

UN/SCEGHS/2/INF.17

**Sub-Committee of Experts on the Globally
Harmonized System of Classification
and Labelling of Chemicals**
(Second session, 12-14 December 2001)

INFORMATION PAPER ON AGENDA ITEM 4

PROPOSALS FOR MODIFICATION OF THE DRAFT GHS-DOCUMENT

**Transmitted by the experts from Belgium, Austria, Finland, Norway,
Sweden and the United Kingdom**

Modifications that are identified in the attached document are proposed on the draft GHS-document (documents ST/SG/AC.10/C.4/2001/22, ST/SG/AC.10/C.4/2001/23, ST/SG/AC.10/C.4/2001/26, ST/SG/AC.10/C.4/2001/28).

Issues that are part of OECD Integrated Document but not included in the draft GHS Document

Document ST/SG/AC.10/C.4/2001/22, page 53, Chapter 3.4, paragraph 11, 7th line

Add "See chapter 1.2, paragraph 17" after the text "Positive data from experimental studies from man".

Document ST/SG/AC.10/C.4/2001/28, page 12, Annex 12, Carcinogenicity, paragraph 4

Add in paragraph 4 after the present text (and repeated in document ST/SG/AC.10/C.4/2001/23, page 16, paragraph 15, lines 5 – 12):

" The proceedings of a WHO/IPCS working group on harmonised risk assessment for carcinogenicity points to a number of scientific questions arising for classification of chemicals e.g. mouse liver tumours, peroxisome proliferation, receptor-mediated reactions, chemicals which are carcinogenic only at toxic doses and which do not demonstrate mutagenicity. Accordingly, there is a need to articulate the principles necessary to resolve these scientific issues, which have led to diverging classifications in the past. Once these issues are resolved, there would be a firm foundation for classification of a number of chemical carcinogens."

Document ST/SG/AC.10/C.4/2001/28, page 13, Annex 12, Carcinogenicity, paragraph 6

Add a new paragraph after paragraph 6 of Annex 12, Carcinogenicity, page 13:

" *Considerations for important factors mentioned in Chapter 3.6 paragraph 9*

Guidance on the importance of the different factors mentioned in paragraph 9 of chapter 3.6 has to be developed in order to indicate their effects or level of concern."

Editorial modifications on the draft GHS-Documents (Documents ST/SG/AC.10/C.4/2001/23, ST/SG/AC.10/C.4/2001/26)

Document ST/SG/AC.10/C.4/2001/23, page 27, Chapter 3.7, Reproductive toxicity

ST/SG/AC.10/C.4/2001/23, page 27, Chapter 3.7, Paragraph 3, 7th line: paragraph number is incorrect. Replace 9 with 5.

ST/SG/AC.10/C.4/2001/23, page 27, Chapter 3.7, Paragraph 5, third line and second box, replace word 'class' by word 'category'.

Document ST/SG/AC.10/C.4/2001/26, Annex 3, page 17, table ‘Organic peroxides’

ST/SG/AC.10/C.4/2001/26, page 17, table ‘Organic peroxides’, 4th column – ‘flame’-symbol should be replaced by ‘oxidising’ symbol.

Document ST/SG/AC.10/C.4/2001/26, Annex 3, page 34

Document ST/SG/AC.10/C.4/2001/26, Annex 3, page 34, add ‘Classification and labelling for environmental classes and categories’, which is missing.

Proposals to improve the 'Guidance text' of draft GHS-Document

ST/SG/AC.10/C.4/2001/28, page 11, Annex 12, add a new paragraph on 'Acute toxicity' after paragraph 2

ST/SG/AC.10/C.4/2001/28, Annex 12, page 11, add a new paragraph after paragraph 2:.

"Acute toxicity

The criteria for acute toxicity should be revised to take account of new test methods replacing the LD50-method. "

ST/SG/AC.10/C.4/2001/28, page 13, Annex 12: add new paragraphs under heading 'Reproductive toxicity'

Replace in ST/SG/AC.10/C.4/2001/28, Annex 12 on page 13 the subheading 'Classification of mixtures containing substances having effects on or via lactation' by 'Classification of substances and mixtures having effects on or via lactation'.

Add in the beginning of paragraph 5.1 under subheading 'Classification of substances and mixtures having effects on or via lactation.' a sentence "Examine whether a separate class is needed for lactation effects. "

Add a new paragraph in Annex 12, page 13, after paragraph 5.1:

"Terminology

The terms "reproductive toxicity", "developmental toxicity" and "reproductive ability and capacity" used in paragraphs 5 and 6 of chapter 3.7 (Document ST/SG/AC.10/C.4/2001/23, page 26 - 27) should be clarified. "

Proposal for modification of Decision Logic schemes, documents

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 only. The responsible person for classification is strongly recommended to study the criteria before and during use of the decision logic."

Chapter 3.2: Skin corrosion/irritation

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

- 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

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

- References to paragraphs of criteria are added in boxes for 'corrosive', 'irritant' and 'mild irritant'
- 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

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

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

- The cases where additivity does not apply and additivity applies are linked in the flowsheet
- In boxes, where summation formula are presented, a reference to specific concentration limits is introduced.

Chapter 3.3: Serious eye damage/Eye irritation

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

- 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

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

- References to paragraphs of criteria 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

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

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

- The cases where additivity does not apply and additivity applies are linked in the flowsheet

Chapter 3.4: Respiratory or Skin Sensitisation

ST/SG/AC.10/C.4/2001/22, page 58 and 60

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

ST/SG/AC.10/C.4/2001/22, page 58

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

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

- The scheme starts with "Substance" instead of "Mixture".
- References to paragraphs in the criteria 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 replaced 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 flowsheet on classification based on data for the mixture as a whole or bridging principles has been changed to a footnote in the new DL on mixtures. Left from the previous version is the first, upper box on Mixture (text slightly modified), followed by the flowsheet on classification based on individual ingredients of the mixture, on page 11.

Chapter 3.6: Carcinogenicity

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

- Footnote 1 is deleted and replaced 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 flowsheet on classification based on data for the mixture as a whole or bridging principles has been changed to a footnote in the new DL on mixtures. Left from the previous version is the first, upper box on Mixture (text slightly modified), followed by the flowsheet on classification based on individual ingredients of the mixture, on page 22. A deletion “ See table of this chapter for explanation of cut-off values/concentration limits” is made in the text of the second vertical box on page 22.

Chapter 3.6: Reproductive toxicity

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

- Footnote 1 is deleted and replaced 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 37-38

Mixture:

- Page 37-38: The part of the flowsheet on classification based on data for the mixture as a whole or bridging principles has been changed to a footnote in the new DL on mixtures. Left from the previous version is the first, upper box on Mixture (text slightly modified), followed by the flowsheet on classification based on individual ingredients of the mixture, on page 38. A deletion “ See table 1 of this chapter for explanation of cut-off values/concentration limits” is made in the text of the second and third vertical box on page 38.

Chapter 3.8: Specific target organ systemic toxicity - Single exposure

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

- The flowsheet is modified following the same model as for acute toxicity
- The wording of boxes is modified to emphasise better the criteria.
- References to paragraphs of criteria 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

- The flowsheet is modified following the same model as for acute toxicity
- The wording of boxes is modified to emphasise better the criteria.
- References to paragraphs of criteria 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 replaced by a corresponding header under the heading.

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.
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 relevant paragraph numbers for detailed explanation of criteria should be used consistently in all decision logic and guidance schemes (e.g. see sensitisation).

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

Reprinted modified Decision Logic schemes are attached.

