries¹ are not related to the GHS."

Document ST/SG/AC.10/C.4/20, page 16, paragraph 28

Add at the end of paragraph 28:

"Notwithstanding the fact that an exporter needs to comply with importing countries GHS implementation, it is hoped that the application of the GHS worldwide will eventually lead to a fully harmonised situation."

¹ IOMC Description and Further Clarification of the Anticipated Application of the Globally Harmonized System (GHS), IFCS/ISG3/98.32B

Proposal for modification of decision logic schemes, documents

ST/SG/AC.10/C.4/2001/21, page 12,
ST/SG/AC.10/C.4/2001/22, page 15,
ST/SG/AC.10/C.4/2001/22, page 31,
ST/SG/AC.10/C.4/2001/22, page 46,
ST/SG/AC.10/C.4/2001/22, page 58,
ST/SG/AC.10/C.4/2001/22, page 60,
ST/SG/AC.10/C.4/2001/23, page 9,
ST/SG/AC.10/C.4/2001/23, page 20,
ST/SG/AC.10/C.4/2001/23, page 35,
ST/SG/AC.10/C.4/2001/23, page 48,
ST/SG/AC.10/C.4/2001/23, page 61,
ST/SG/AC.10/C.4/2001/23, page 79

Footnotes indicating the guidance nature (Documents ST/SG/AC.10/C.4/2001/22, p. 15, 31, 46, 58, 60 and ST/SG/AC.10/C.4/2001/23, p. 9, 20, 35, 48, 61, 79)

The footnote indicating a guidance nature of the Decision Logic schemes is proposed to be replaced by a text to be added in front of each Decision Logic scheme as a header. Following text is proposed:

"The decision logic which follows is not part of the harmonised classification system, but has been provided here as additional guidance. It is strongly recommended that the person responsible for classification studies the criteria before and during use of the decision logic."

Chapter 2.2: Flammable gases

ST/SG/AC10/C.4/2001/21, page 12

- The text in lowest box of the Decision Logic on the left should be reformulated as the text gives results which are opposite to the criteria. The modified text is included in the attached new version of the Decision Logic.

Chapter 3.1: Acute toxicity

ST/SG/AC.10/C.4/2001/22, page 15

- Footnote 3 is deleted and replaced by a corresponding header under the heading.
- Contents of boxes on page 18, Decision Logic 2, is proposed to be modified as indicated in the attached new version of the Decision Logic.

Chapter 3.2: Skin corrosion/irritation

ST/SG/AC.10/C.4/2001/22, page 31 - 32

- Footnote 3 is deleted and replaced by a corresponding header under the heading.
- The flowsheet is modified following the same model as for acute toxicity.
- References are added in boxes to criteria paragraphs
- Footnote is added referring to acid/alkali capacity
- The word 'material' is replaced by 'substance' and 'mixture'

- The wording of boxes for 'corrosive', 'irritant' and 'mild irritant' is modified to correspond better to wording of criteria.

ST/SG/AC.10/C.4/2001/22, page 33 -34

- Heading for Decision Logic 2 is added
- Wording of boxes is modified to correspond better to the wording of criteria
- The information of boxes listing example substances and cases, where 'additivity' does not apply, are merged
- Footnotes are added to cover certain special cases.

Chapter 3.3: Serious eye damage/Eye irritation

ST/SG/AC.10/C.4/2001/22, page 46 - 47

- Footnote 5 is deleted and replaced by a corresponding header under the heading.
- The flowsheet is modified following the same model as for acute toxicity
- Footnote is added referring to acid/alkali capacity
- References to criteria paragraphs are added in boxes for 'irreversible eye damage', 'eye irritant' and 'mild irritant'
- The word 'material' is replaced by 'substance' and 'mixture'
- The wording of boxes for 'irreversible eye damage', 'eye irritant' and 'mild irritant' is modified to correspond better to wording of criteria.

ST/SG/AC.10/C.4/2001/22, page 48 - 49

- Heading for Decision Logic 2 is added
- The information of boxes listing example substances and cases, where 'additivity' does not apply, are merged
- Footnotes are added to cover certain special cases.

Chapter 3.4: Respiratory or skin sensitisation

ST/SG/AC.10/C.4/2001/22, page 59 and 62

- Footnotes 6 and 8 are deleted and moved to the top of the page under the heading

ST/SG/AC.10/C.4/2001/22, page 59

- The scheme starts with “Substance” instead of “Mixture” and the scheme is modified accordingly.
- The wording of the criteria in the box with the two bullets is amended to give the correct wording of the criteria.
- References to criteria paragraphs are introduced in relevant boxes

ST/SG/AC.10/C.4/2001/22, page 62

- The scheme starts with “Substance” instead of “Mixture” and the scheme is modified accordingly.
- References to criteria paragraphs are introduced in relevant boxes.

Chapter 3.5: Germ cell mutagenicity

ST/SG/AC.10/C.4/2001/23, page 9

- Footnote 1 is deleted and moved to the top of the page under the heading.

Substance:

- Changes made in the texts of first, second and third vertical box .

ST/SG/AC.10/C.4/2001/23, page 10-11

Mixture:

- Page 10: the part of the scheme concerning mixtures is started with application of cut-off limits for classification, following with 'a case by case'-consideration on the basis of available test data on mixtures.

Chapter 3.6: Carcinogenicity

ST/SG/AC.10/C.4/2001/23, page 20

- Footnote 1 is deleted and moved to the top of the page under the heading.

ST/SG/AC.10/C.4/2001/23, page 20

Substance:

- Changes made in the texts of first, second and third vertical box

ST/SG/AC.10/C.4/2001/23, page 21-22

Mixture:

- Page 21: the part of the scheme concerning mixtures is started with application of cut-off limits for classification, following with a 'case by case'-consideration on the basis of available test data on mixtures.

Chapter 3.6: Reproductive toxicity

ST/SG/AC.10/C.4/2001/23, page 35

- Footnote 1 is deleted and moved to the top of the page under the heading

ST/SG/AC.10/C.4/2001/23, page 35

Substance:

- Changes made in the texts of first, second and third vertical box

ST/SG/AC.10/C.4/2001/23, page 36

- Decision logic for effects on or via lactation is moved to the end of the whole scheme.

ST/SG/AC.10/C.4/2001/23, page 37-38

Mixture:

- Page 37-38: the part of the scheme concerning mixtures is started with application of cut-off limits for classification, following with 'a case by case'-consideration on the basis of available test data on mixtures.

Chapter 3.8: Specific target organ systemic toxicity - Single exposure

ST/SG/AC.10/C.4/2001/23, page 48

- Footnote 2 is deleted and moved to the top of the page under the heading
- The flowsheet is modified following the same model as for acute toxicity
- The flowsheet is started with substances and modified accordingly.
- The wording of boxes is modified to emphasise better the criteria.

- References to criteria paragraphs are added in boxes.
- Reference to 'expert judgement' and 'weight of evidence' is placed as the last sentence in the box.

Chapter 3.8: Specific target organ systemic toxicity - Repeated exposure

ST/SG/AC.10/C.4/2001/23, page 61

- Footnote 2 is deleted and moved to the top of the page under the heading.
- The flowsheet is modified following the same model as for acute toxicity
- The flowsheet is started with substances and modified accordingly.
- The wording of boxes is modified to emphasise better the criteria.
- References to criteria paragraphs are added in boxes.
- Reference to 'expert judgement' and 'weight of evidence' is placed as the last sentence in the box.

Chapter 3.10: Hazardous to the aquatic environment

ST/SG/AC.10/C.4/2001/23, p. 79

- The heading is changed from 'Decision logic and guidance' to 'Decision logic'.
- Footnote 1 is deleted and moved under the heading.
- Footnote is added making a reference to Note 4 of Table 1 and Chapter 5.

ST/SG/AC.10/C.4/2001/23, p. 80

- The first bullet point of the second Chronic box "Is it poorly soluble with no acute toxicity up to the water solubility," has been changed in the following way:
"Is it poorly soluble with no acute toxicity* up to the water solubility,..."
And the added footnote say:

* See Table 1, Note 5 further developed in Annex 9, paras 66 and 67.

- Footnotes are added for clarification.

ST/SG/AC.10/C.4/2001/23, p. 82-83

- Wherever the M factor is included a footnote has been added to say:

*For explanation of the M factor see paragraph 56.

Miscellaneous

The numbering and references to paragraphs and footnotes in the final text has to be re-checked.

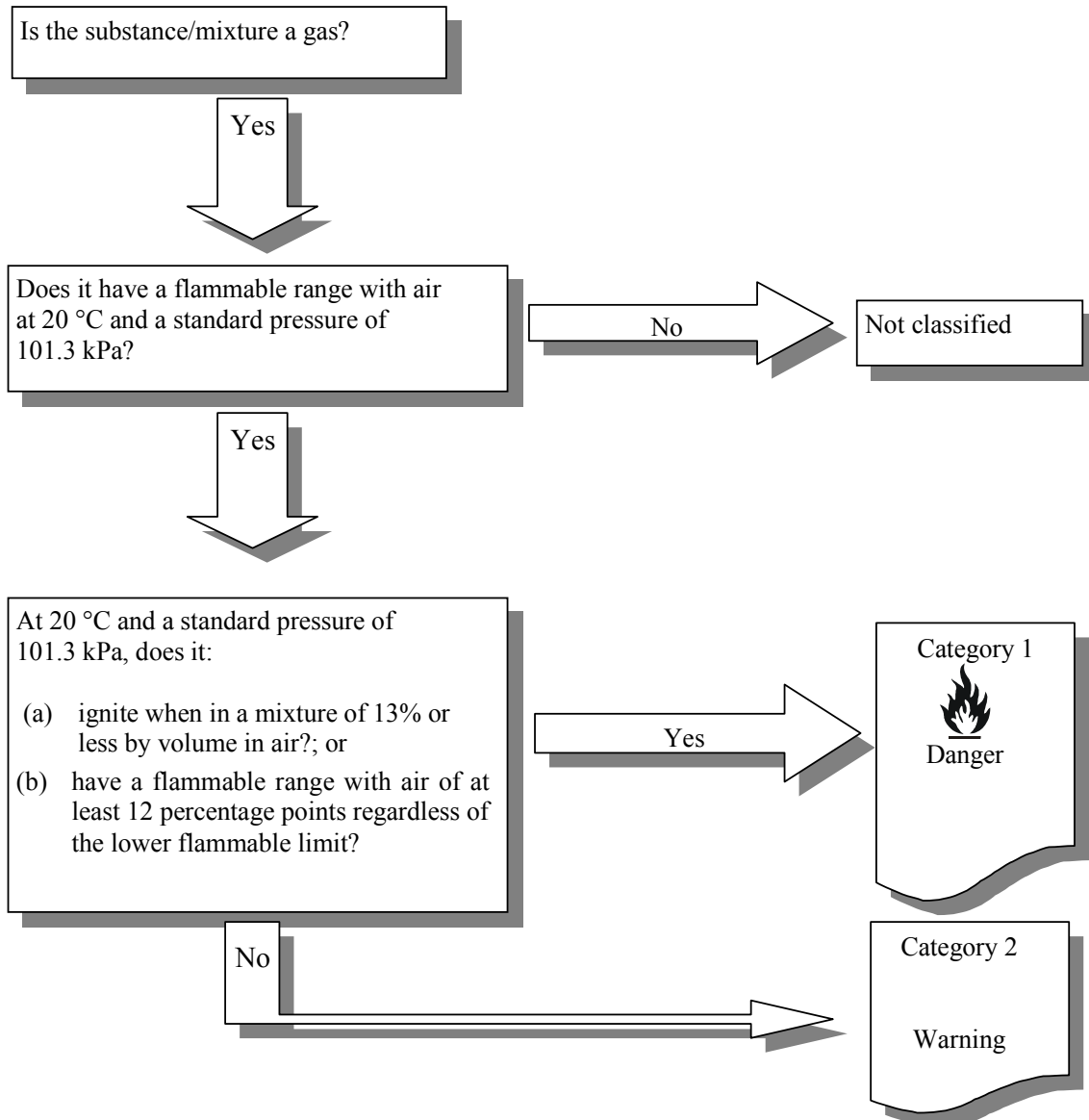
Reprinted modified Decision Logic schemes are attached.

ST/SG/AC.10/C.4/2001/21, page 12

Replace the Decision Logic for flammable gases by the following:

Decision logic

6. To classify a flammable gas, data on its flammability are required. The classification is according to the following decision logic.

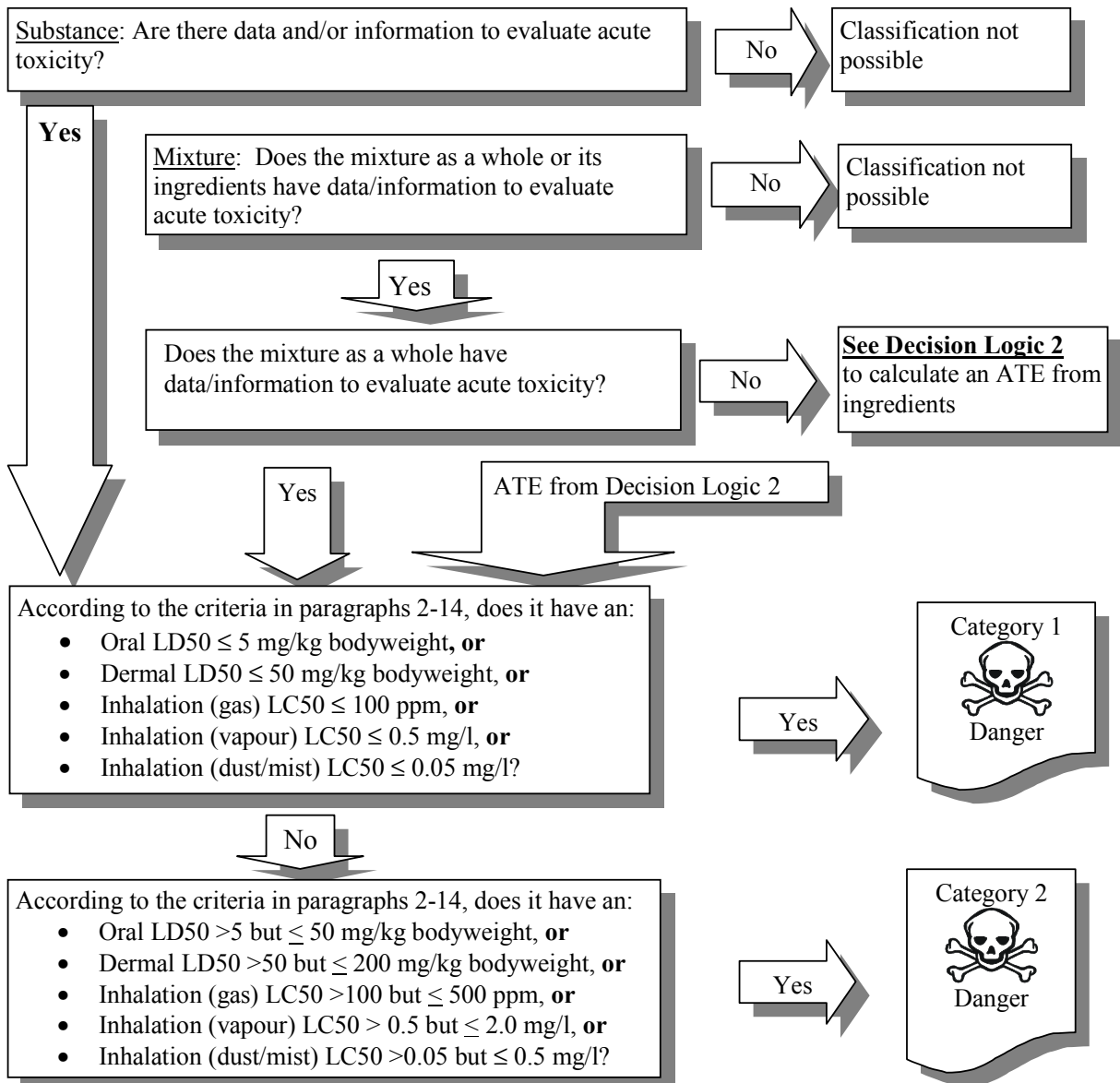


Replace the Decision Logic for acute toxicity by the following:

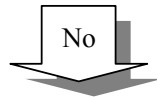
Decision logic for acute toxicity

The decision logic, which follows is not part of the harmonised classification system, but has been provided here as additional guidance. It is strongly recommended that the person responsible for classification studies the criteria before and during use of the decision logic.