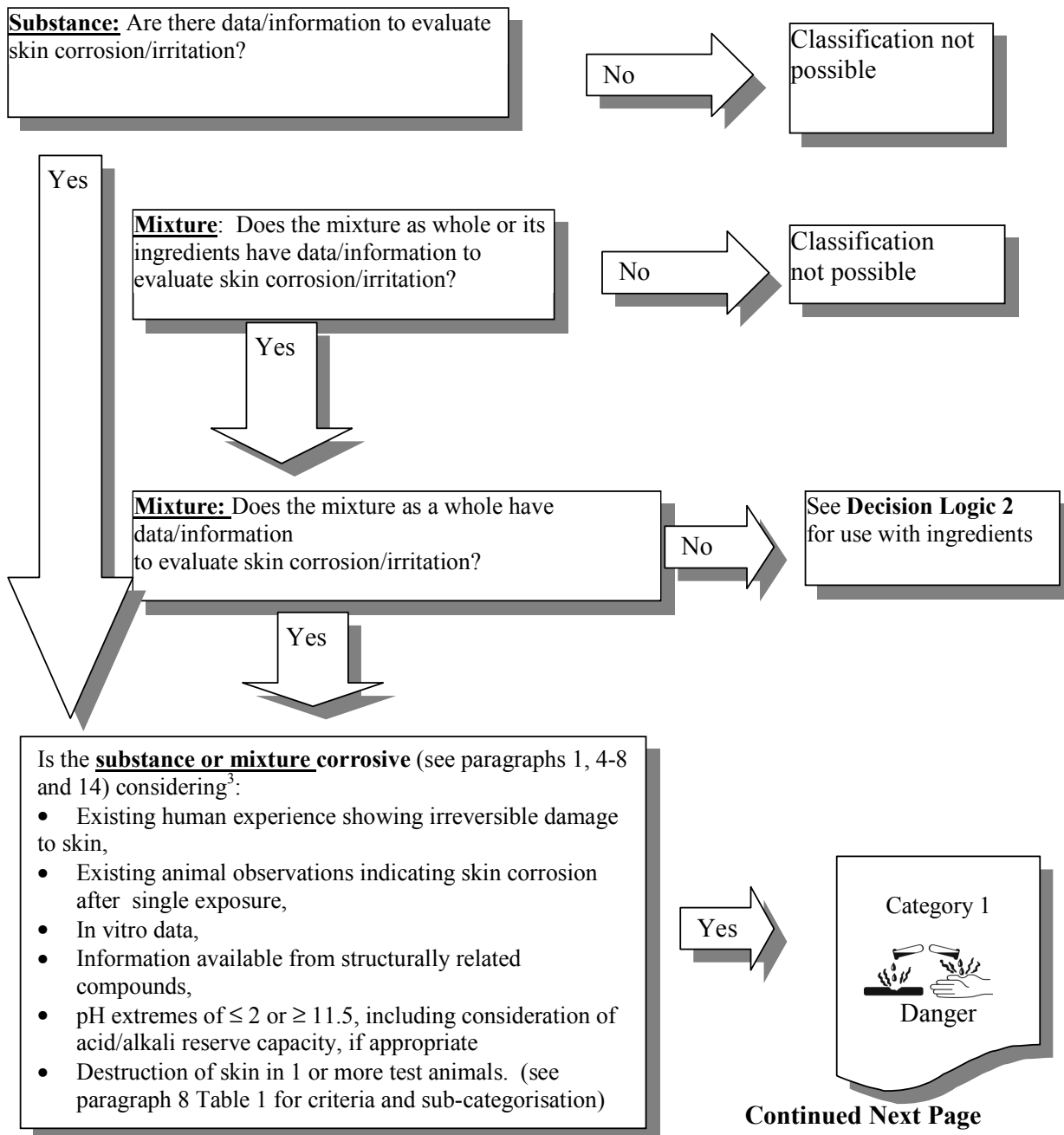
ST/SG/AC.10/C.4/2001/22, page 31

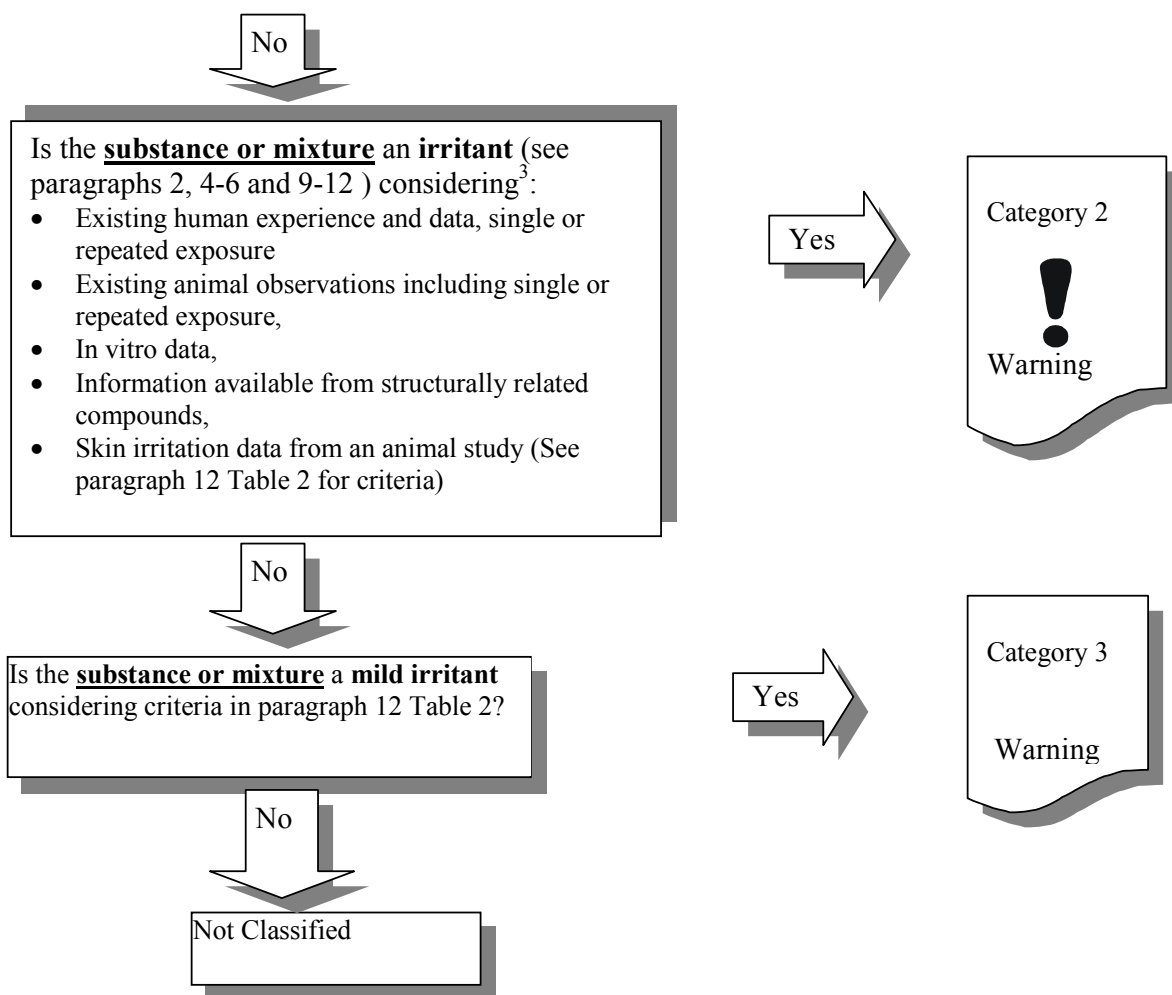
Replace the Decision Logic for skin corrosion/irritation by the following:

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 (only). The responsible person for classification is strongly recommended to study the criteria before and during use of the decision logic.

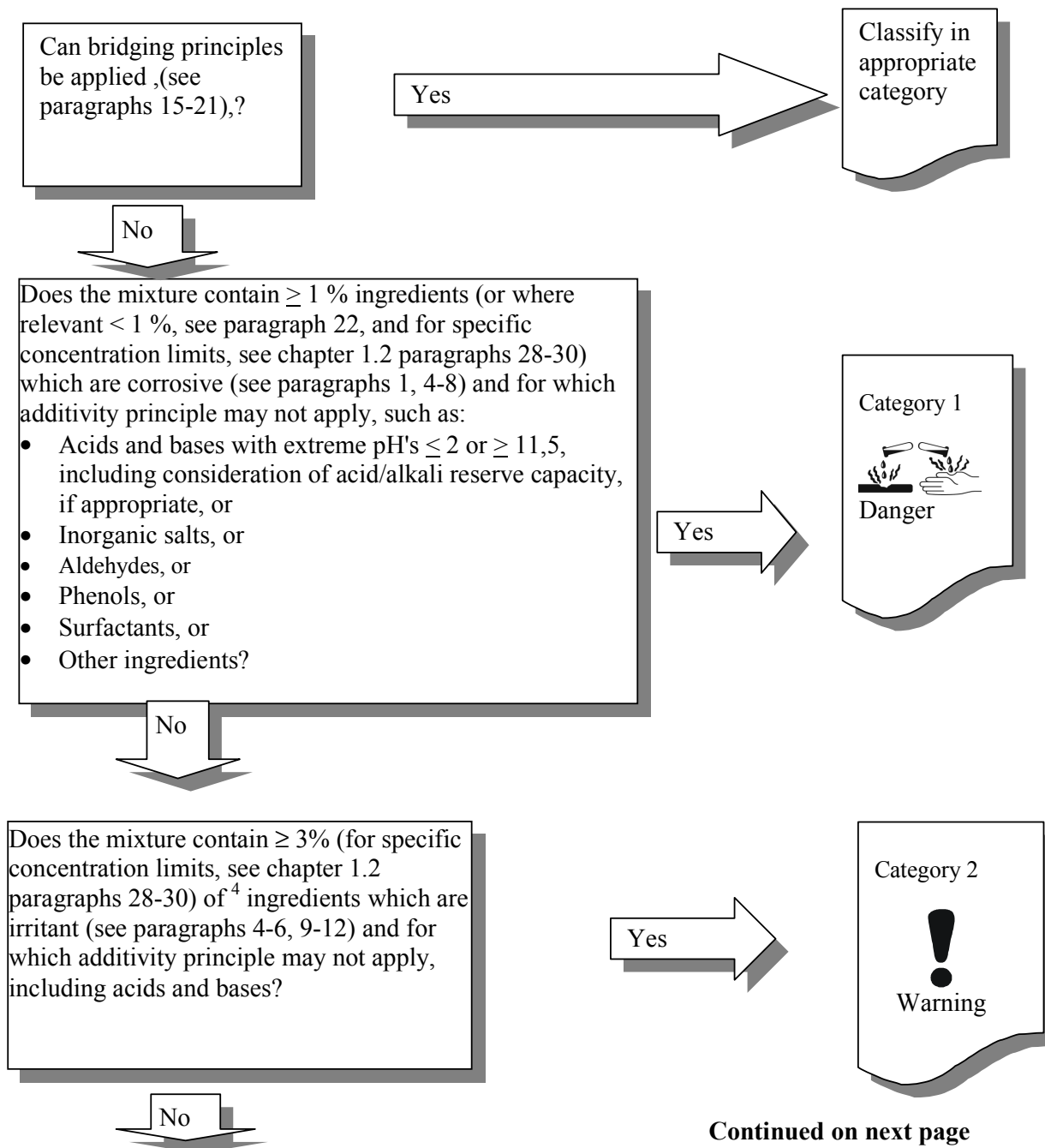
Decision Logic 1



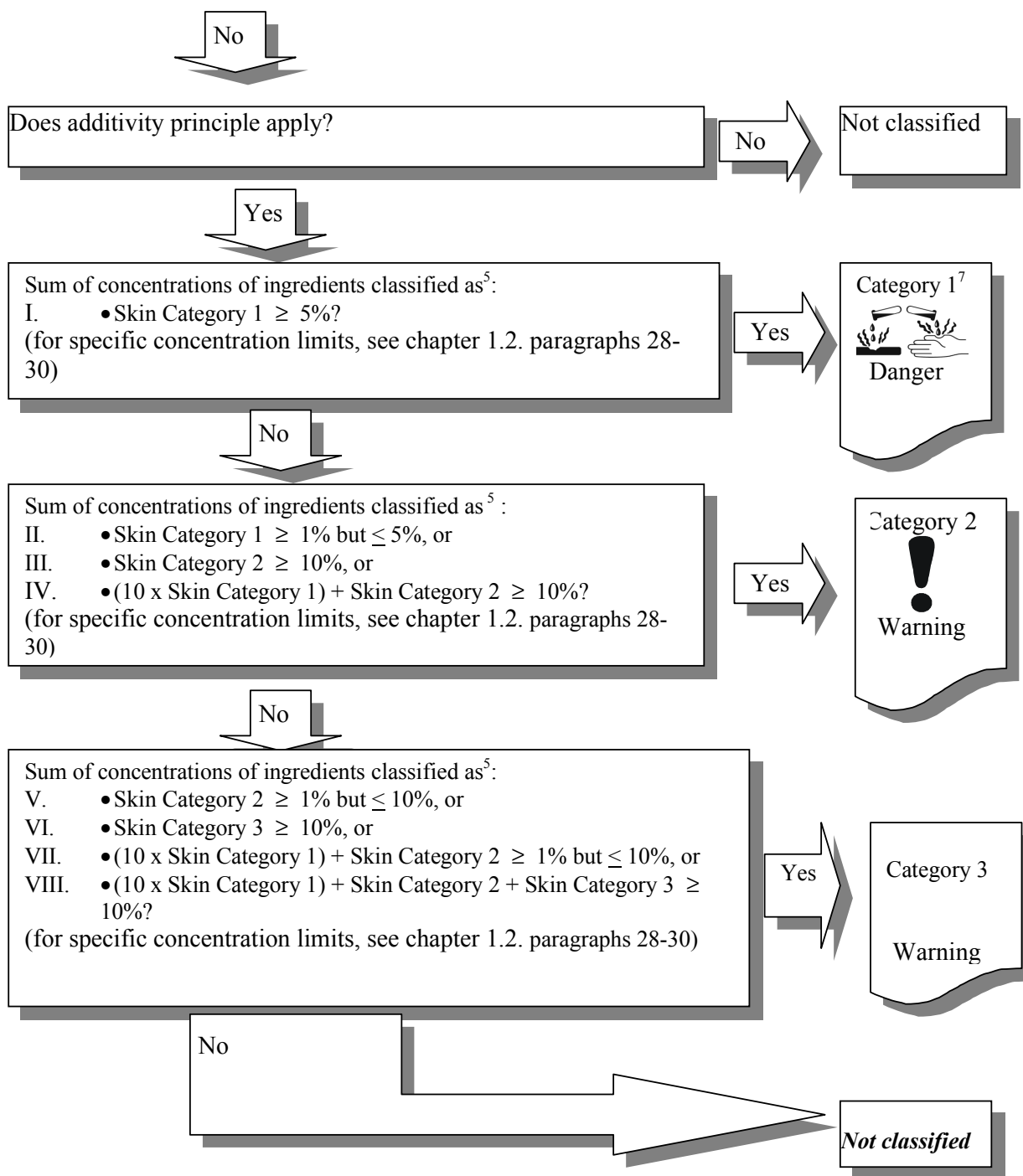


³ Figure 1 contains details for testing and evaluation.

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



⁴ See Chapter 1.2 for "The Use of Cut-off Values/Concentration Limits" as well as paragraph 27 of this chapter.



⁵ See 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.

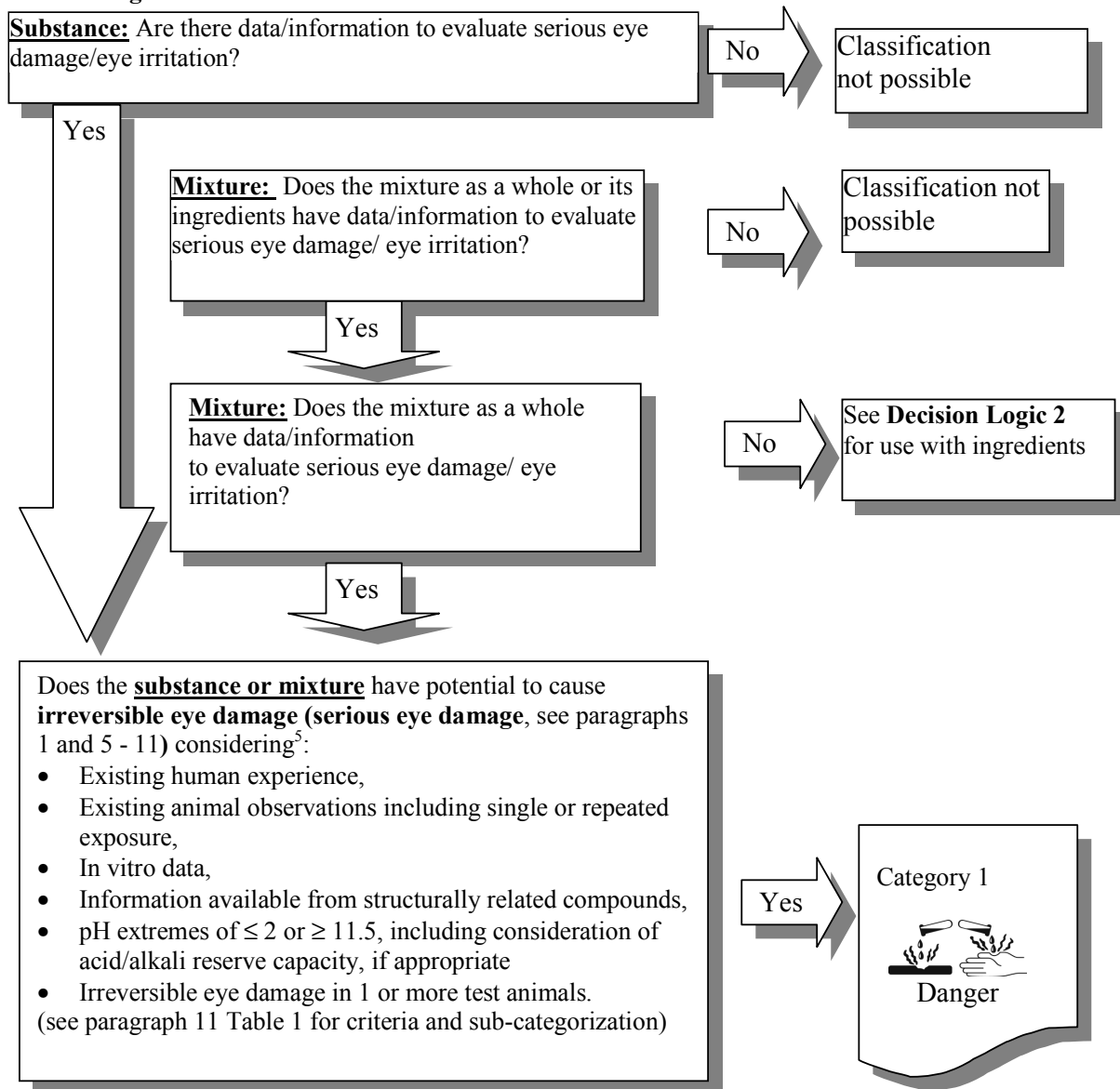
ST/SG/AC.10/C.4/2001/22, page 46

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

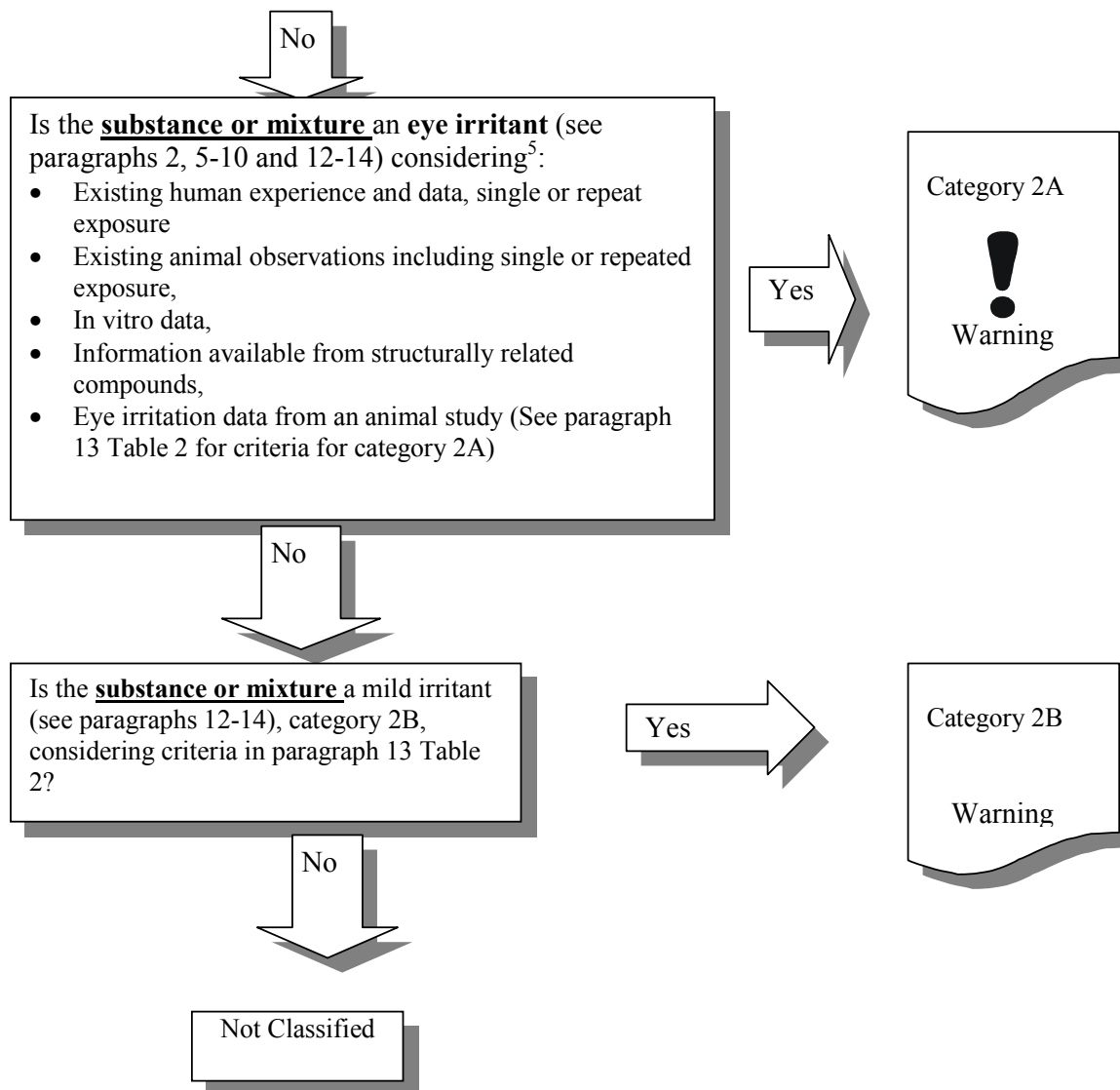
Decision Logic for serious eye damage/ eye irritation:

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

Decision Logic 1

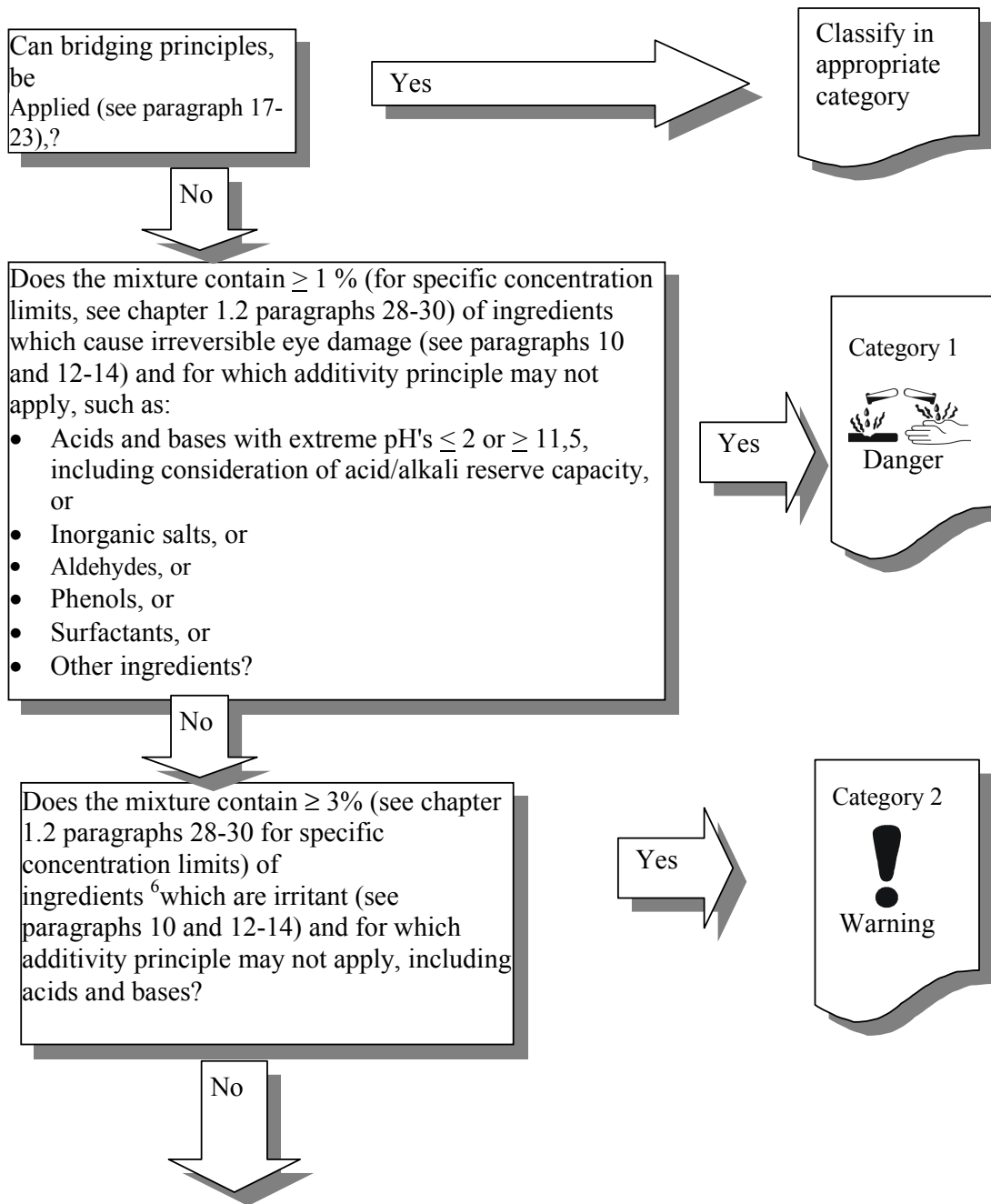


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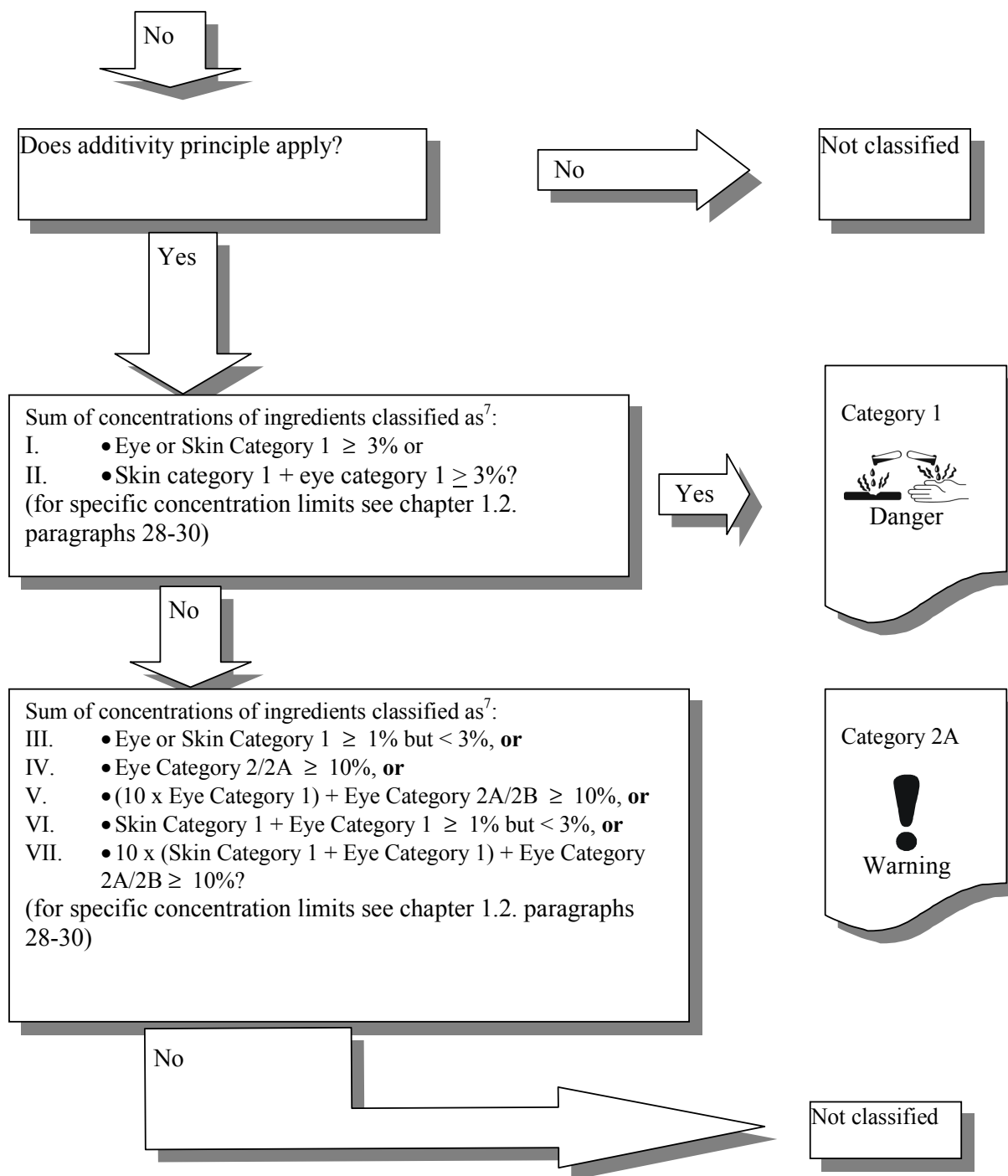
⁵ Figure 1 contains details for testing and evaluation.

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



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⁶ See Chapter 1.2 for “The Use of Cut-Off Values/Concentration Limits”, as well as paragraphs 24-29.



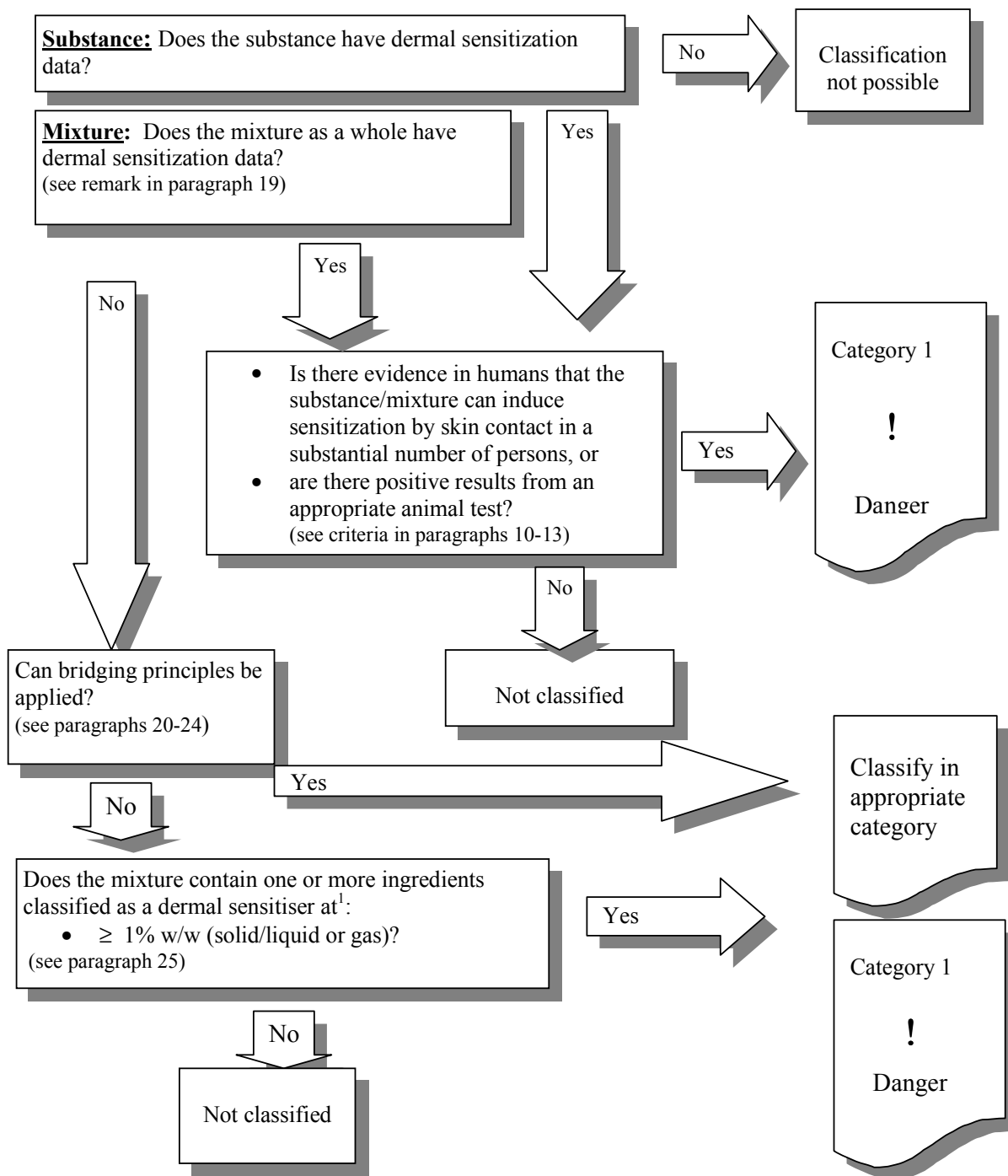
⁷ See Chapter 1.2 for “The Use of Cut-off Values/Concentration Limits”, as well as paragraphs 24-29 of this Chapter.

ST/SG/AC.10/C.4/2001/22, page 58

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

Decision Logic for Classification of Dermal Sensitisation

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



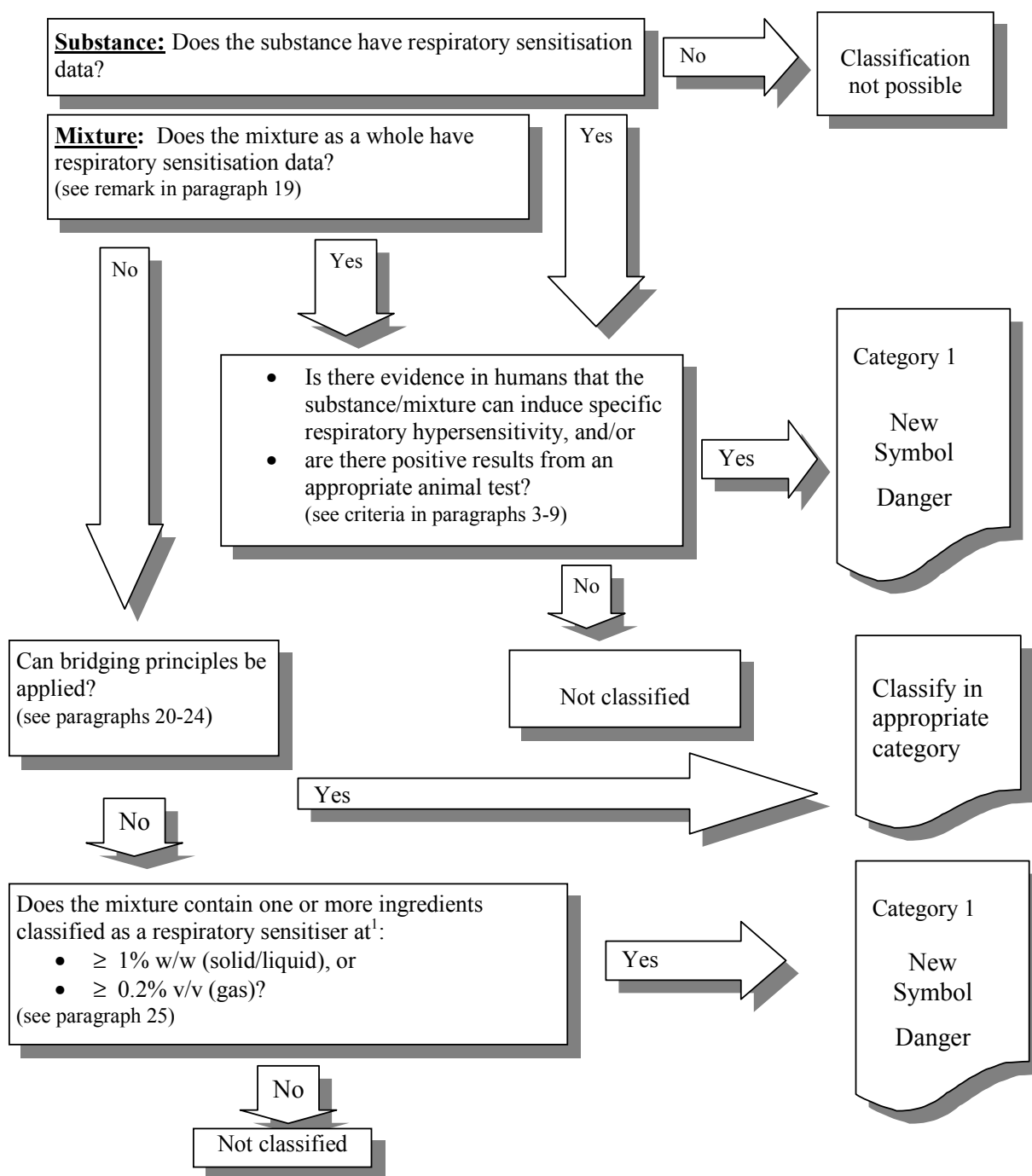
¹ See “The use of Cut-off Values/Concentration Limits” in Chapter 1.2.