Decision logic 1 for acute toxicity

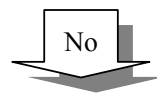
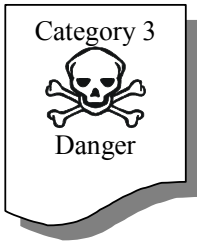
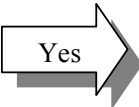


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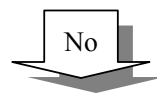
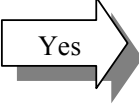
According to the criteria in paragraphs 2-14, does it have an:

- Oral LD50 >50 but ≤ 300 mg/kg bodyweight, **or**
- Dermal LD50 > 200 but ≤ 1000 mg/kg bodyweight, **or**
- Inhalation (gas) LC50 >500 but ≤ 2500 ppm, **or**
- Inhalation (vapour) LC50 >2 but ≤ 10.0 mg/l, **or**
- Inhalation (dust/mist) LC50 >0.5 but ≤ 1.0 mg/l?



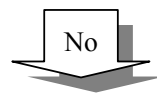
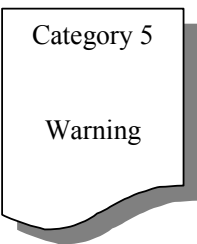
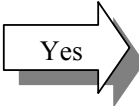
According to the criteria in paragraphs 2-14, does it have an:

- Oral LD50 >300 but ≤ 2000 mg/kg bodyweight, **or**
- Dermal LD50 >1000 but ≤ 2000 mg/kg bodyweight, **or**
- Inhalation (gas) LC50 >2500 but ≤ 5000 ppm, **or**
- Inhalation (vapour) LC50 >10 but ≤ 20 mg/l, **or**
- Inhalation (dust/mist) LC50 >1 but ≤ 5 mg/l?

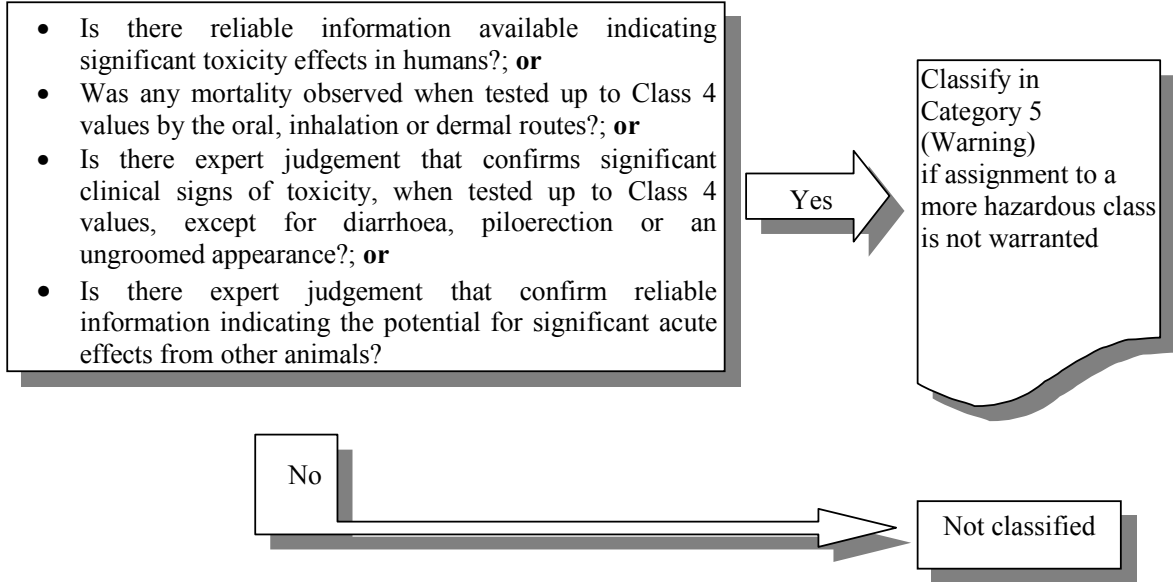


According to the criteria in paragraphs 2-14, does it have an:

- Oral LD50 >2000 but ≤ 5000 mg/kg bodyweight, **or**
- Dermal LD50 >2000 but ≤ 5000 mg/kg bodyweight, **or**
- Inhalation (gas, vapour and/or dust/mist) LC50 in the equivalent range of the oral and dermal LD50 (i.e., 2000-5000 mg/kg body weight)

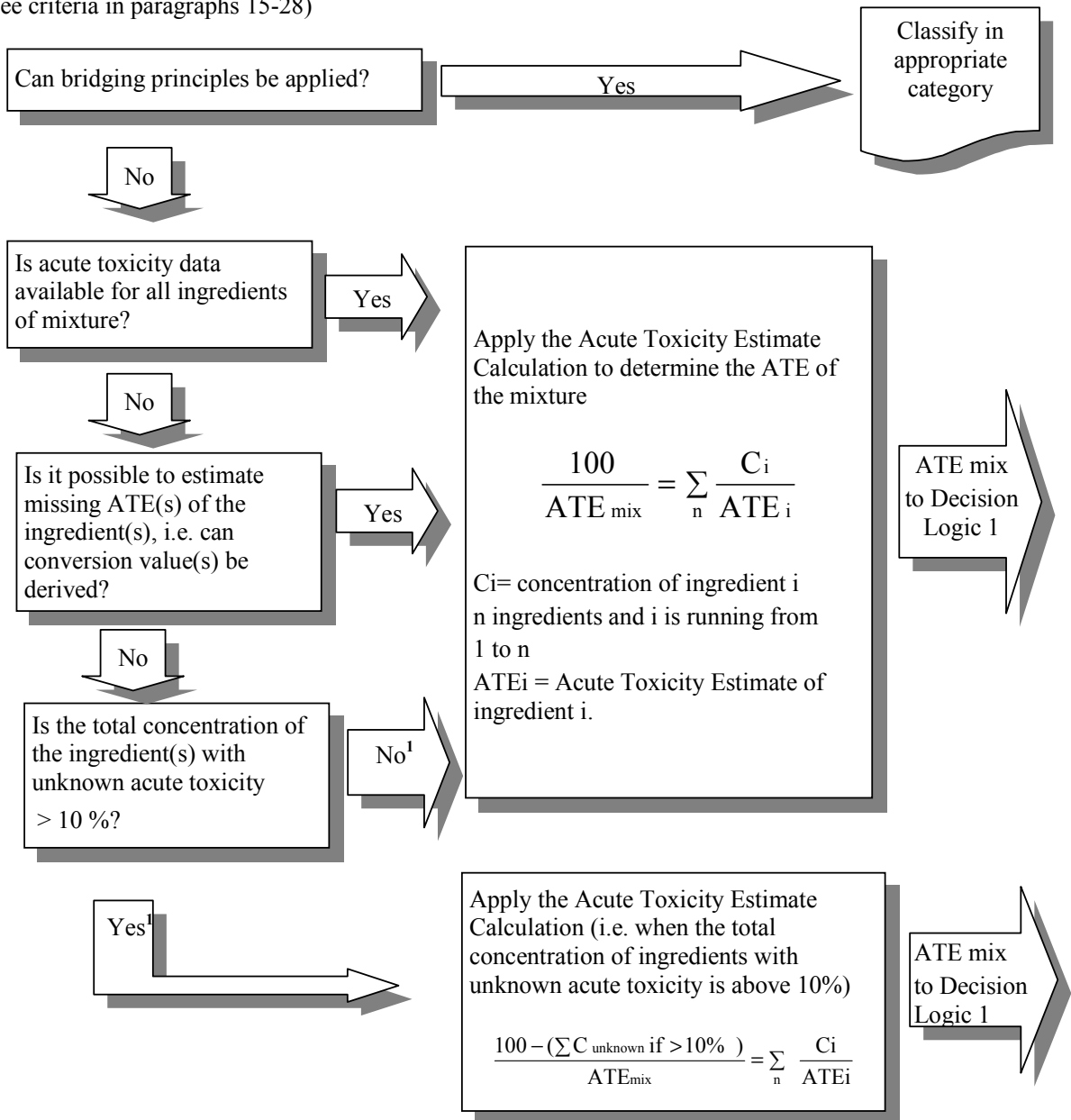


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Decision Logic 2 of mixtures for Acute toxicity

(See criteria in paragraphs 15-28)



¹ In the event that an ingredient without any useable information is used in a mixture at a concentration $\geq 1\%$, the classification should be based on the ingredients with the known acute toxicity only, and an additional statement on the label should identify the fact that the acute toxicity of x percent of the mixture is unknown.

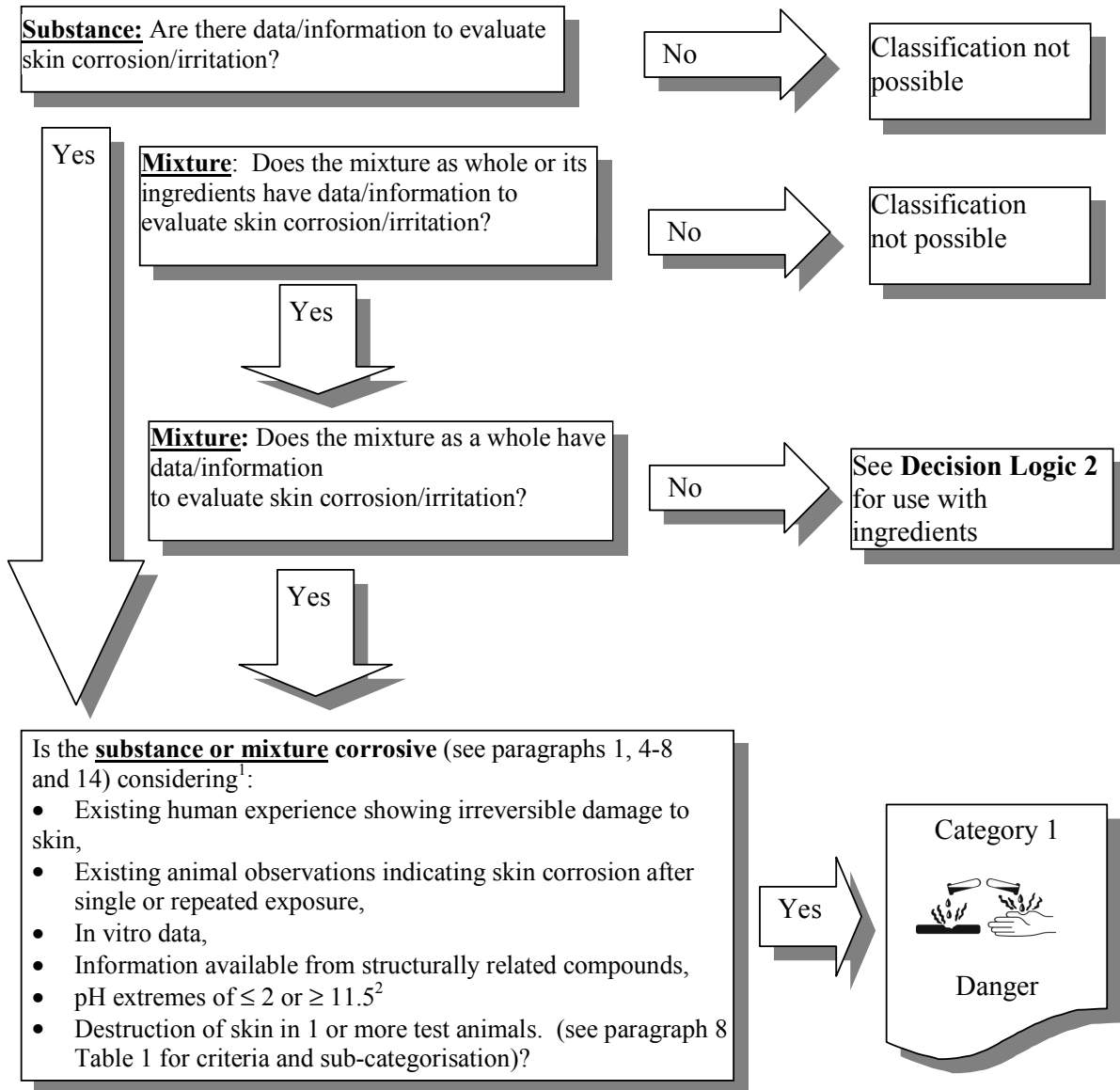
ST/SG/AC.10/C.4/2001/22, page 31

Replace the Decision Logic for skin corrosion/irritation by the following:

Decision Logic for skin corrosion/irritation

The decision logic, which follows is not part of the harmonised classification system, but has been provided here as additional guidance. It is strongly recommended that the person responsible for classification studies the criteria before and during use of the decision logic.