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 Classification of Respiratory Sensitisation

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



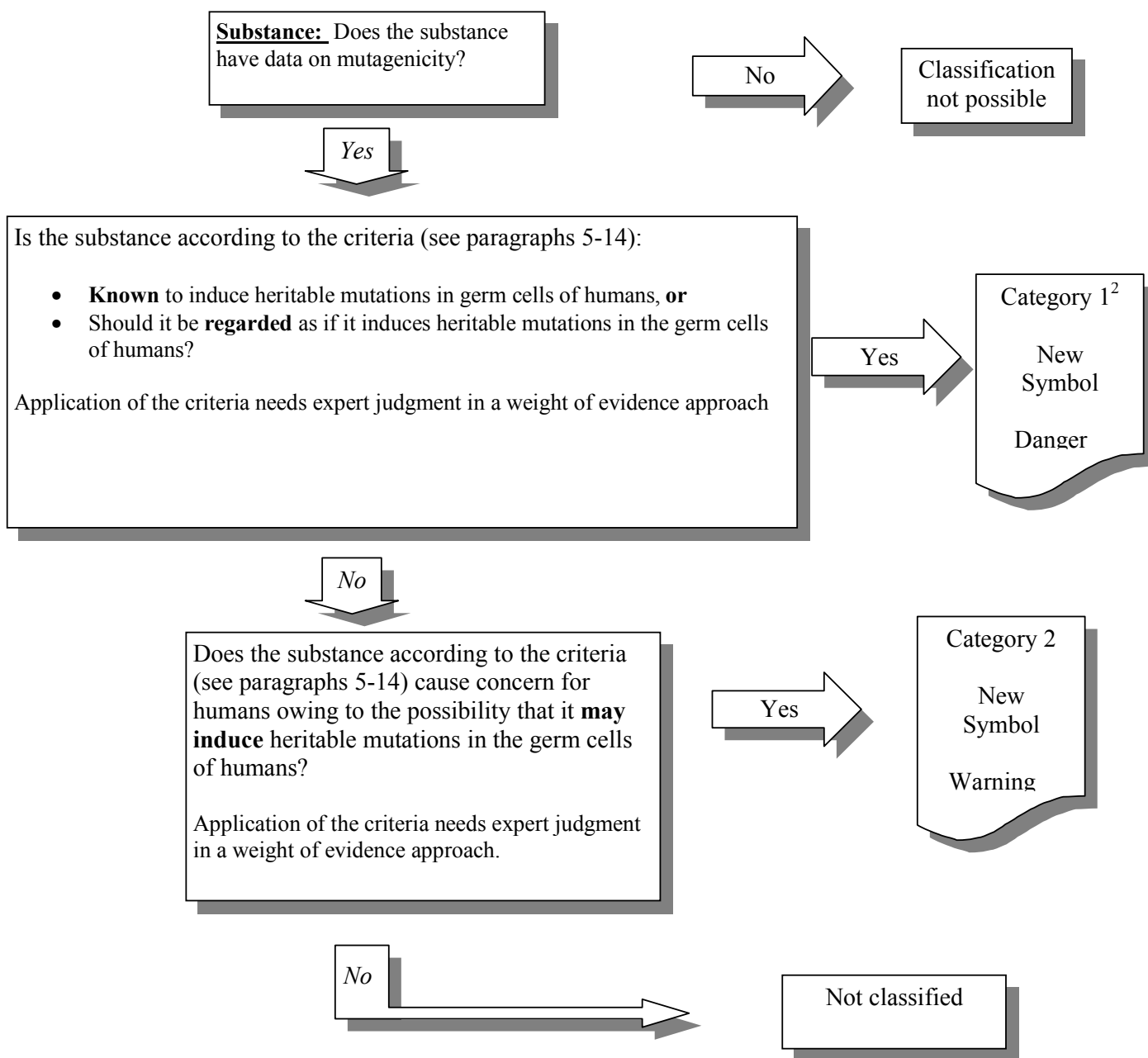
1) See “The use of Cut-off Values/Concentration Limits” in Chapter 1.2

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 the Classification of Germ Cell Mutagenicity

The decision logic, which follows is not part of the harmonised classification system, but has been provided here as additional guidance only. 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 according to the criteria (paragraphs 15-20) on the available test data for the individual ingredients of the mixture, using cut-off values/concentration limits for those ingredients^{3,4}

Does the mixture contain one or more ingredients classified as Category 1 mutagen at:

- $\geq 0.1\%$ ³?

Yes

Category 1²
New
Symbol
Danger

No

Does the mixture contain one or more ingredients classified as a Category 2 mutagen at:

- $\geq 1.0\%$ ³?

Yes

Category 2
New
Symbol
Warning

No

Not classified

Note on the applications of the mutagenic properties of a chemical for its potential classification as a carcinogen⁵

- 22 It is increasingly accepted that the process of chemical-induced tumorigenesis in man and animals involves genetic changes in proto-oncogenes and/or tumour suppressor genes of somatic cells. Therefore, the demonstration of mutagenic properties of chemicals in somatic and/or germ cells of mammals *in vivo* may have implications for the potential classification of these chemicals as carcinogens (see also Carcinogenicity, Chapter 3.6, paragraph 10)

² See text for detailed criteria on subclasses

³ See “The use of Cut-off Values/Concentration Limits” in Chapter 1.2 and Table 1 of this Chapter

⁴ The classification may sometimes be modified on a case by case basis on the available test data for the mixture as a whole. If bridging principles will be applied, classify in the same category as the similar mixture. See criteria for further details

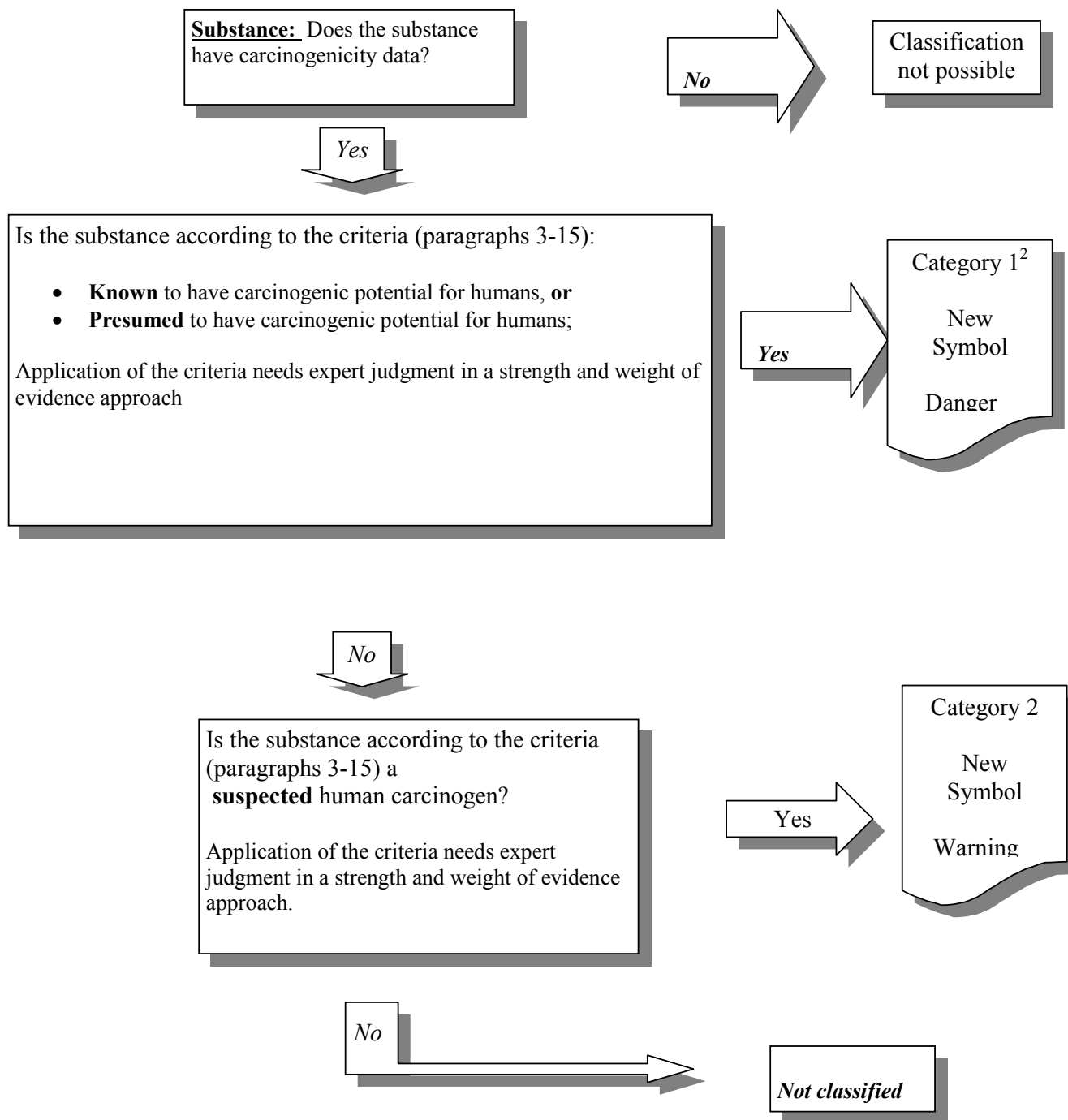
⁵ The text which follows is not part of the agreed text on the harmonised classifications system developed by the OECD Task Force-HCL, but has been provided here as additional guidance.

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

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

Decision Logic for Classification of Carcinogenicity

The decision logic, which follows is not part of the harmonised classification system, but has been provided here as additional guidance only. 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, see paragraphs 16-21.^{3,4}

Does the mixture contain one or more ingredients classified as a Category 1 carcinogen at:

- $\geq 0.1\%$ ^{3?}

Yes

Category 1²

New
Symbol
Danger

No

Does the mixture contain one or more ingredients classified as a Category 2 carcinogen at:

- $\geq 0.1\%$ ^{3?}
- $\geq 1.0\%$ ^{3?}

Yes

Category 2

New
Symbol
Warning

No

Not classified

² See text for detailed criteria on subclasses.