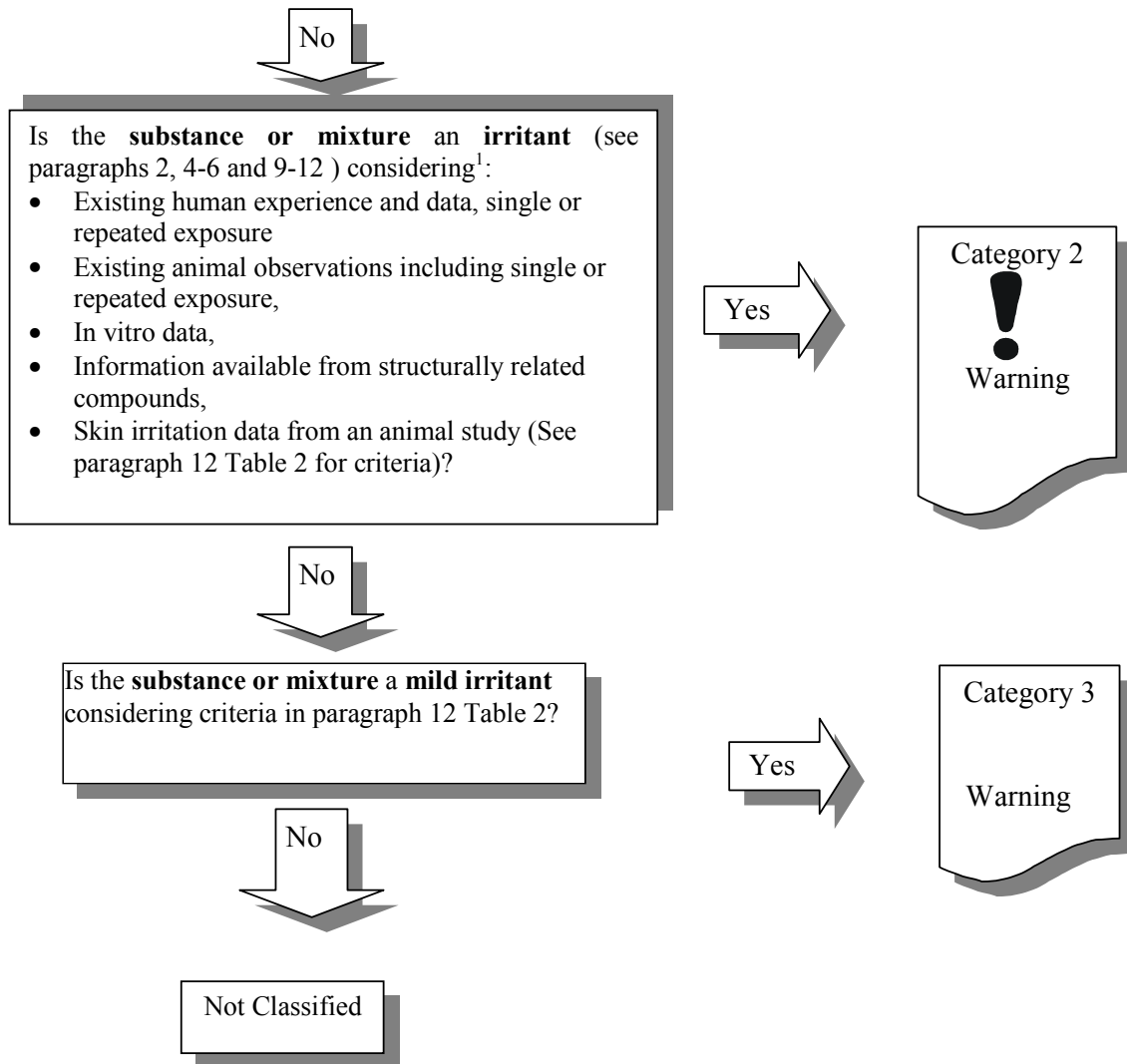
Decision Logic 1



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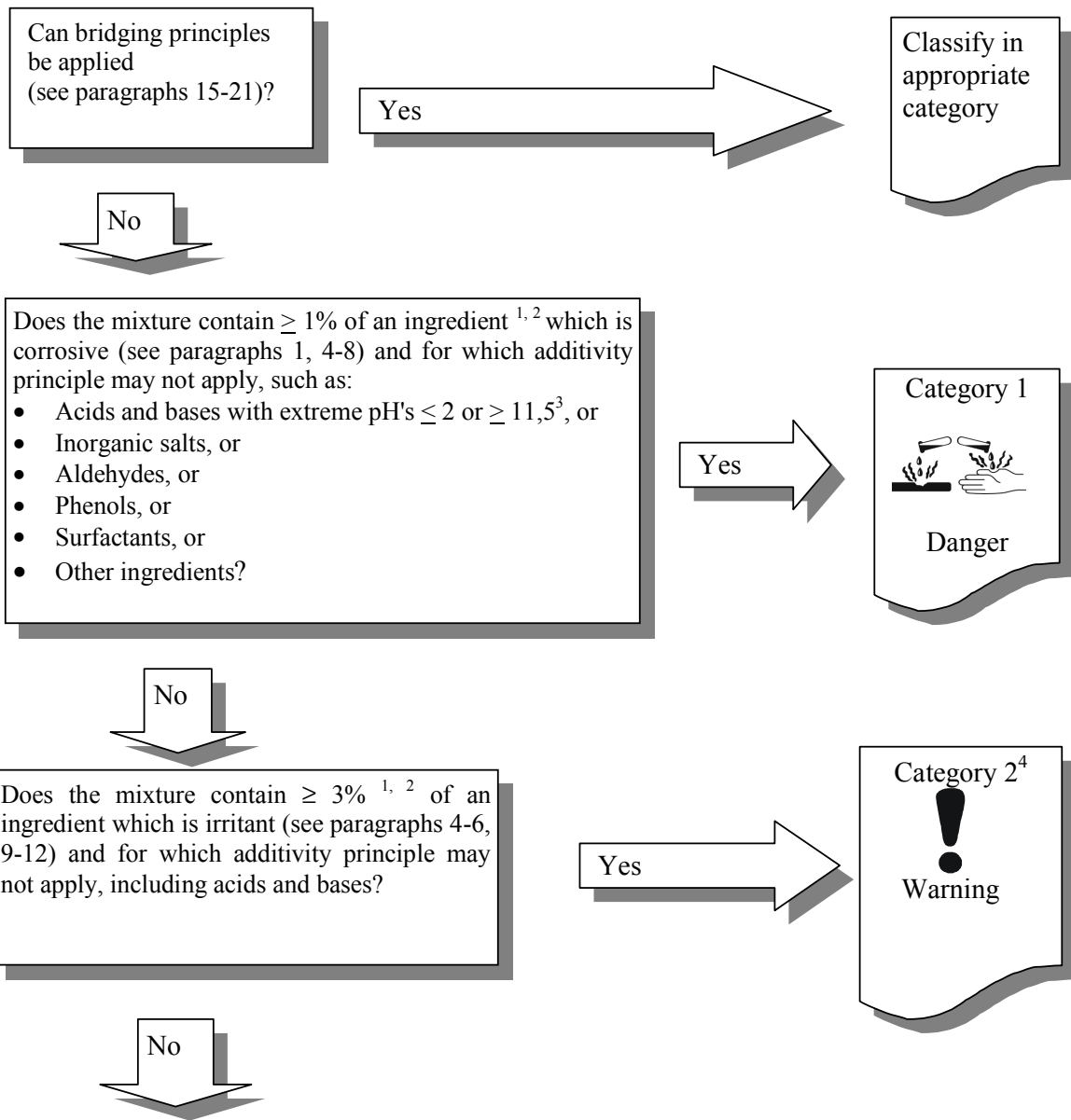
¹ Figure 1 contains details for testing and evaluation.

² Including consideration of acid/alkali reserve capacity, if appropriate



¹ Figure 1 contains details for testing and evaluation.

Decision Logic 2 Classification of mixtures on the basis of information/data on ingredients



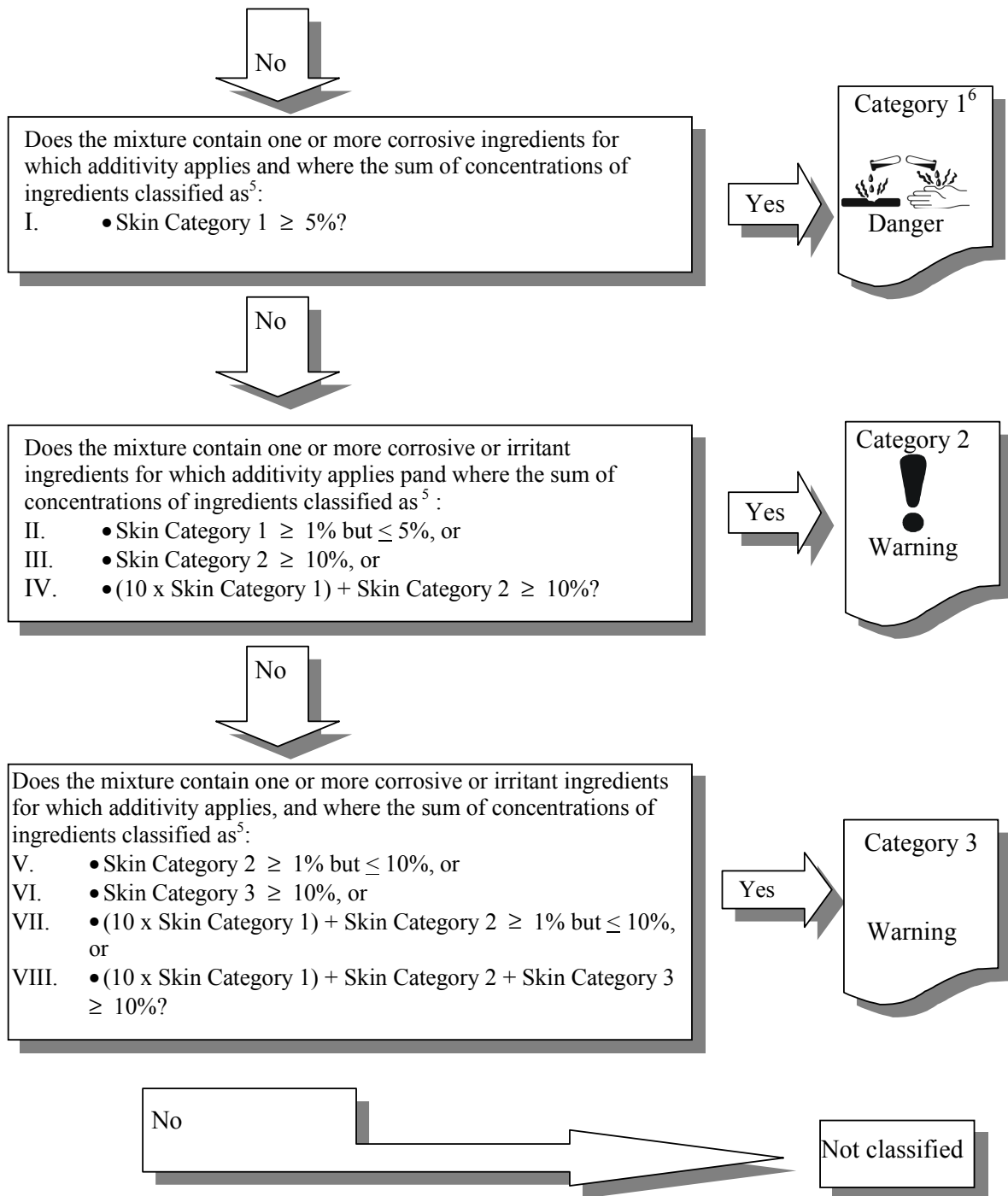
Continued on next page

¹ or where relevant $< 1\%$, see paragraph 22.

² For specific concentration limits, see paragraph 27 of this chapter. See also Chapter 1.2 for "The use of Cut-off Values/Concentration Limits".

³ including consideration of acid/alkali reserve capacity, if appropriate.

⁴ If the mixture also contains corrosive ingredient(s) for which additivity applies, move to the box below.



⁵ For specific concentration limits, See paragraph 27 of this chapter. See also Chapter 1.2 for "The Use of Cut-off Values/Concentration Limits" as well as paragraph 27 of this chapter.

⁶ See note to Table 3 for details on use of Category 1 subcategories.

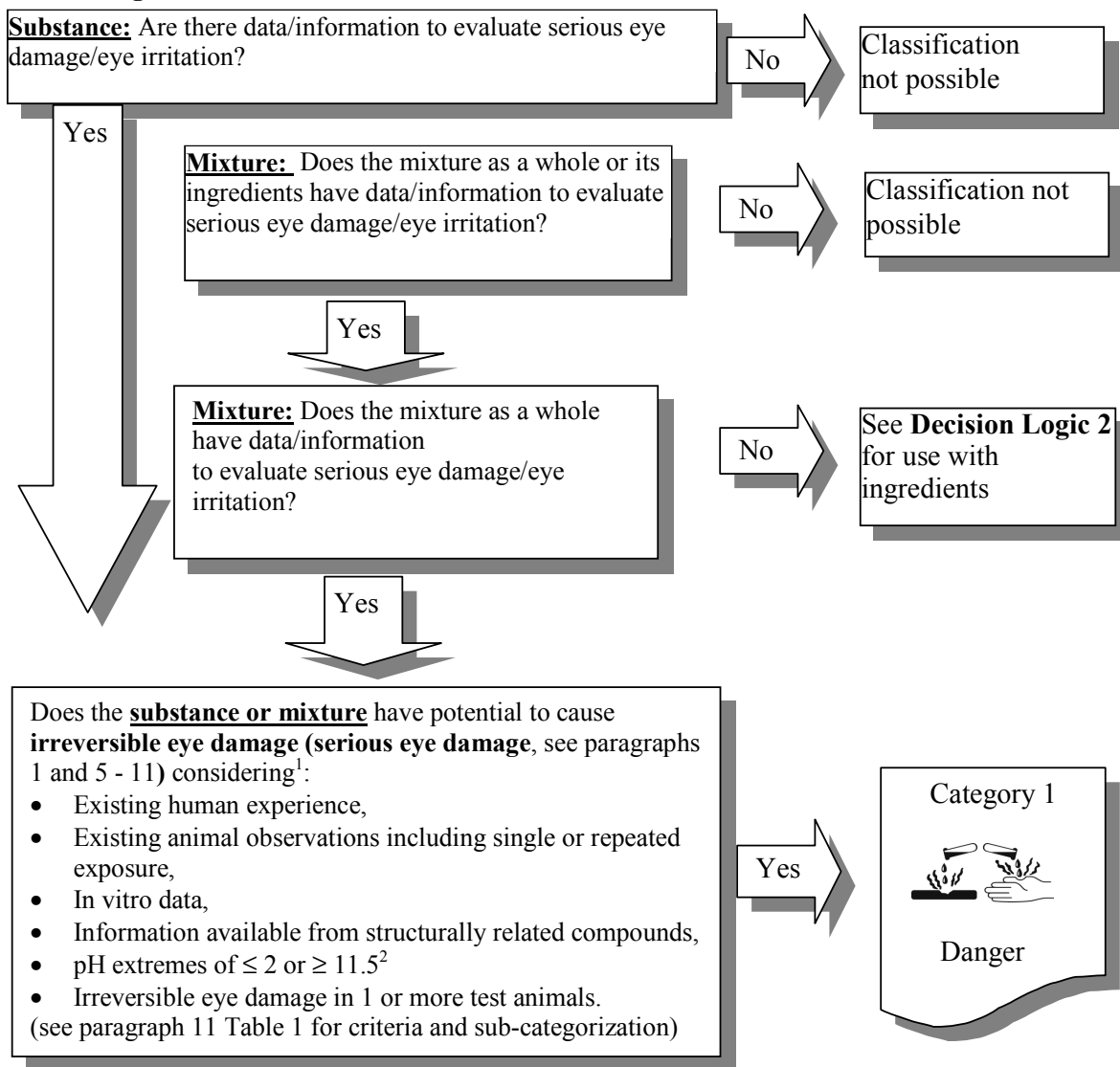
ST/SG/AC.10/C.4/2001/22, page 46

Replace the Decision Logic for serious eye damage/eye irritation by the following:

Decision Logic for serious eye damage/ eye irritation:

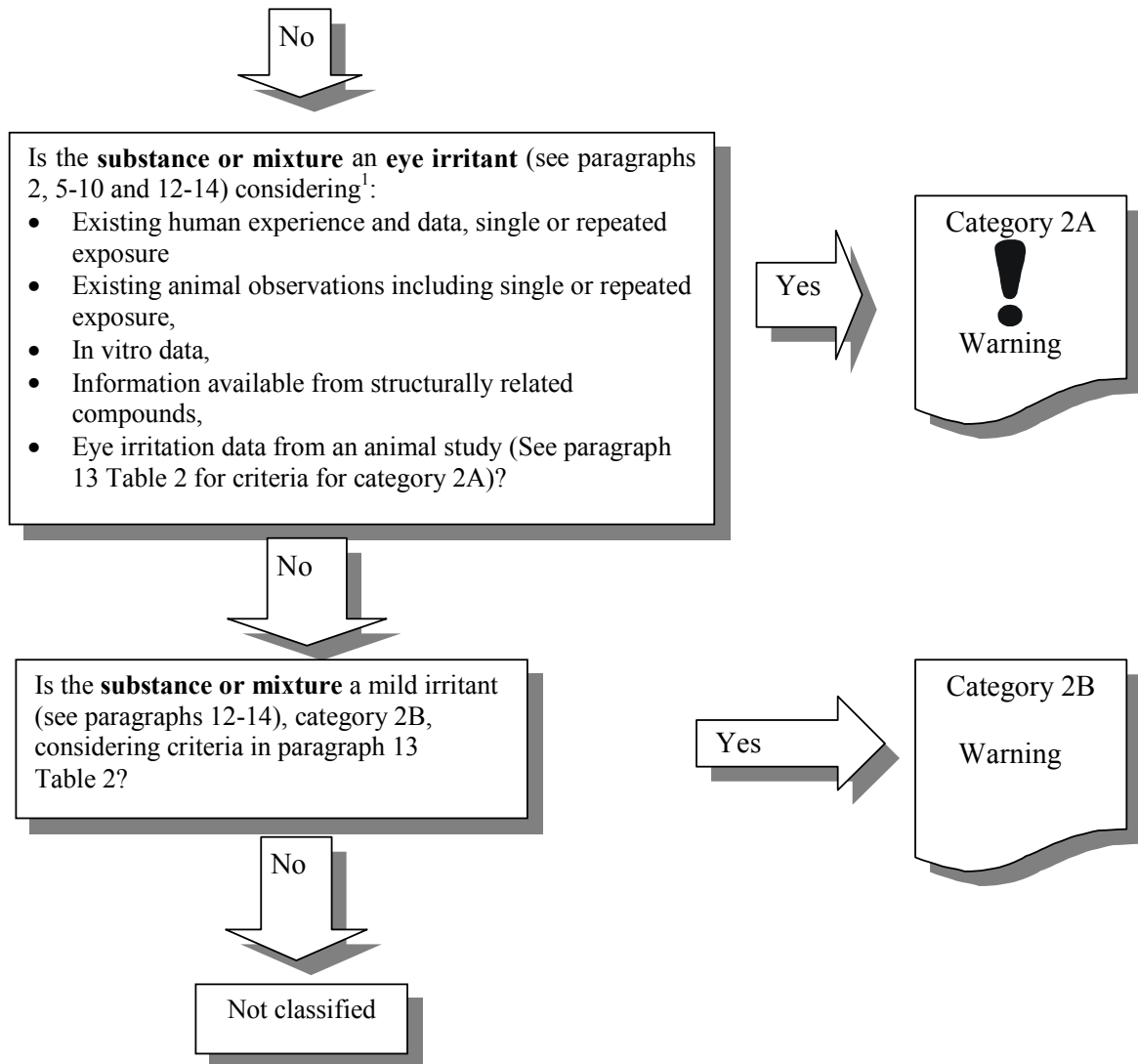
The decision logic, which follows is not part of the harmonised classification system, but has been provided here as additional guidance. The responsible person for classification is strongly recommended to study the criteria before and during use of the decision logic.

Decision Logic 1

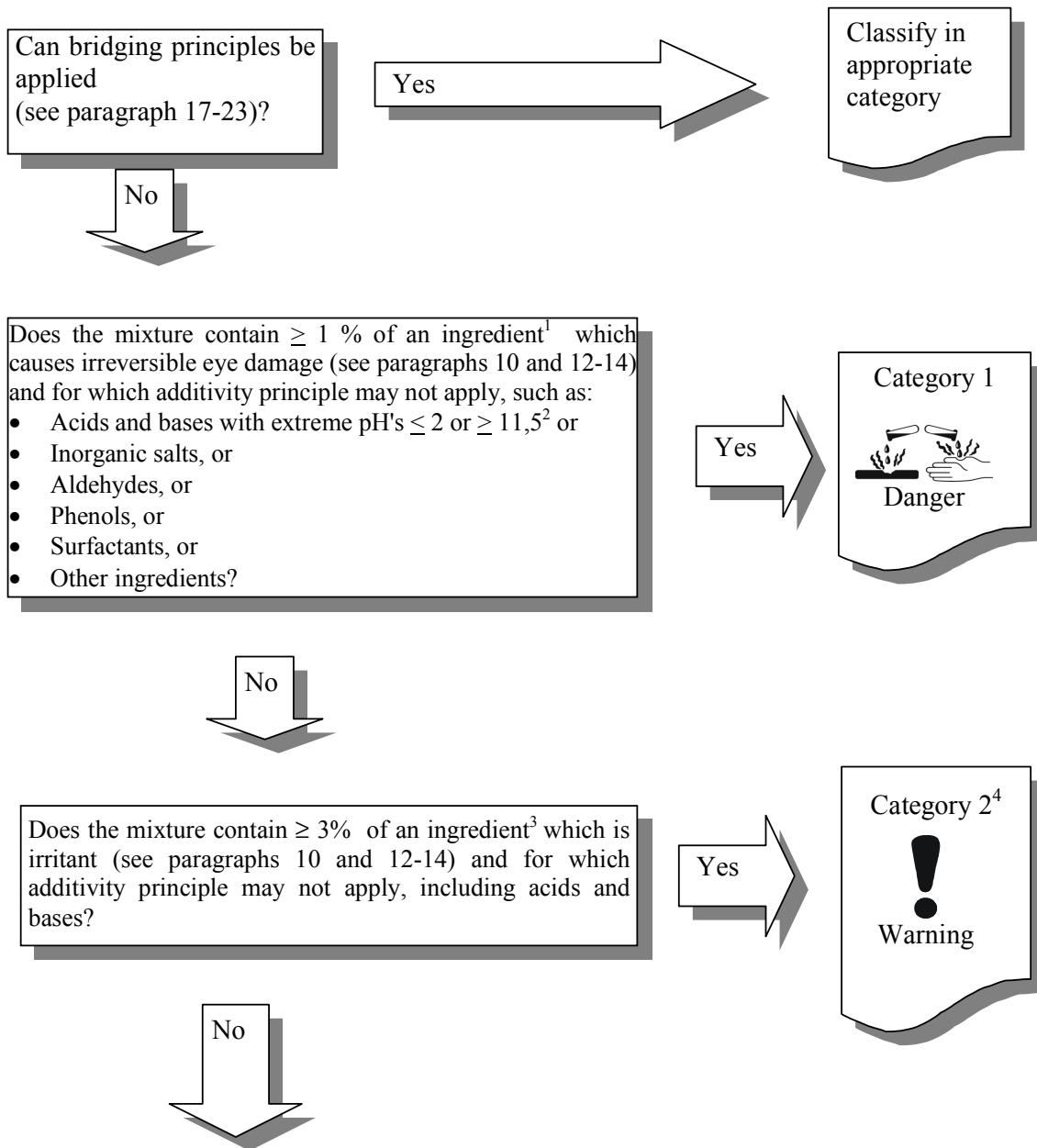


1 Figure 1 contains details for testing and evaluation.
2 including consideration of acid/alkali reserve capacity, if appropriate.

Continued on next page



¹ Figure 1 contains details for testing and evaluation.

Decision Logic 2 Classification of mixtures on the basis of information/data on ingredients

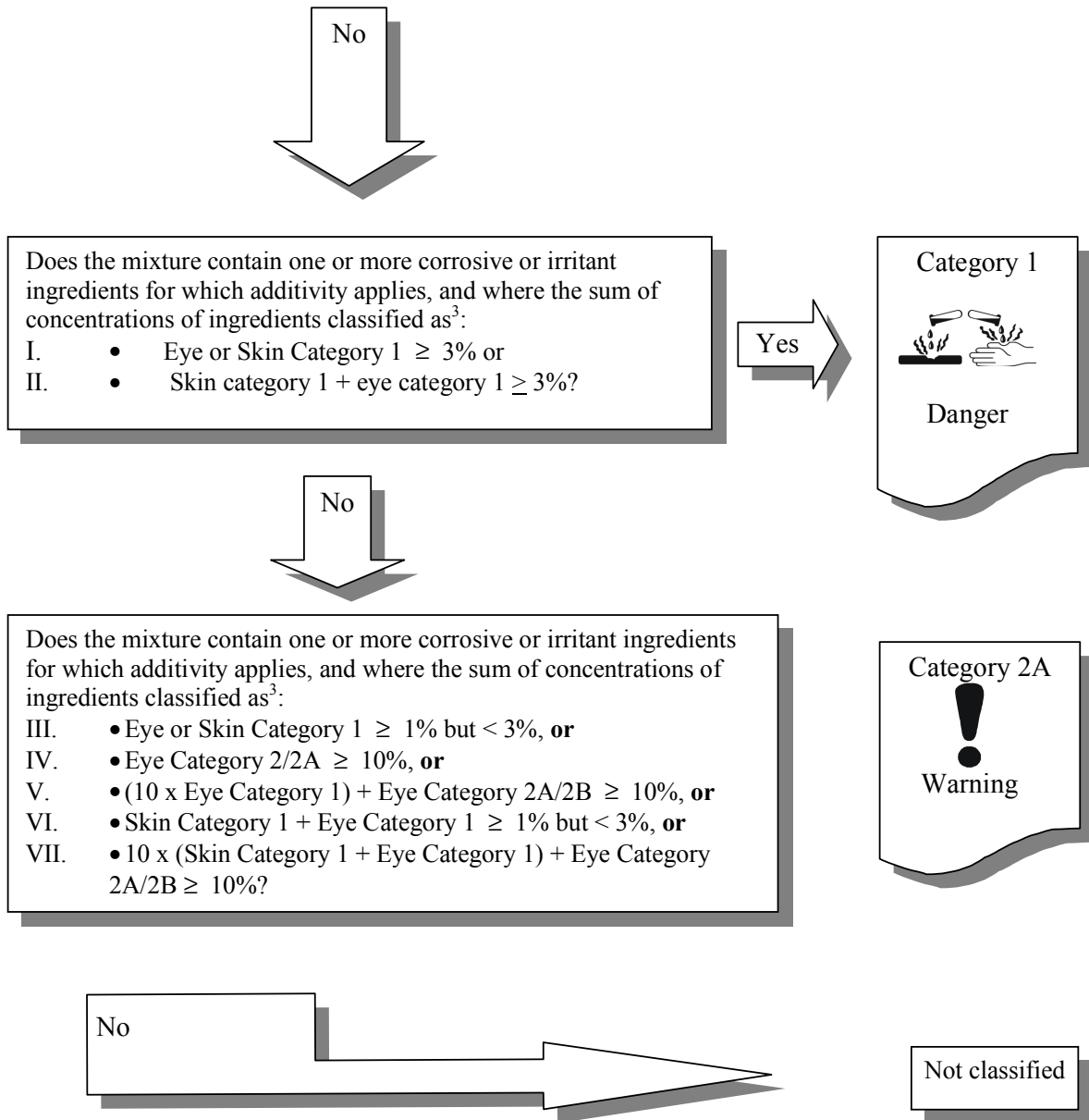
Continued on next page

¹ or where relevant $< 1\%$, see paragraph 24.

² including consideration of acid/alkali reserve capacity, if appropriate.

³ For specific concentration limits, see paragraph 27 of this chapter. See also Chapter 1.2 for "The Use of Cut-Off Values/Concentration Limits."

⁴ If the mixture also contains corrosive ingredient(s) for which additivity applies move to the box below.



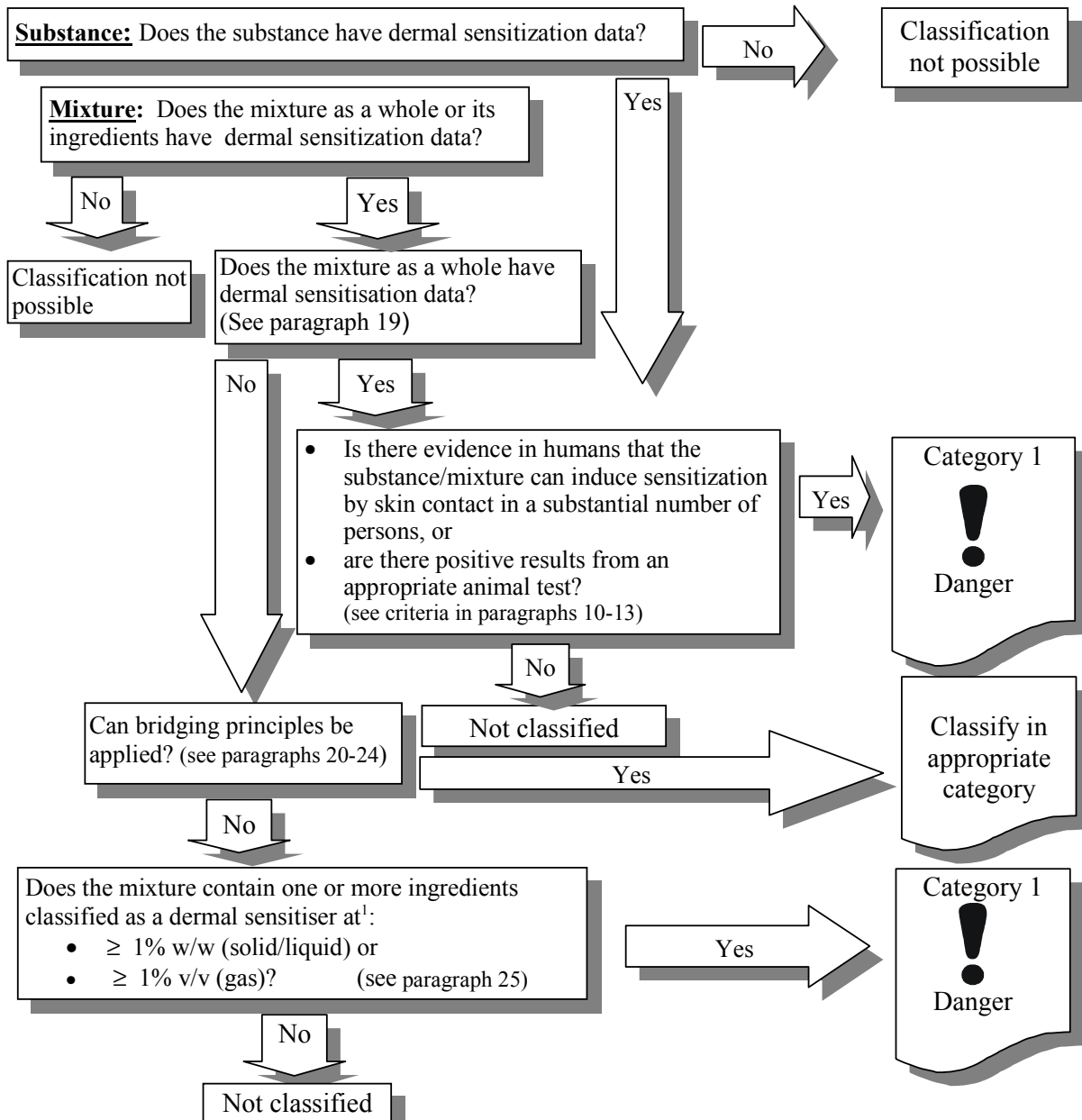
³ For specific concentration limits, see paragraph 27 of this chapter. See also Chapter 1.2 for "The Use of Cut-off Values/Concentration Limits."

ST/SG/AC.10/C.4/2001/22, page 59

Replace the Decision Logic for Classification of Dermal Sensitisation by the following:

DECISION LOGIC for Dermal Sensitisation

The decision logic, which follows is not part of the harmonised classification system, but has been provided here as additional guidance. It is strongly recommended that the person responsible for classification studies the criteria before and during use of the decision logic.



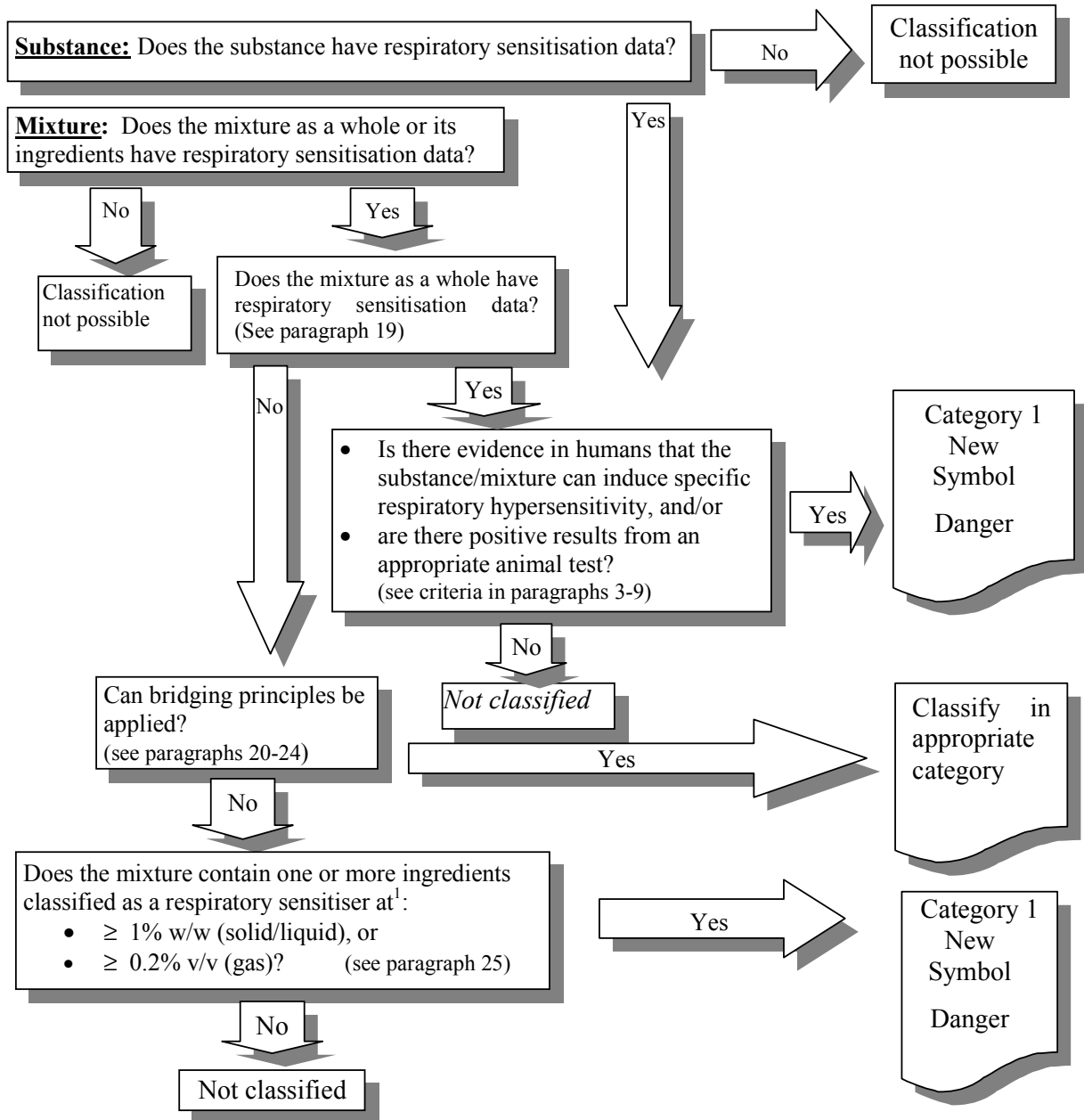
¹ For specific concentration limits, see “The use of Cut-off Values/Concentration Limits” in Chapter 1.

ST/SG/AC.10/C.4/2001/22, page 60

Replace the Decision Logic for Classification of Respiratory Sensitisation by the following:

Decision Logic for Respiratory Sensitisation

The decision logic, which follows is not part of the harmonised classification system, but has been provided here as additional guidance. It is strongly recommended that the person responsible for classification studies the criteria before and during use of the decision logic.