³ See “The use of Cut-off Values/Concentration Limits” in Chapter 1.2 and in Table 1 of this Chapter

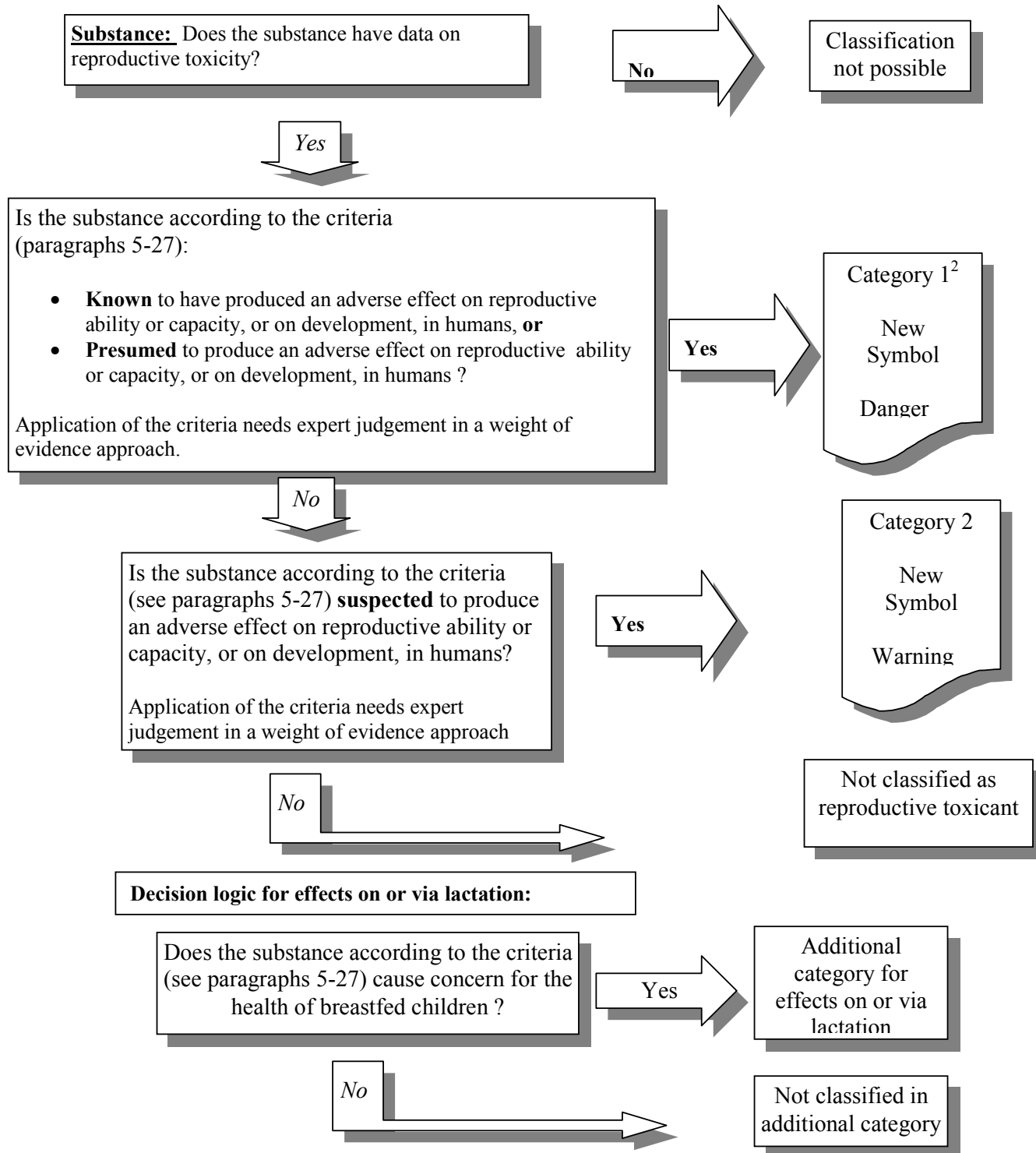
⁴ The classification may sometimes may be modified on a case by case basis on the available test data for the mixture as a whole. If bridging principles will be applied, classify in the same category as the similar mixture. See criteria for further details.

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 only. 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 according to the criteria (paragraphs 28-33) on the available test data for the individual ingredients of the mixture, using cut-off values/concentration limits for those ingredients^{3,4}

Does the mixture contain one or more ingredients classified as a Category 1 reproductive toxicant at:

- $\geq 0.1\%$ ^{3?}

Yes

Category 1²

New
Symbol

Danger

No

Does the mixture contain one or more ingredients classified as a Category 2 reproductive toxicant at:

- $\geq 0.1\%$ ^{3?}
- $\geq 1.0\%$ ^{3?}

Yes

Category 2

New
Symbol

Warning

No

Not classified

² See text for detailed criteria on subclasses.

³ See “The use of Cut-off Values/Concentration Limits” in Chapter 1.2 and in Table 1 of this Chapter

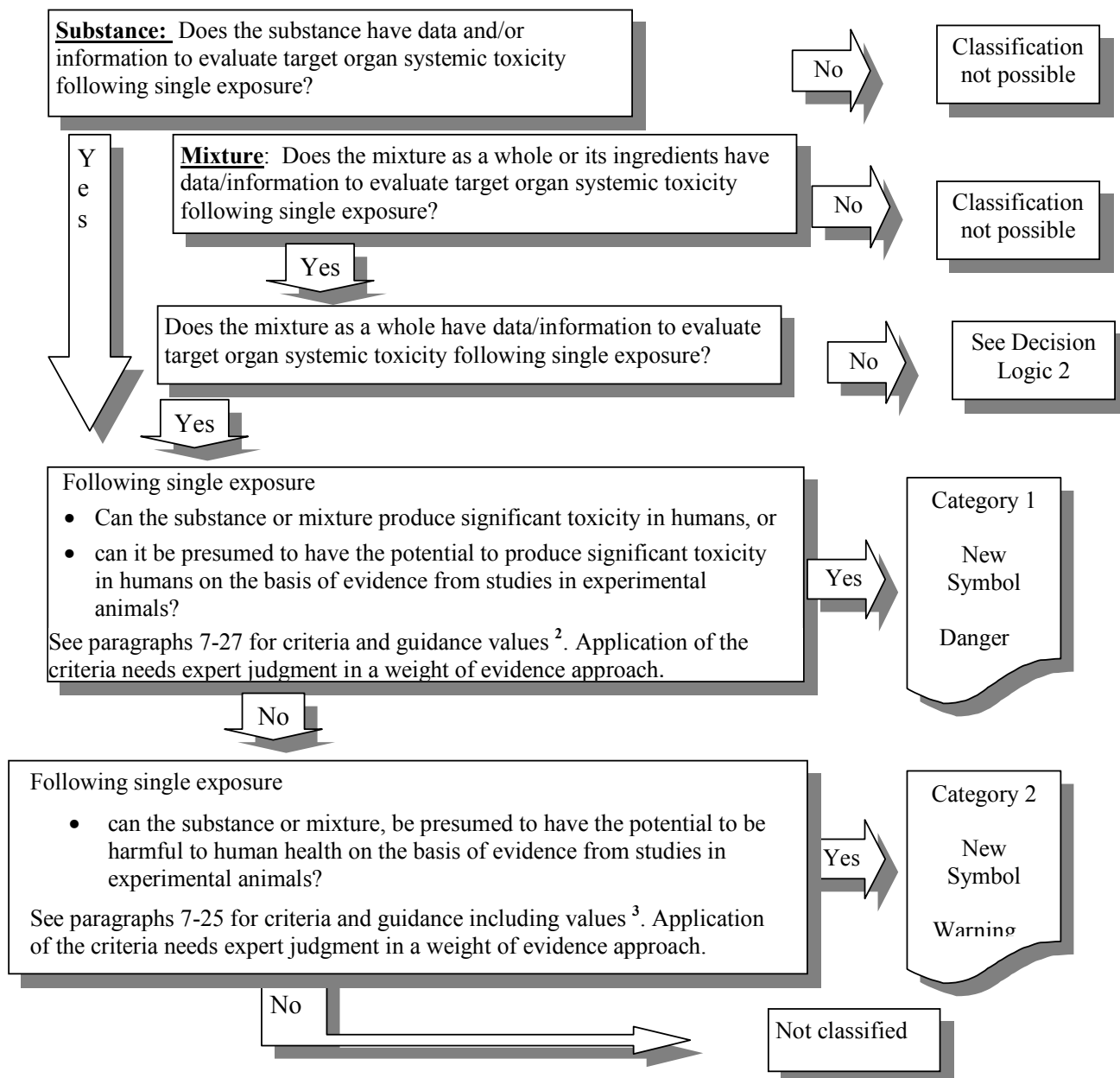
⁴ The classification may sometimes be modified on a case by case basis on the available test data for the mixture as a whole. If bridging principles will be applied, classify in the same category as the similar mixture. See criteria for further details

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:

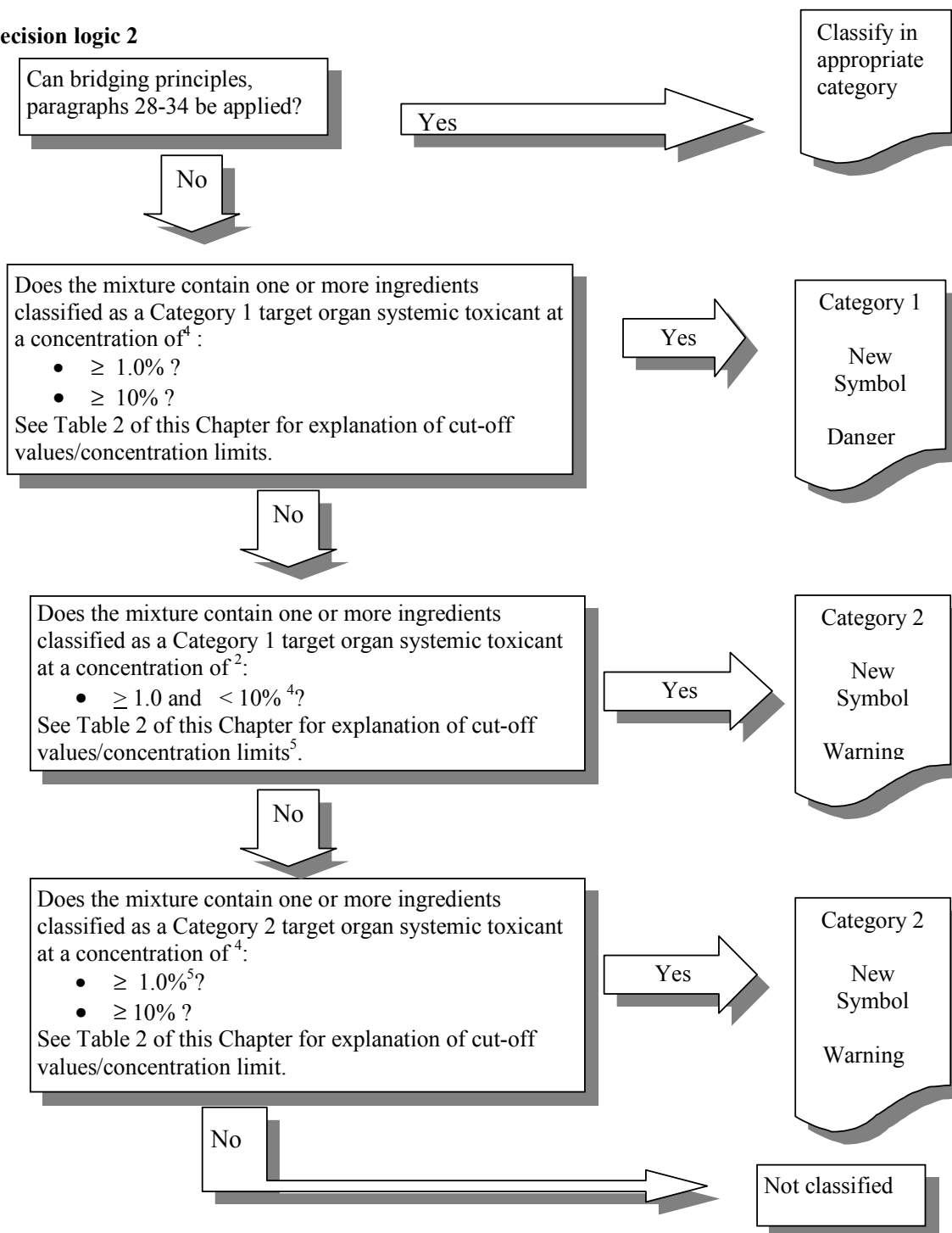
Decision Logic for Target Organ Systemic Toxicity from Single Exposure

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



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Decision logic 2



⁴ See paragraphs 7-25 of this Chapter and “The Use of Cut-off Values/Concentration Limits” in Chapter 1.2.