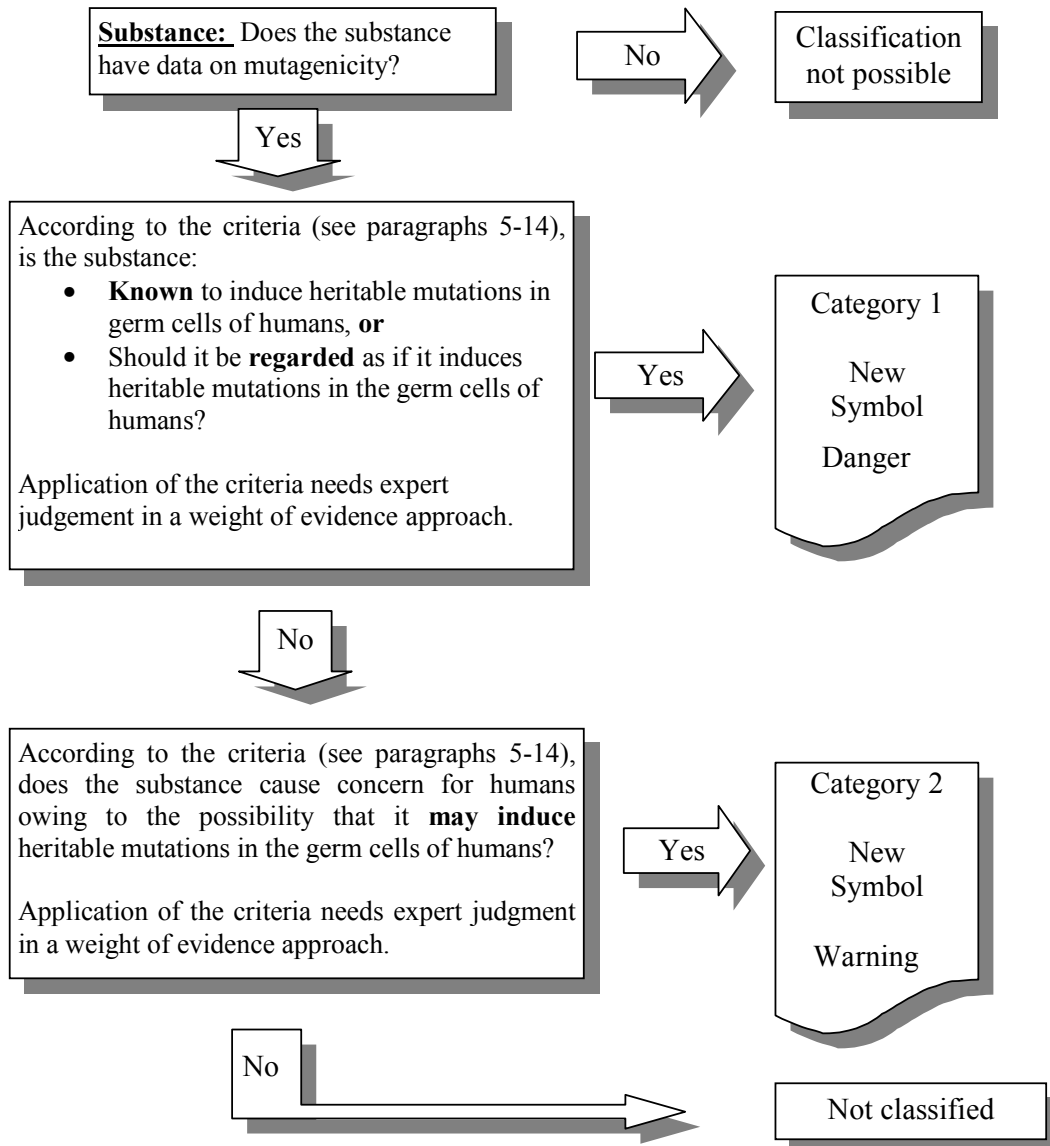
¹ For specific concentration limits, see “The use of Cut-off Values/Concentration Limits” in Chapter 1.2

ST/SG/AC.10/C.4/2001/23, page 9

Replace the Decision Logic for the Classification of Germ Cell Mutagenicity by the following:

Decision Logic for Germ Cell Mutagenicity

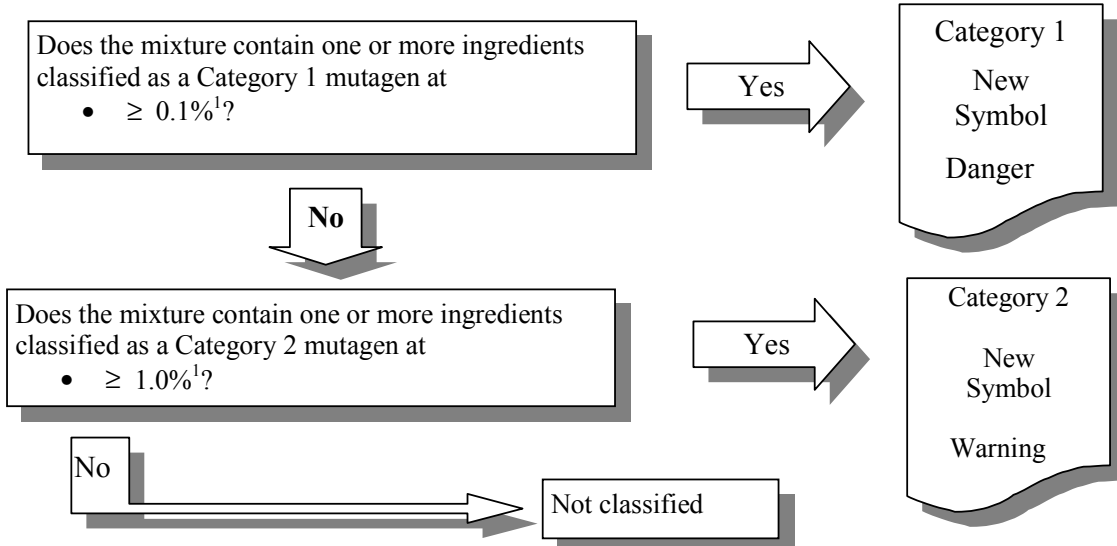
The decision logic, which follows is not part of the harmonised classification system, but has been provided here as additional guidance. It is strongly recommended that the person responsible for classification studies the criteria before and during use of the decision logic.



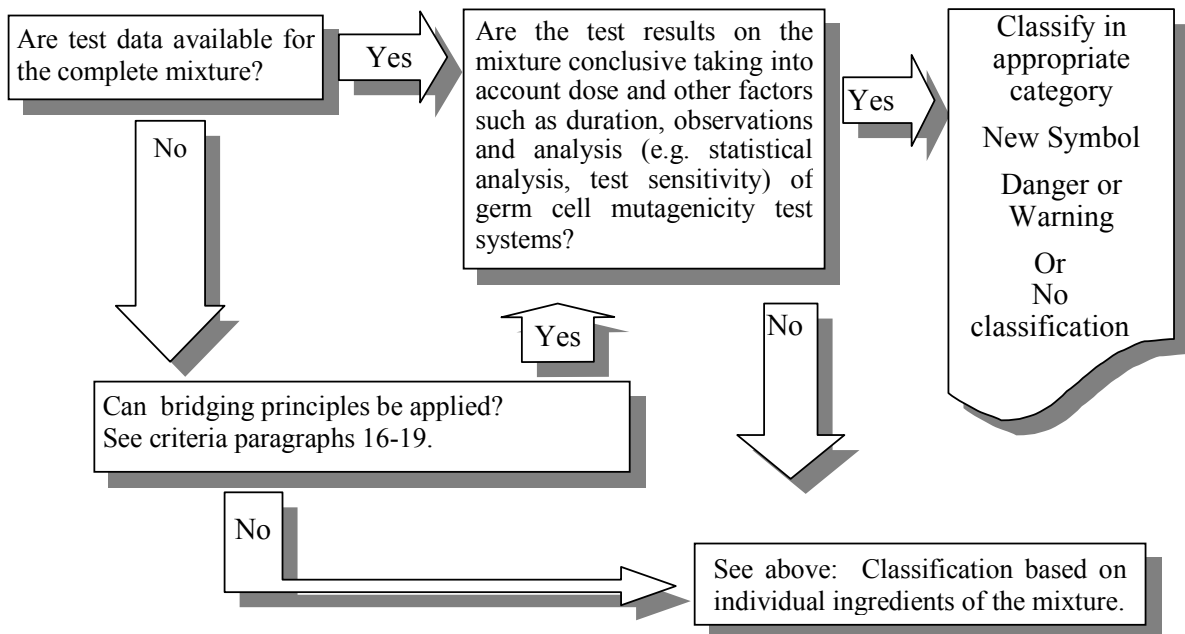
Mixture:

Classification of mixtures will be based on the available test data for the **individual ingredients** of the mixture, using cut-off values/concentration limits for those ingredients. The classification may be **modified on a case-by-case basis** based on the available test data for the mixture as a whole or based on bridging principles. See Modified classification on a case-by-case basis below. For further details see criteria (paragraphs 15-20).

Classification based on Individual Ingredients of the Mixture



Modified classification on a case-by-case basis



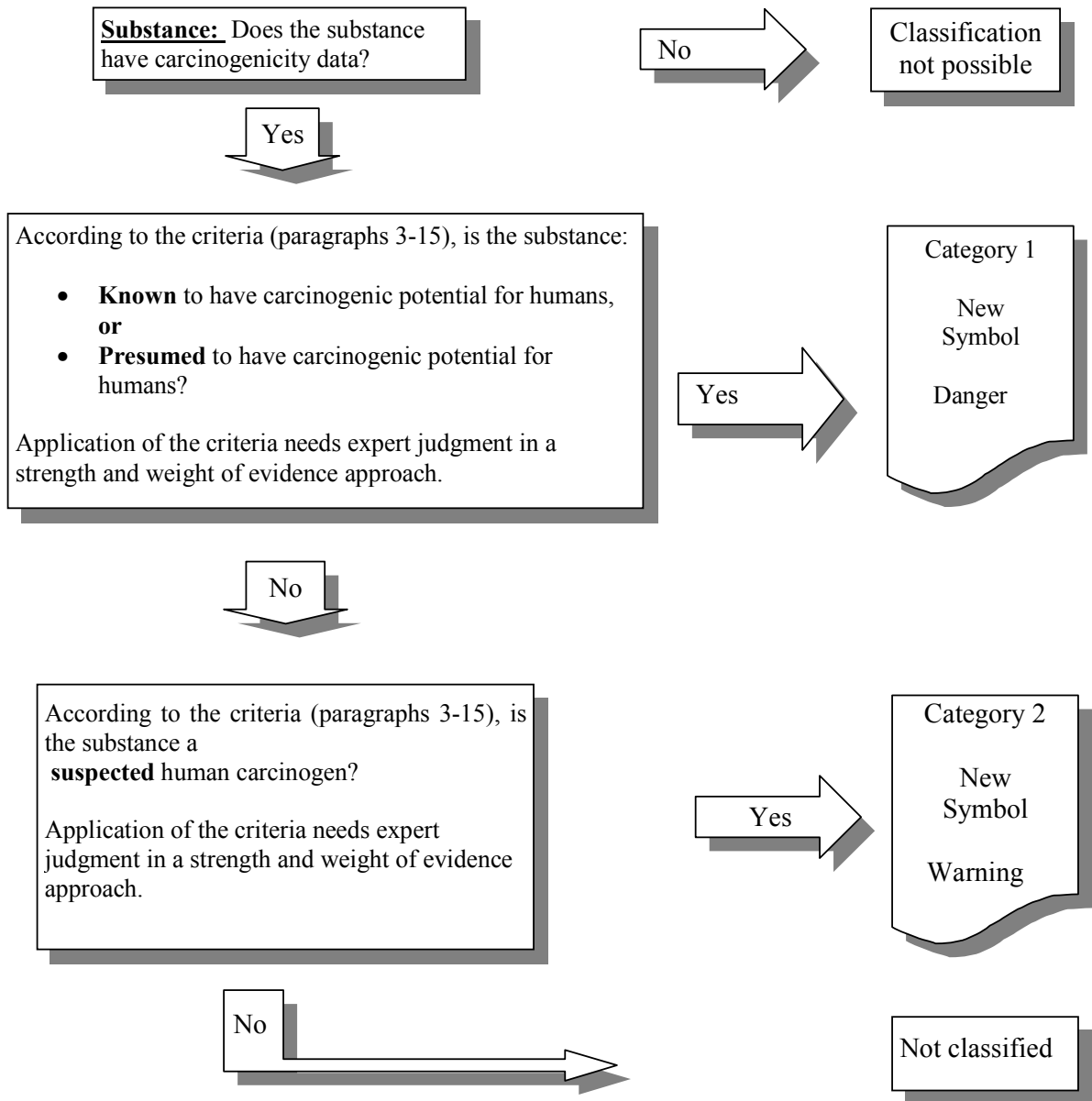
¹ For specific concentrations limits, see “The use of Cut-off Values/Concentration Limits” in Chapter 1.2 and Table 1 of this Chapter.

ST/SG/AC.10/C.4/2001/23, page 20

Replace the Decision Logic for Classification of Carcinogenicity by the following:

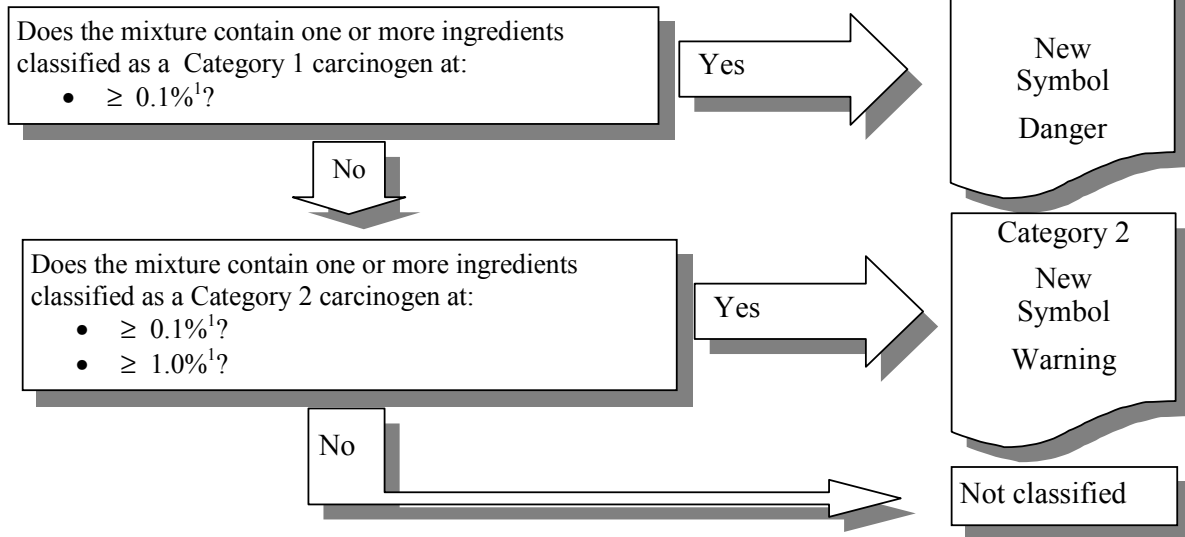
Decision Logic for Carcinogenicity

The decision logic, which follows is not part of the harmonised classification system, but has been provided here as additional guidance. The responsible person for classification is strongly recommended to study the criteria before and during use of the decision logic.

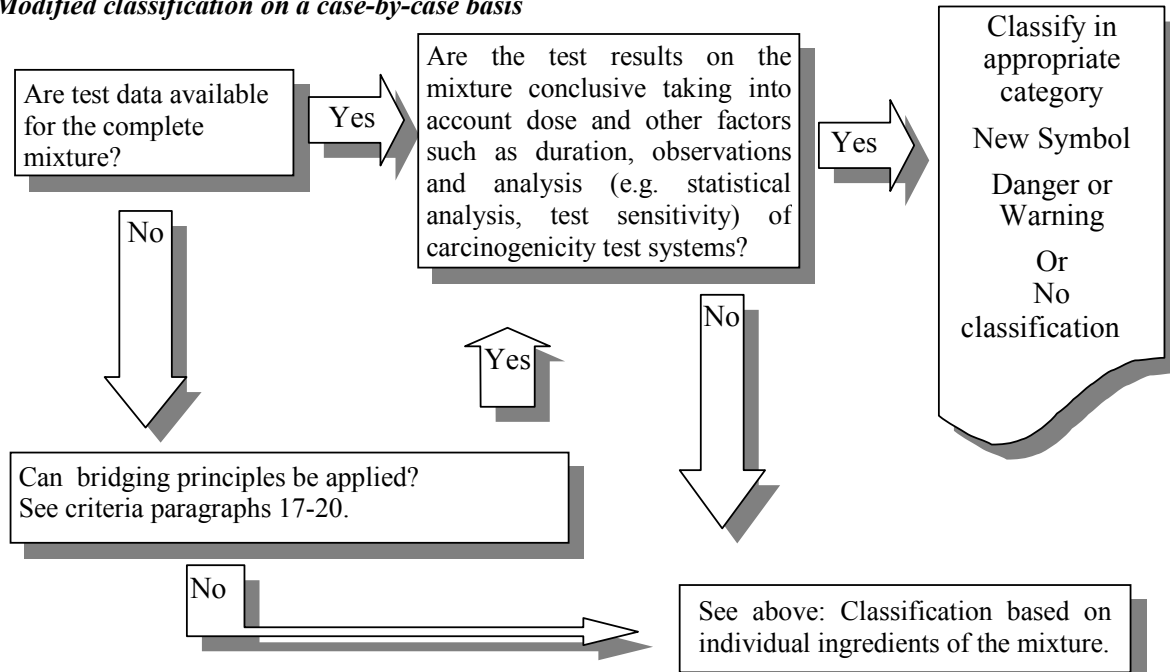


Mixture:
Classification of mixtures will be based on the available test data for the **individual ingredients** of the mixture, using cut-off values/concentration limits for those ingredients. The classification may be **modified on a case-by-case basis** based on the available test data for the mixture as a whole or based on bridging principles. See Modified classification on a case-by-case basis below. For further details see criteria (paragraphs 15-20).

Classification based on individual ingredients of the mixture



Modified classification on a case-by-case basis



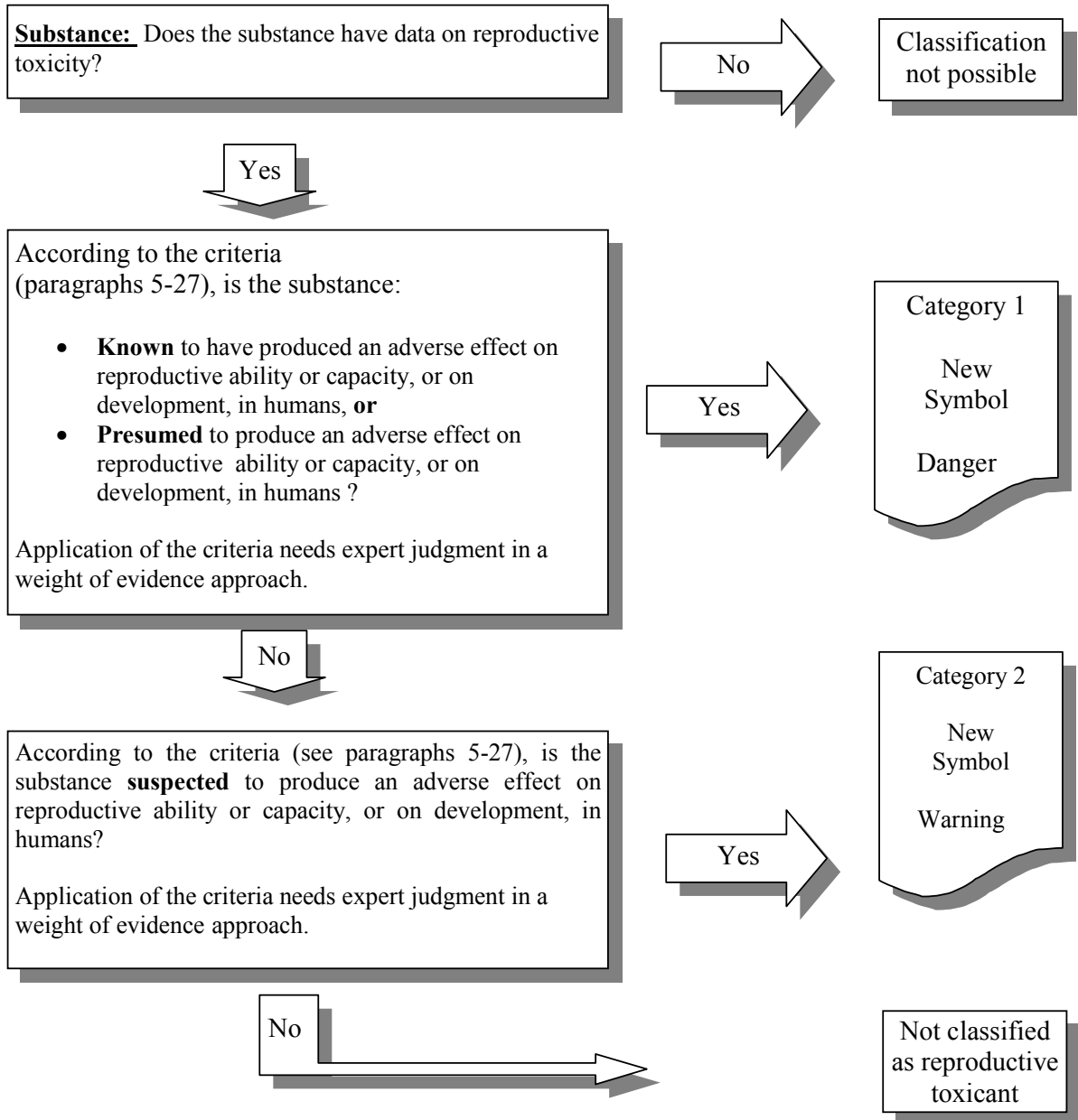
¹ For specific concentration limits, see "The use of Cut-off Values/Concentration Limits" in Chapter 1.2 and in Table 1 of this Chapter.

ST/SG/AC.10/C.4/2001/23, page 35

Replace the Decision Logic for Classification of Reproductive Toxicity by the following:

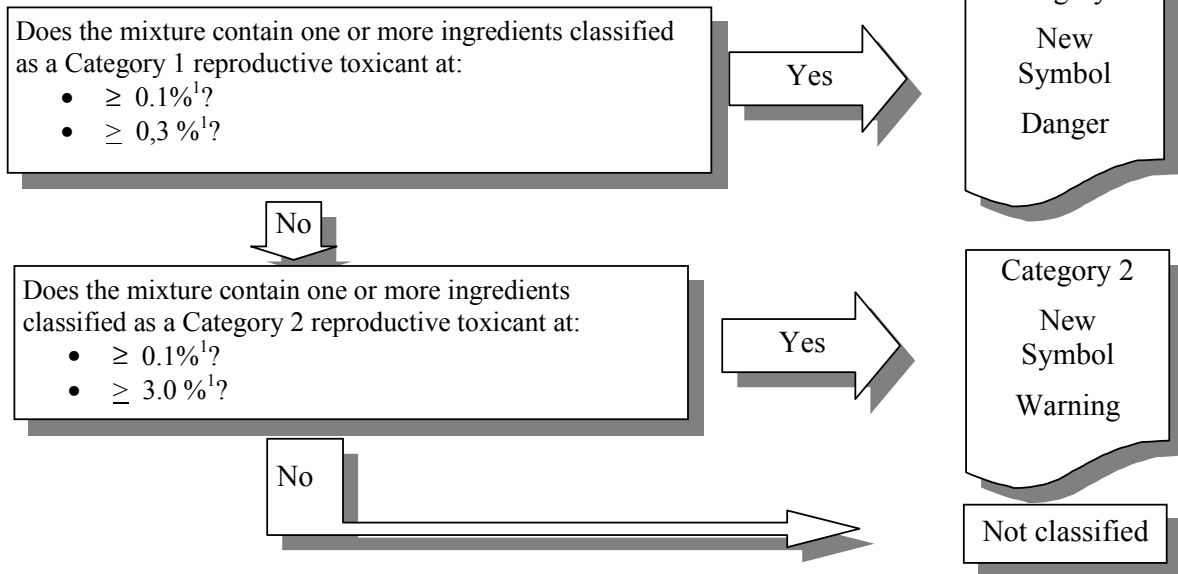
Decision Logic for Classification of Reproductive Toxicity

The decision logic, which follows is not part of the harmonised classification system, but has been provided here as additional guidance. It is strongly recommended that the person responsible for classification studies the criteria before and during use of the decision logic.

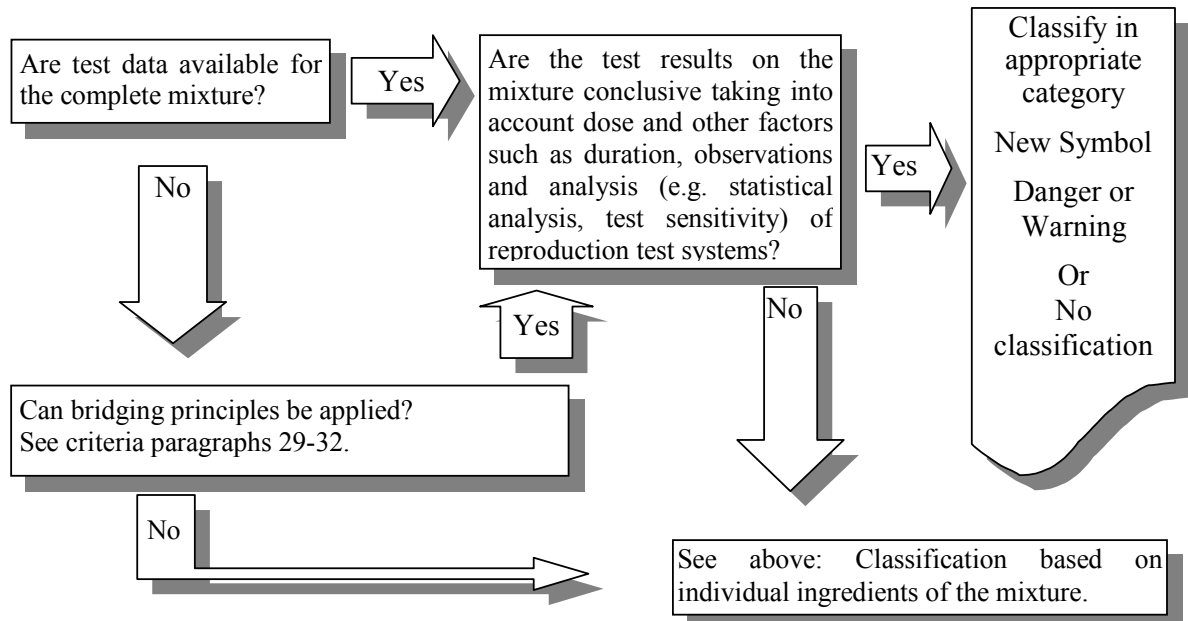


Mixture: Classification of mixtures will be based on the available test data for the **individual ingredients** of the mixture, using cut-off values/concentration limits for those ingredients. The classification may be **modified on a case-by-case basis** based on the available test data for the mixture as a whole or based on bridging principles. See modified classification on a case-by-case basis below. For further details see criteria (paragraphs 28-33).

Classification based on individual ingredients of the mixture

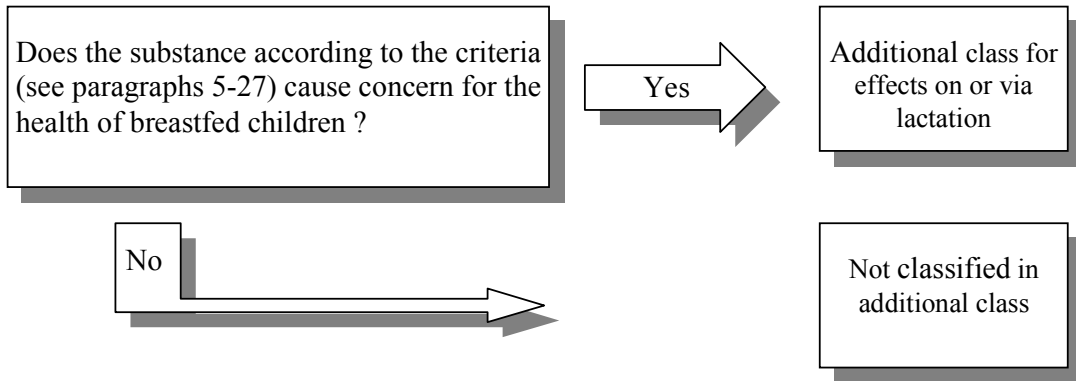


Modified classification on a case-by-case basis



¹ For specific concentration limits, see "The use of Cut-off Values/Concentration Limits" in Chapter 1.2 and in Table 1 of this Chapter.

Decision logic for effects on or via lactation:

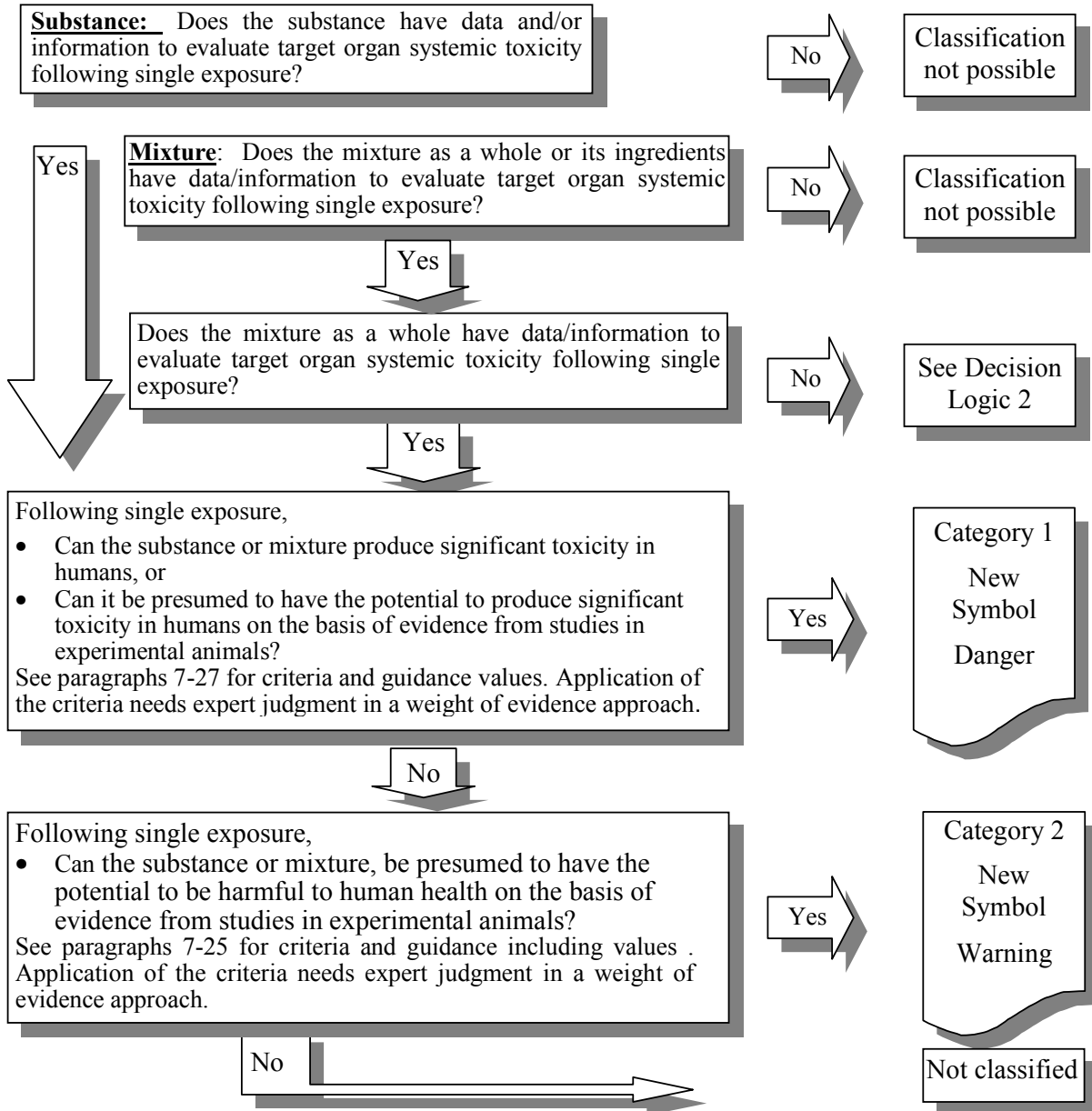


ST/SG/AC.10/C.4/2001/23, page 48

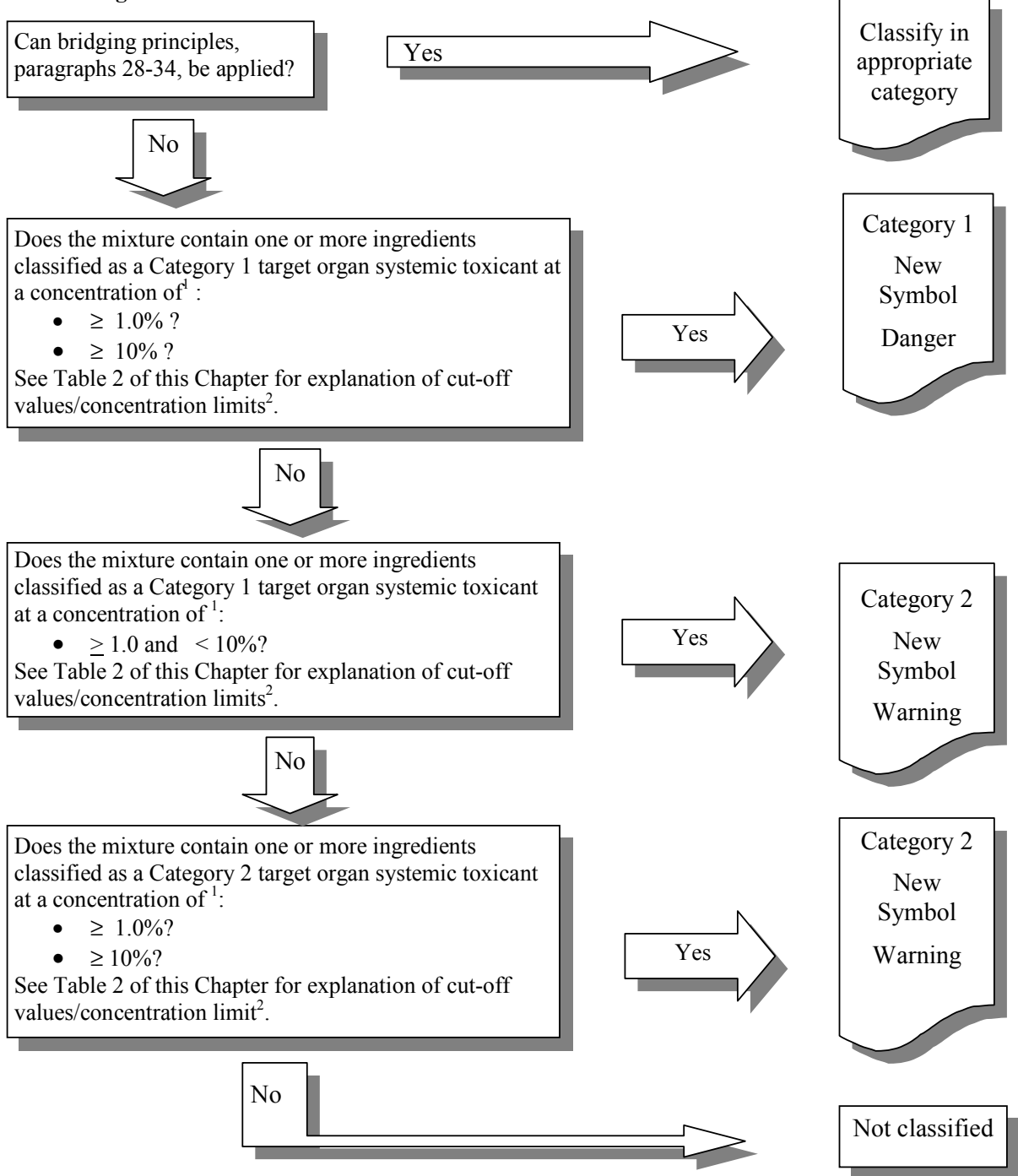
Replace the Decision Logic for Target Organ Systemic Toxicity from single exposure by the following:

Decision Logic for Target Organ Systemic Toxicity from Single Exposure

The decision logic, which follows is not part of the harmonised classification system, but has been provided here as additional guidance. The responsible person for classification is strongly recommended to study the criteria before and during use of the decision logic.



Continued on next page

Decision logic 2

¹ See paragraphs 7-25 of this Chapter and "The Use of Cut-off Values/Concentration Limits" in Chapter 1.2.

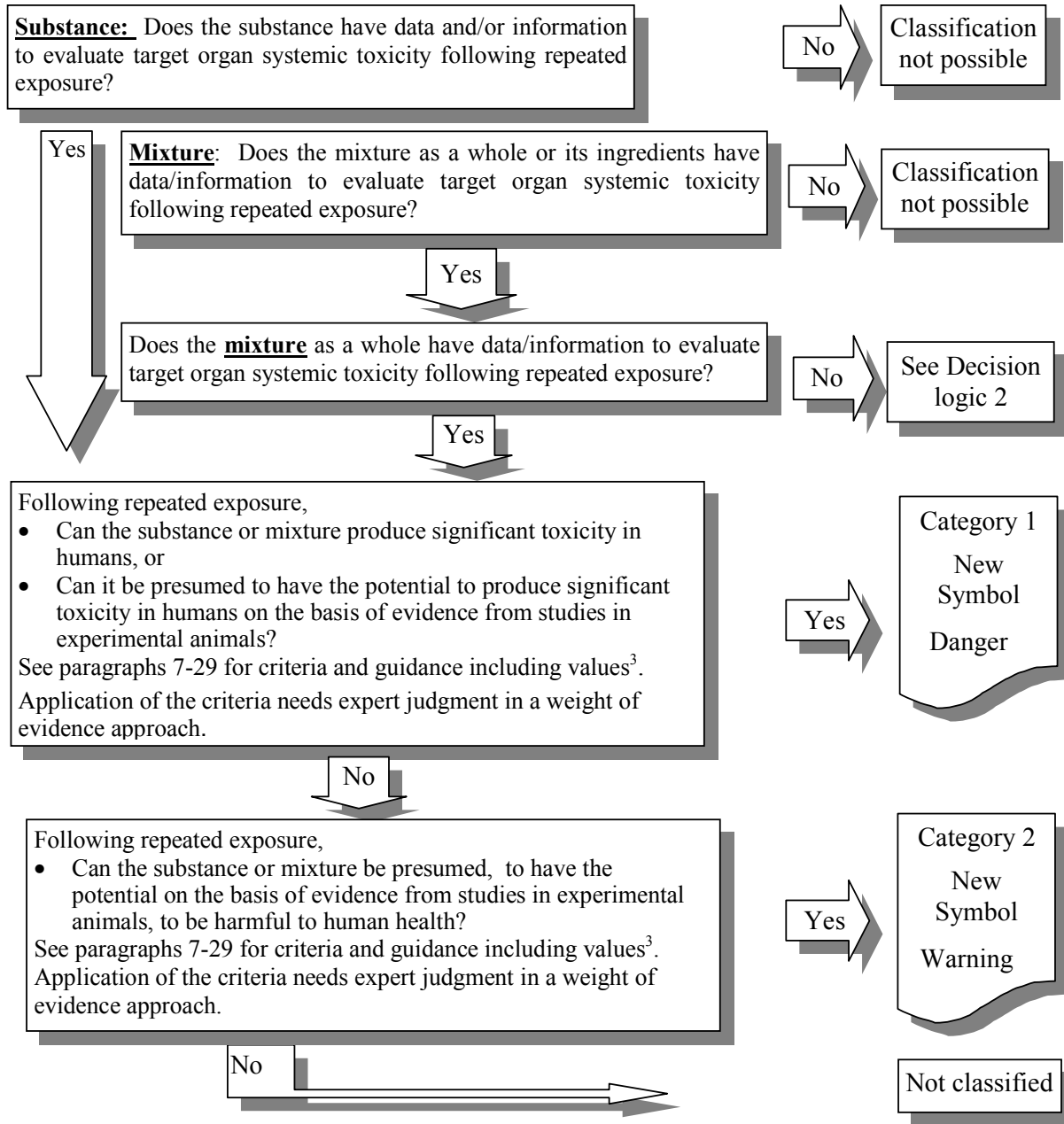
² See paragraphs 35-38 and Table 2 for explanation and guidance.

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Replace the Decision Logic for classification of Target Organ Systemic Toxicity, repeated exposure, by the following:

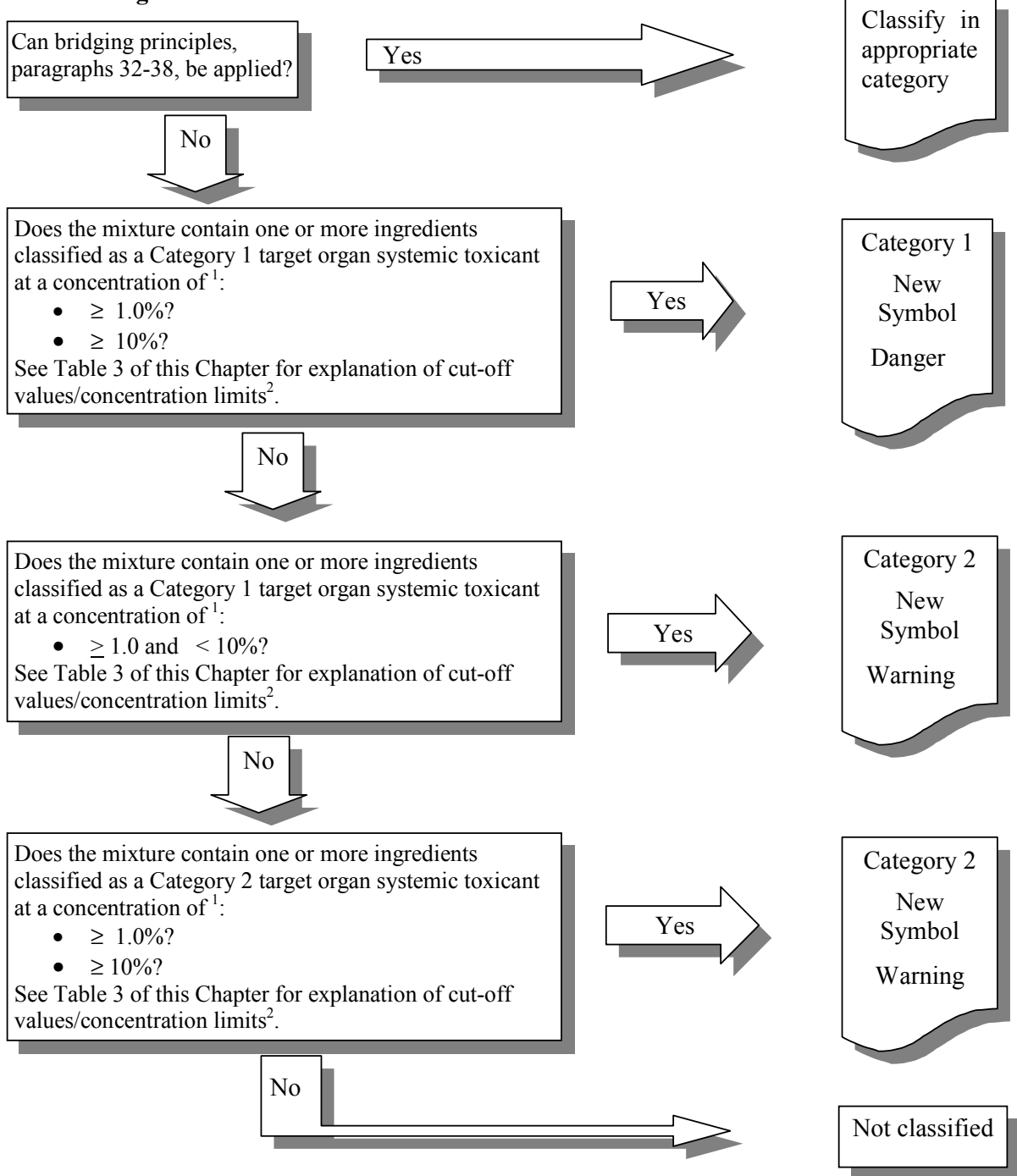
Decision Logic for Target Organ Systemic Toxicity following Repeated Exposure

The decision logic, which follows, is not part of the harmonised classification system, but has been provided here as additional guidance. The responsible person for classification is strongly recommended to study the criteria before and during use of the decision logic.



Continued on next page

Decision Logic 2



¹ In this chapter, see paragraphs 7-29, Tables 1 and 2, and in Chapter 1.2, see “The Use of Cut-off Values/Concentration Limits”.

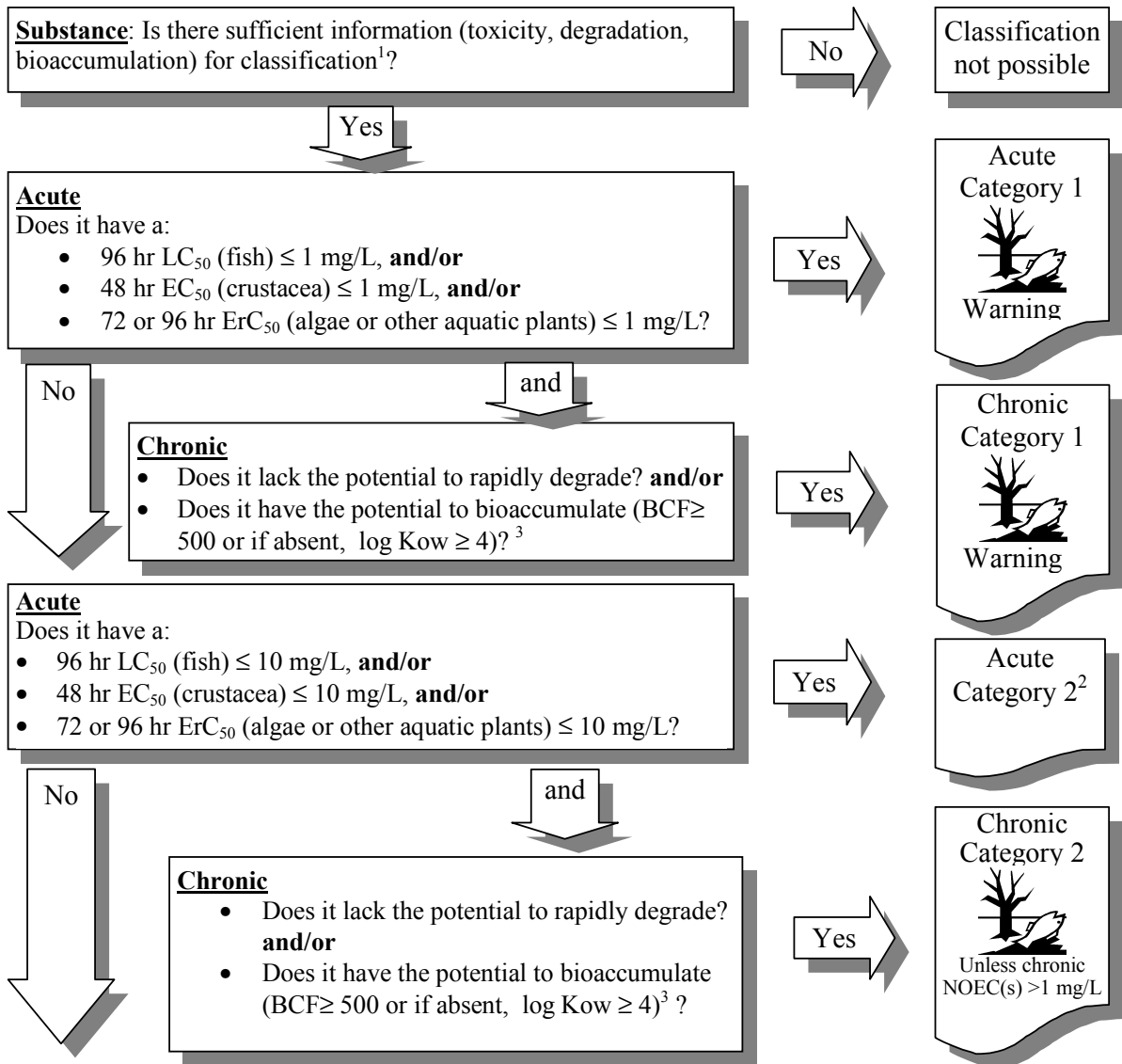
² See paragraphs 39-43 and Table 3 for explanation and guidance.

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Replace the Decision Logic and Guidance on page 79 by the following:

Decision Logic for Hazardous to the Aquatic Environment

The decision logic, which follows, is not part of the harmonised classification system, but has been provided here as additional guidance. It is strongly recommended that the person responsible for classification studies the criteria before and during use of the decision logic.