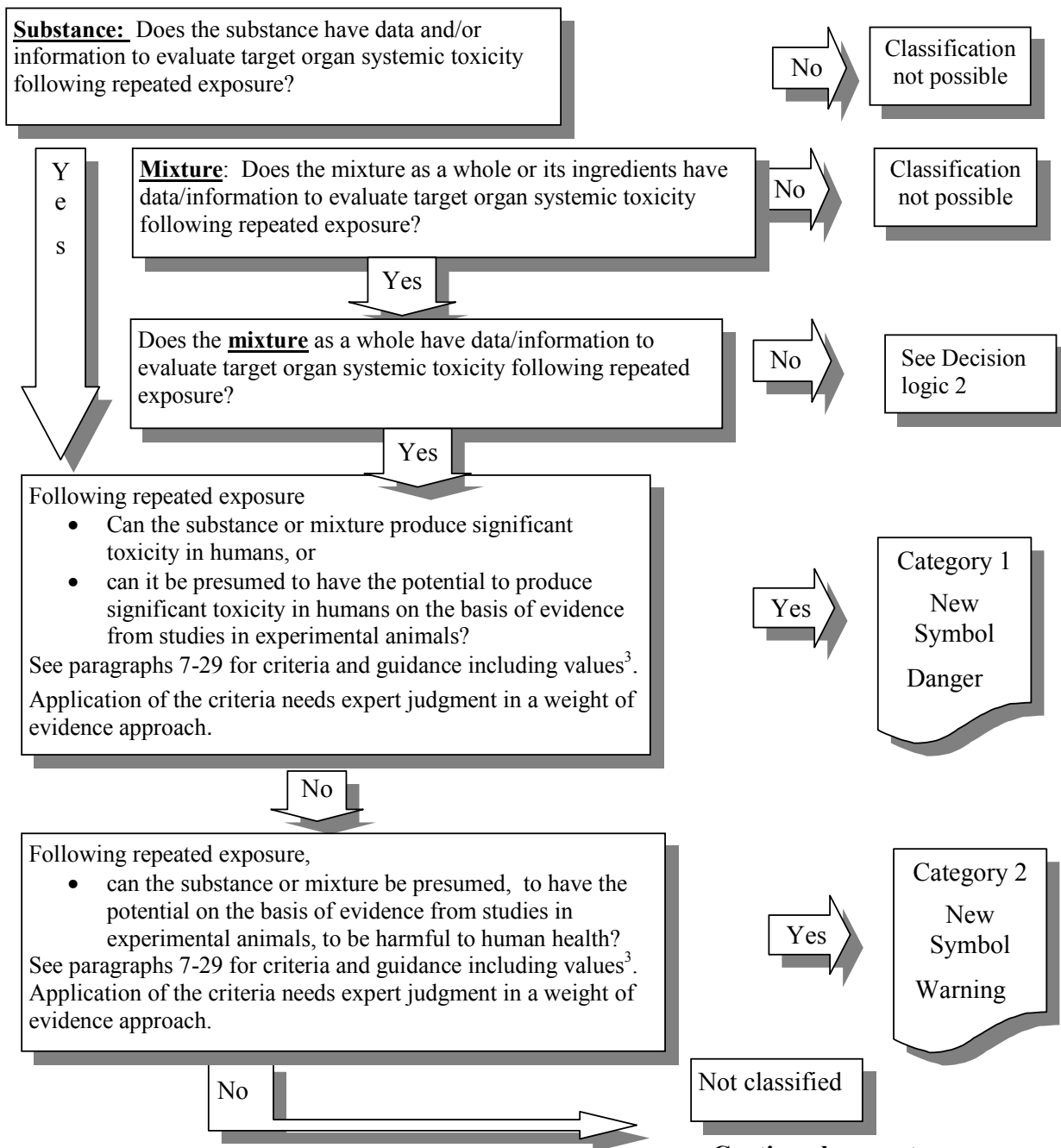
⁵ See paragraphs 35-38 and Table 2 for explanation and guidance.

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

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

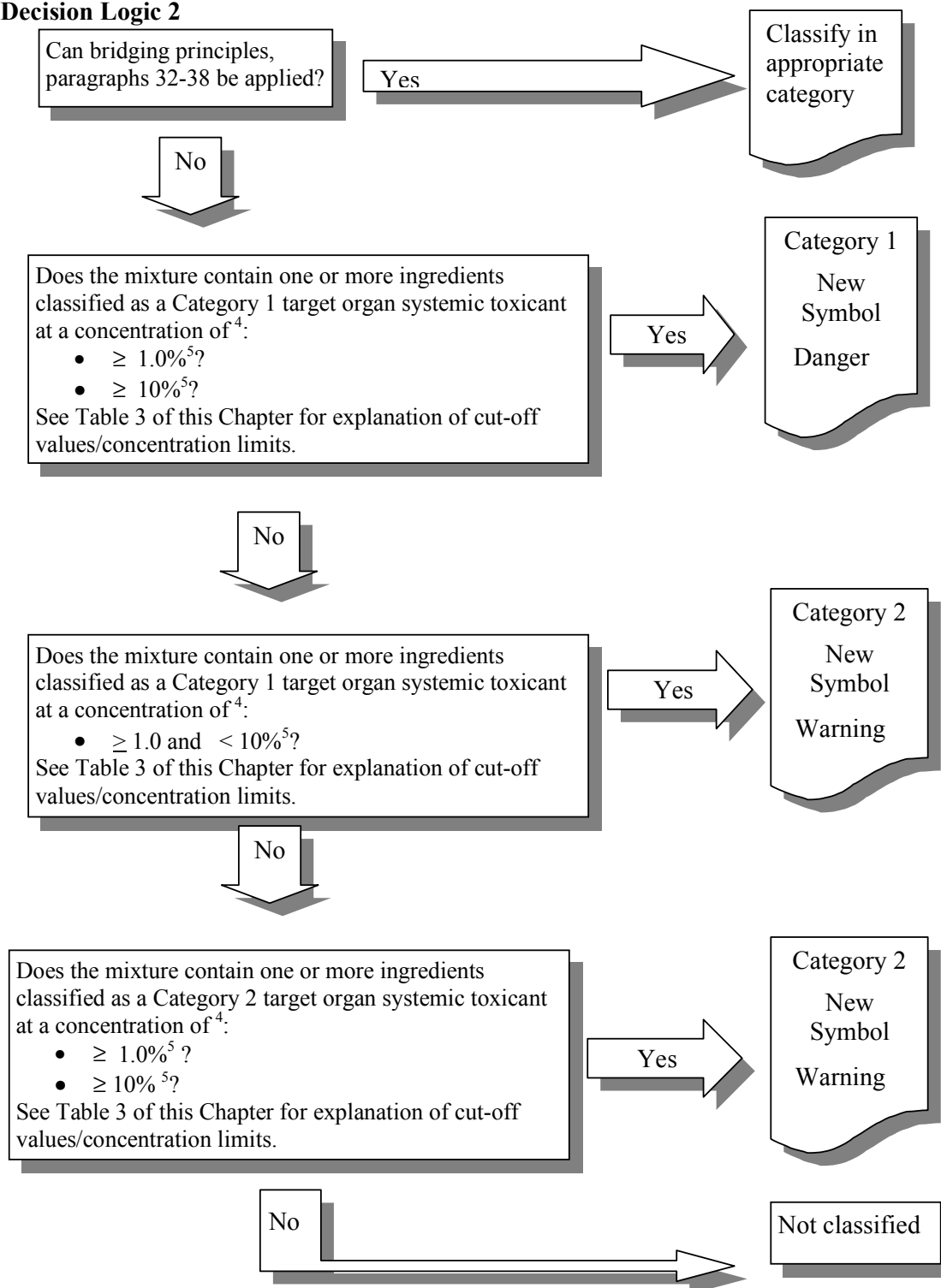
Decision Logic for Classification of Target Organ Systemic Toxicity following Repeated Exposure

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



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Decision Logic 2



⁴ 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".

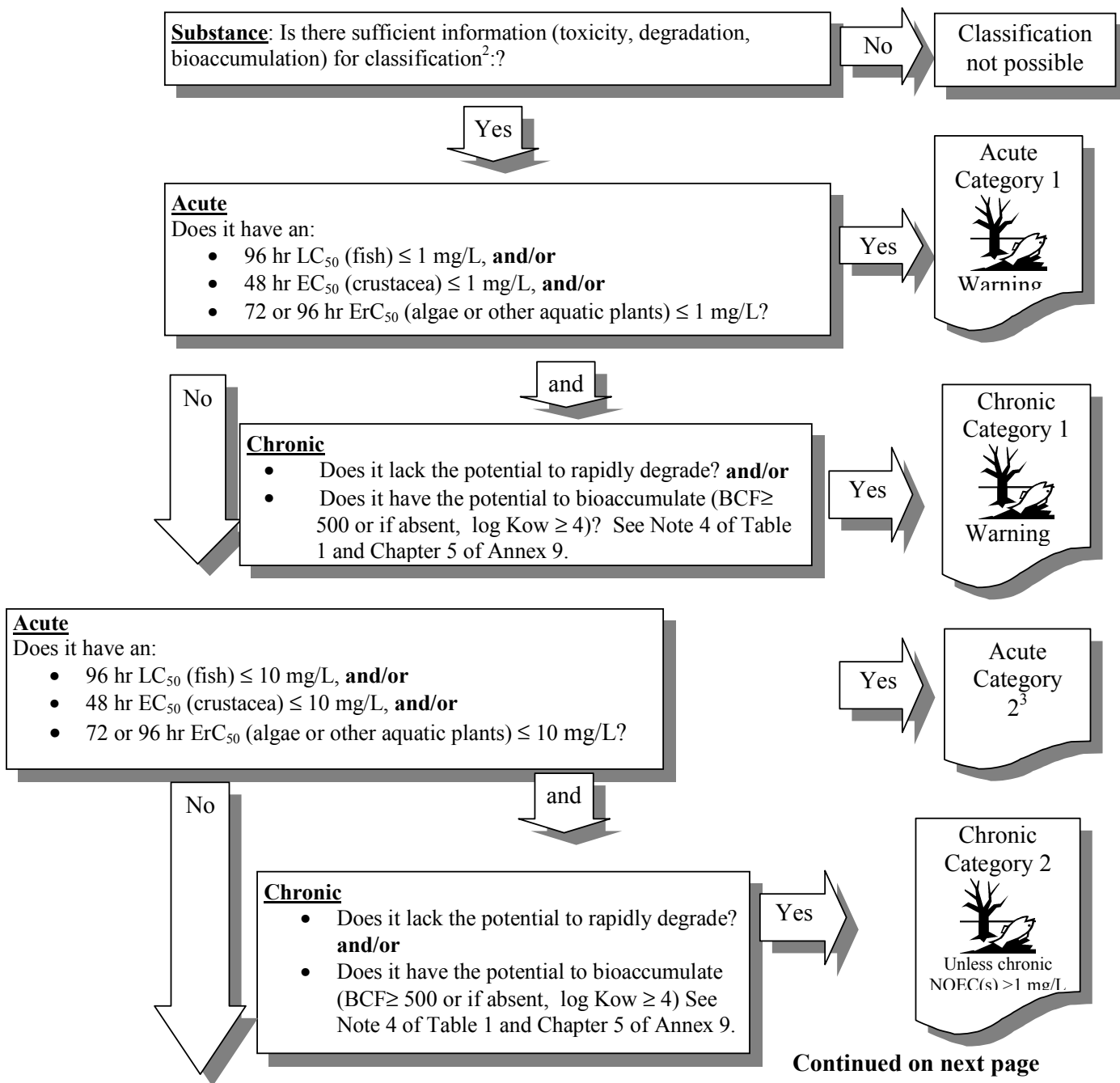
⁵ See paragraphs 39-43 and Table 3 for explanation and guidance.