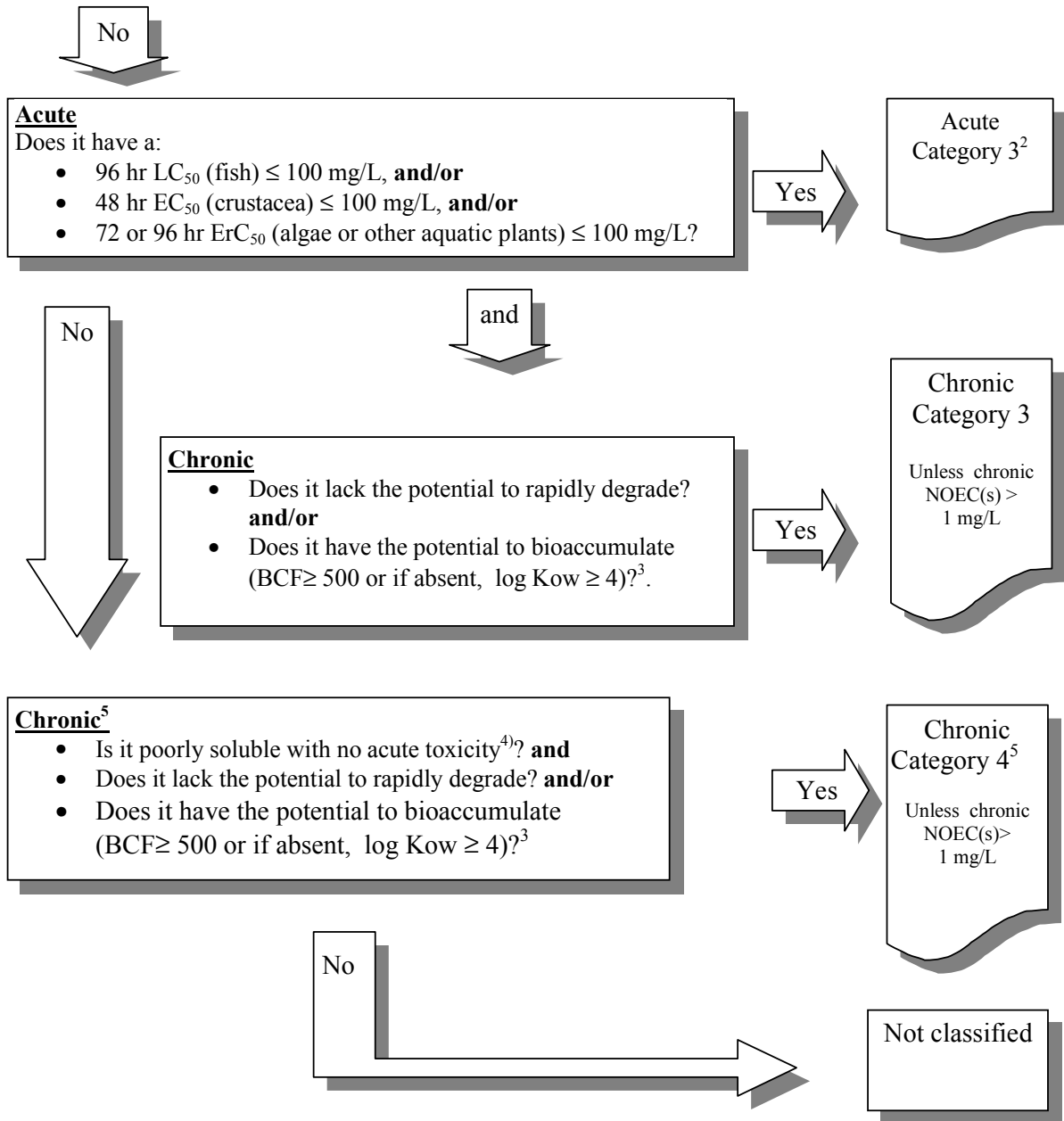


¹ Classification can be based on either measured data and/or calculated data (see paragraph 28 of this chapter and Annex 9) and/or analogy decisions (see paragraph 277 of Annex 9).

² Labelling requirements differ from on regulatory system to another, and certain classification categories may only be used in one or a few regulations.

³ See Note 4 of Table 1 and Chapter 5 of Annex 9.

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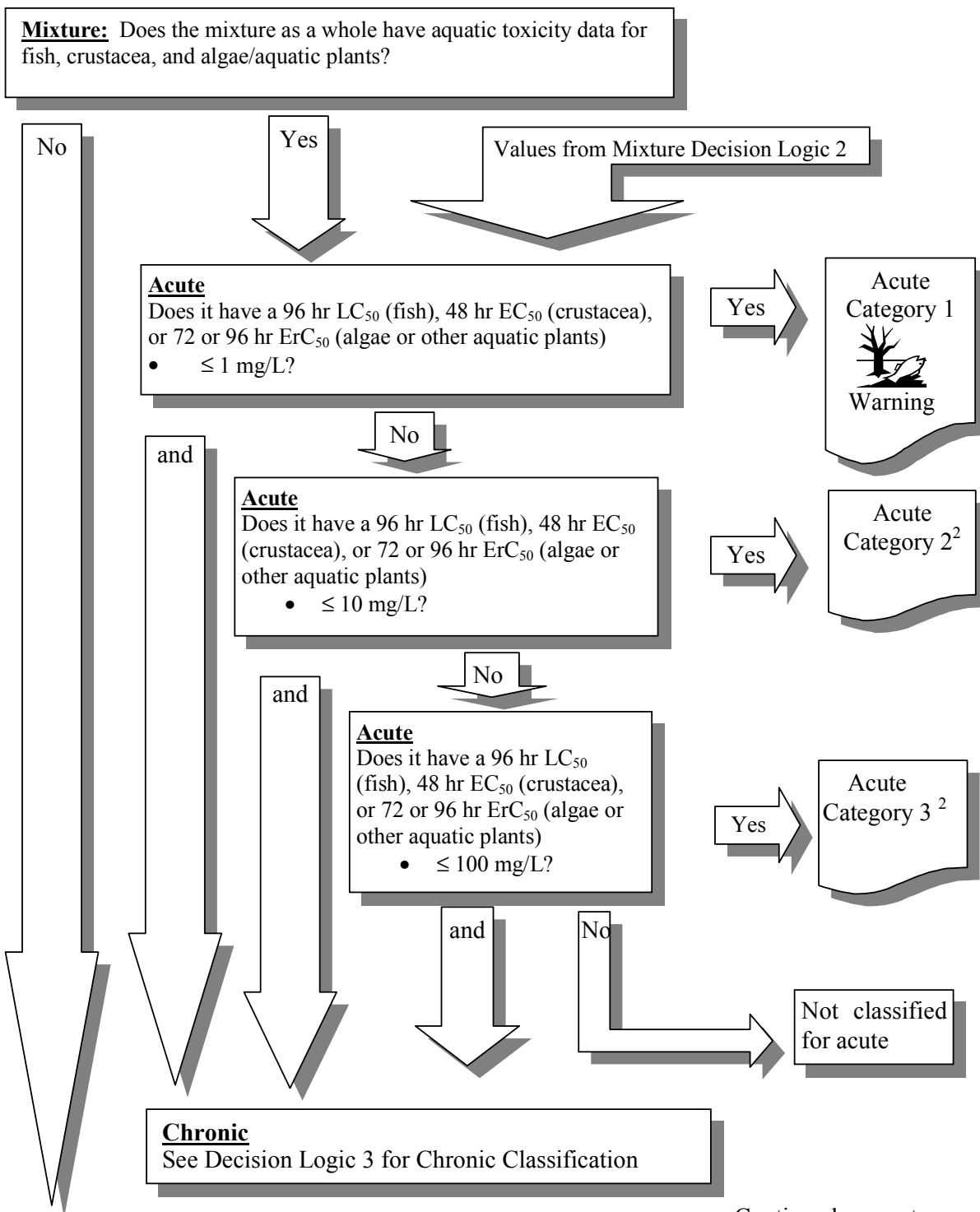


² Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.

³ See Note 4 of Table 1 and Chapter 5 of Annex 9.

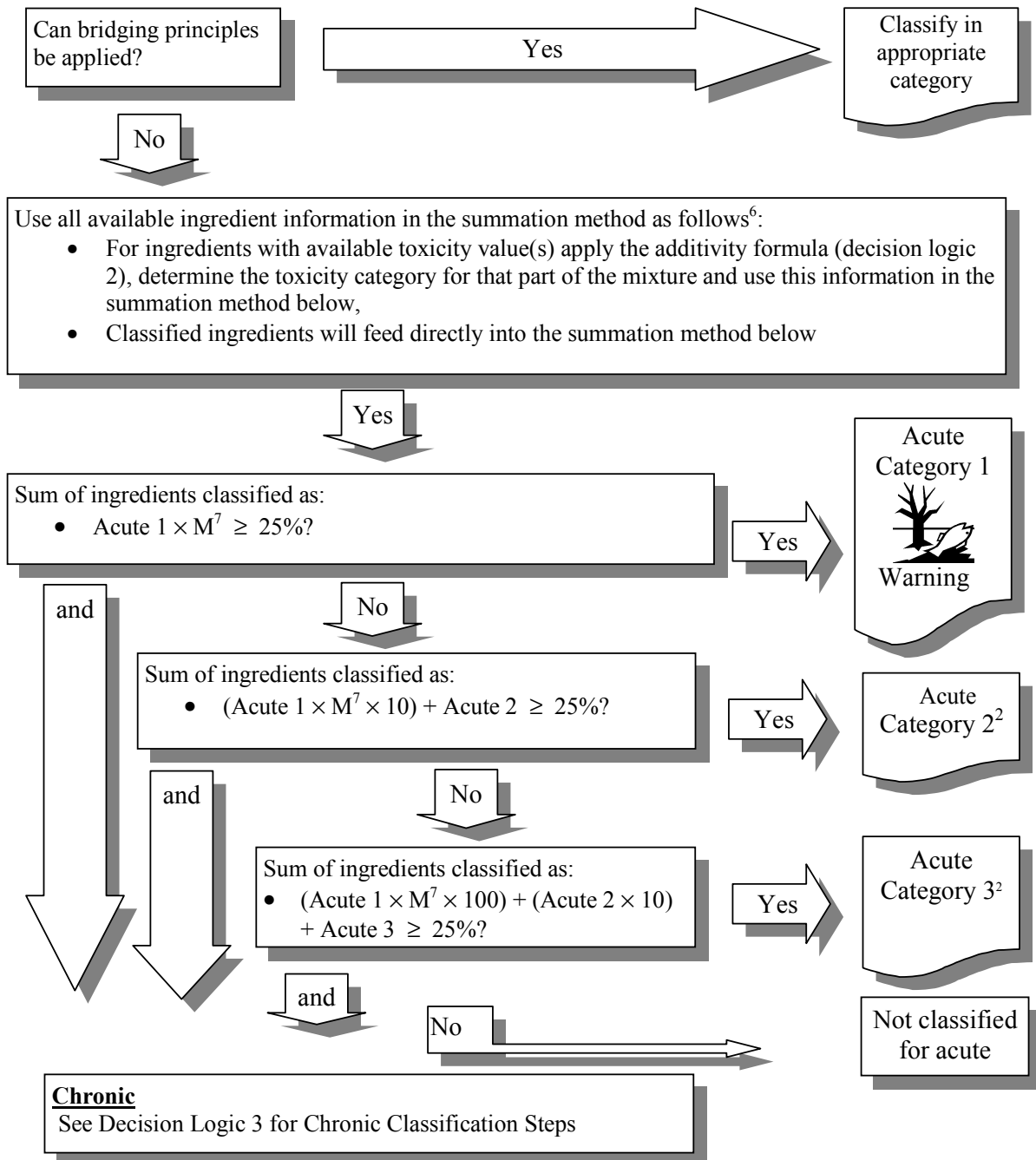
⁴ See Table 1, Note 5 further developed in Annex 9, paragraphs 66 and 67.

⁵ See paragraph 27.



Continued on next page

² Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.



² Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.

⁶ If not all components have information, include the statement “x percent of the mixture consists of ingredient(s) of unknown hazards to the aquatic environment” on the label. Alternatively, in the case of a mixture with highly toxic ingredients, if toxicity values are available for these highly toxic ingredients and all other ingredients do not significantly contribute to the hazard of the mixture, then the additivity formula may be applied. (See paragraph 56). In this case and other cases where toxicity values are available for all ingredients, the acute classification may be made solely on the basis of the additivity formula.

⁷ For explanation of M factor see paragraph 56.

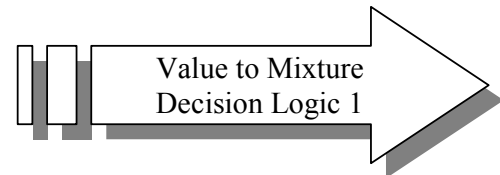
Mixtures decision logic 2 (Additivity method)

Apply the Additivity Method:

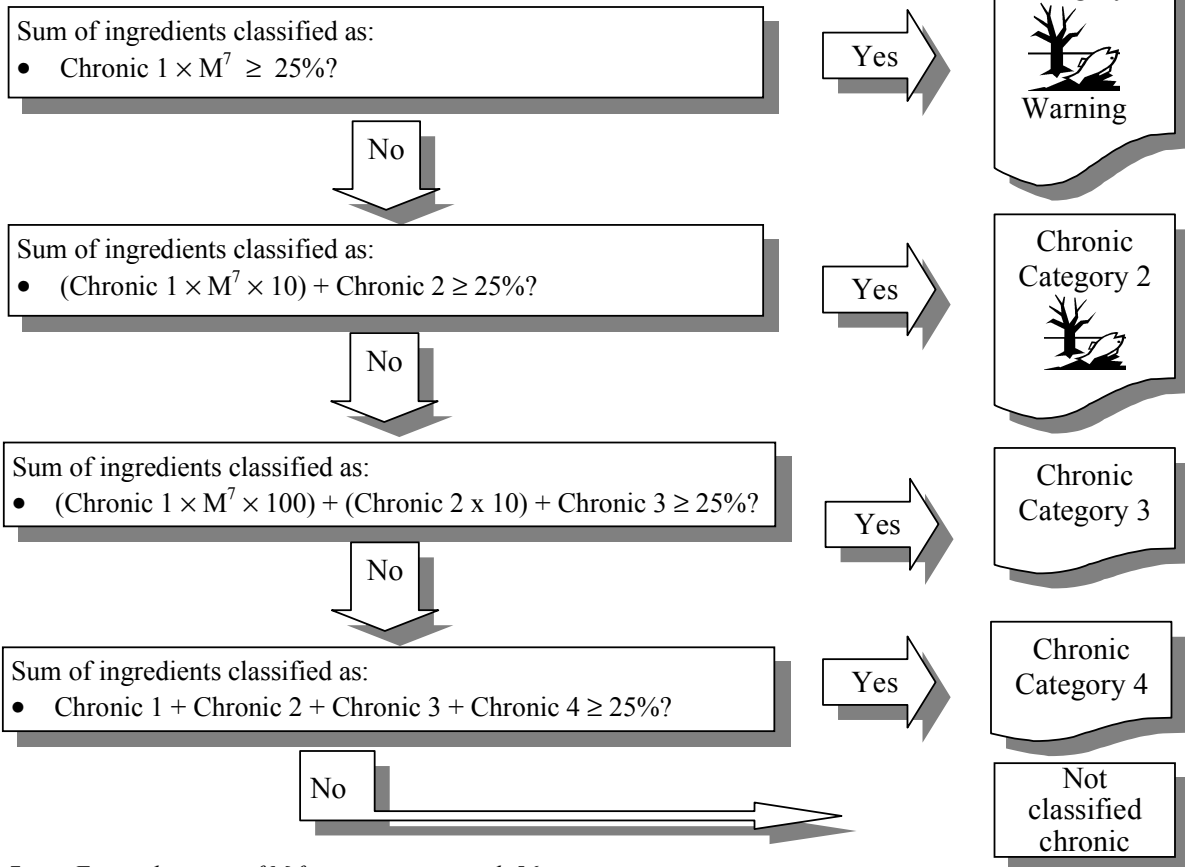
$$\frac{\sum C_i}{L(E)C_{50m}} = \sum \frac{C_i}{\eta L(E)C_{50i}}$$

where:

C_i = concentration of component i (weight percentage)
 $L(E)C_{50i}$ =(mg/L) LC_{50} or EC_{50} for component i
 η = number of components
 $L(E)C_{50m}$ = $L(E)C_{50}$ of the part of the mixture with test data



Mixtures decision logic 3 (Chronic classification)



7 For explanation of M factor see paragraph 56.