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

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

Decision Logic for Classification of 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 only. The responsible person for classification is strongly recommended to study the criteria before and during use of the decision logic.



No

Acute

Does it have an:

- 96 hr LC₅₀ (fish) ≤ 100 mg/L, **and/or**
- 48 hr EC₅₀ (crustacea) ≤ 100 mg/L, **and/or**
- 72 or 96 hr ErC₅₀ (algae or other aquatic plants) ≤ 100 mg/L?

Yes

Acute
Category 3⁴

No

and

Chronic

- Does it lack the potential to rapidly degrade?
and/or
- Does it have the potential to bioaccumulate (BCF ≥ 500 or if absent, log Kow ≥ 4)? See Note 4 of Table 1 and Chapter 5 of Annex 9.

Yes

Chronic
Category 3

Unless chronic
NOEC(s) >
1 mg/L

Chronic

- Is it poorly soluble with no acute toxicity⁵), **and**
- Does it lack the potential to rapidly degrade? **and/or**
Does it have the potential to bioaccumulate (BCF ≥ 500 or if absent, log Kow ≥ 4)? See Note 4 of Table 1 and Chapter 5 of Annex 9.

Yes

Chronic
Category 4

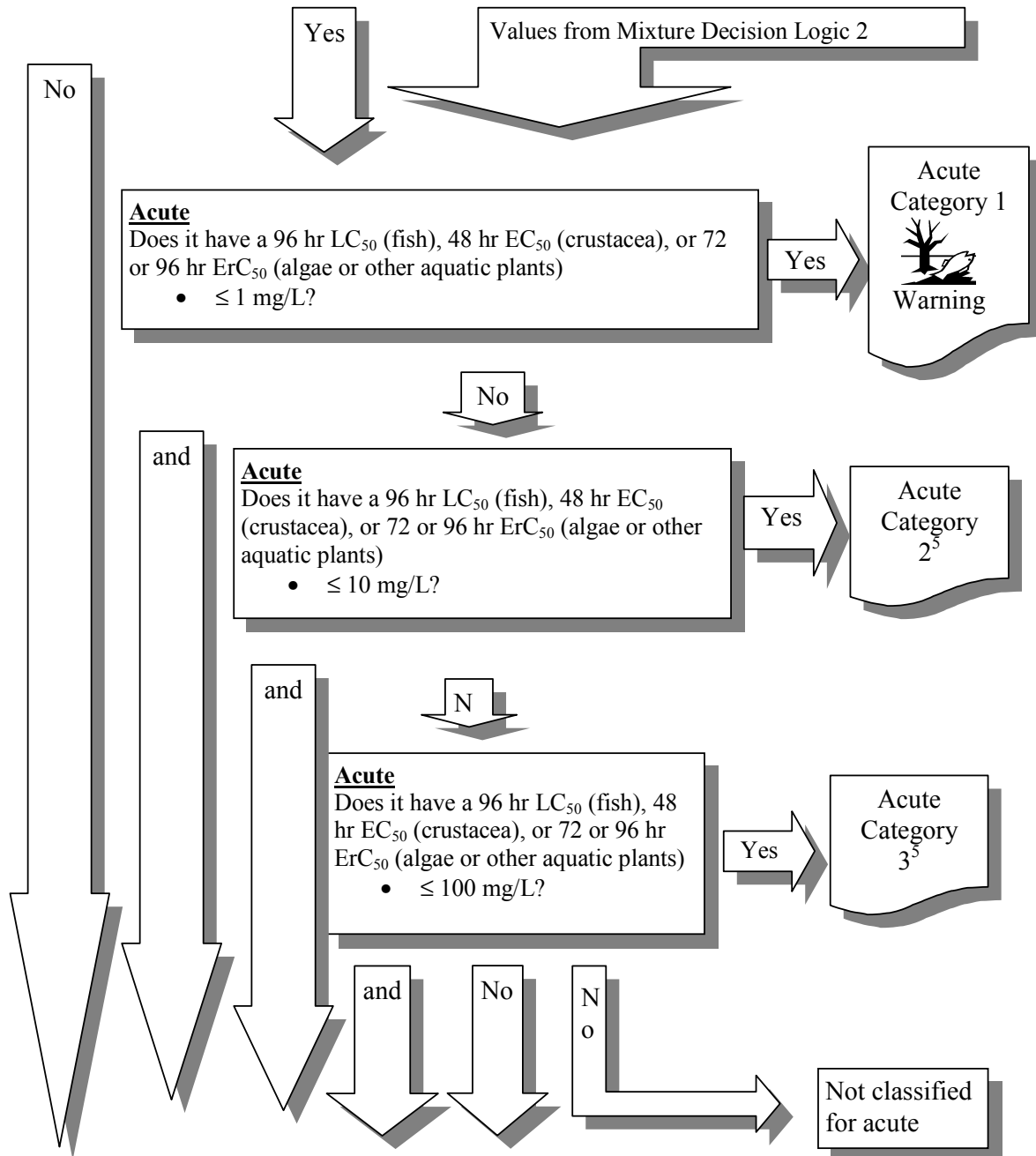
Unless chronic
NOEC(s) >
1 mg/L

No

Not
classified

4 Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.
5 See Table 1, Note 5 further developed in Annex 9, paragraphs 66 and 67

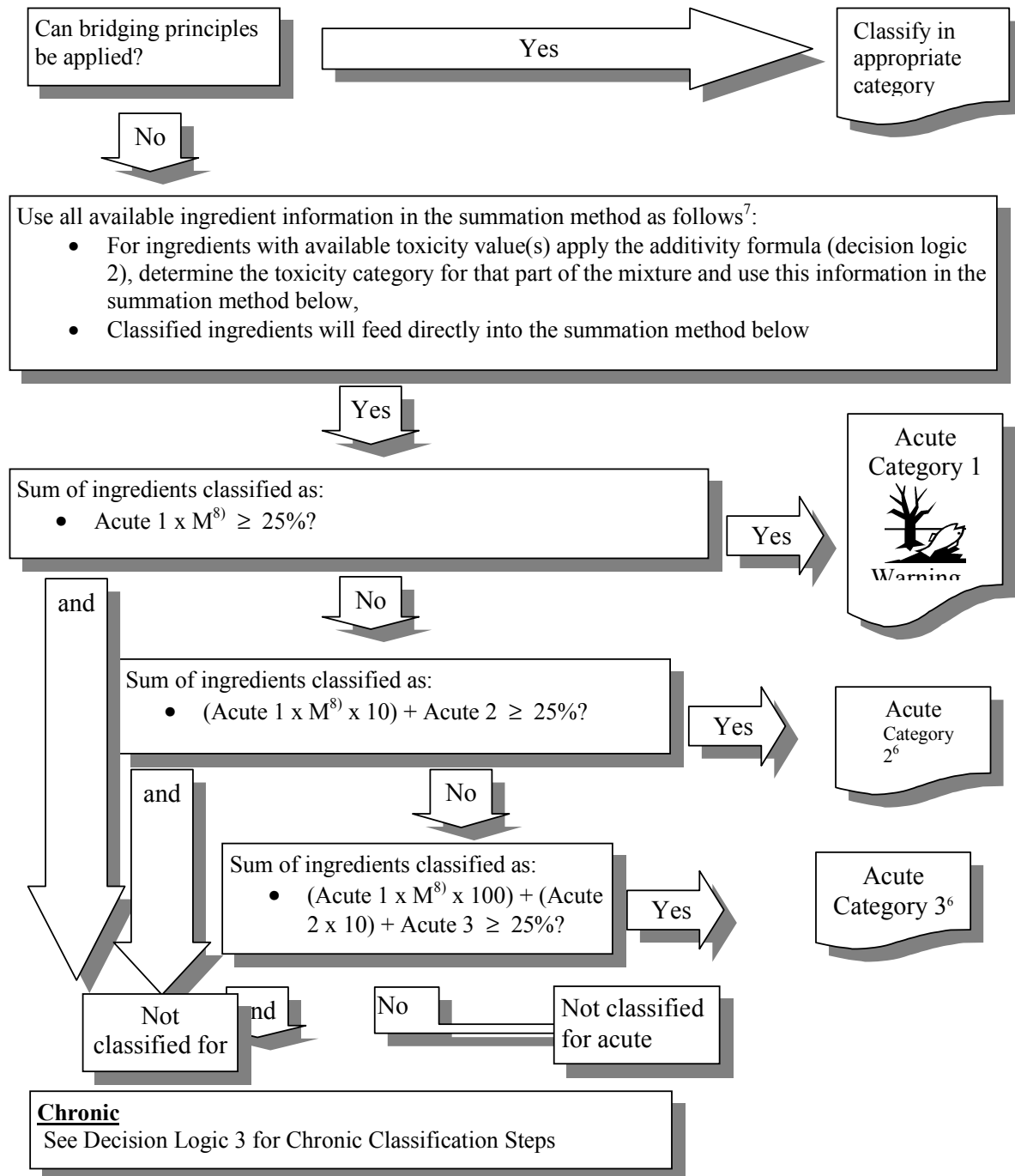
Mixture: Does the mixture as a whole have aquatic toxicity data for fish, crustacea, and algae/aquatic plants?



Chronic
See Decision Logic 3 for Chronic Classification

Continued on next page

⁵ Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.



⁶ Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.

⁷ 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.

⁸ For explanation of M factor see paragraph 56.

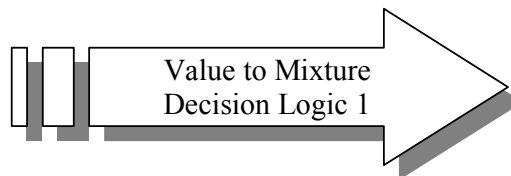
Mixtures decision logic 2 (Additivity method)

Apply the Additivity Method:

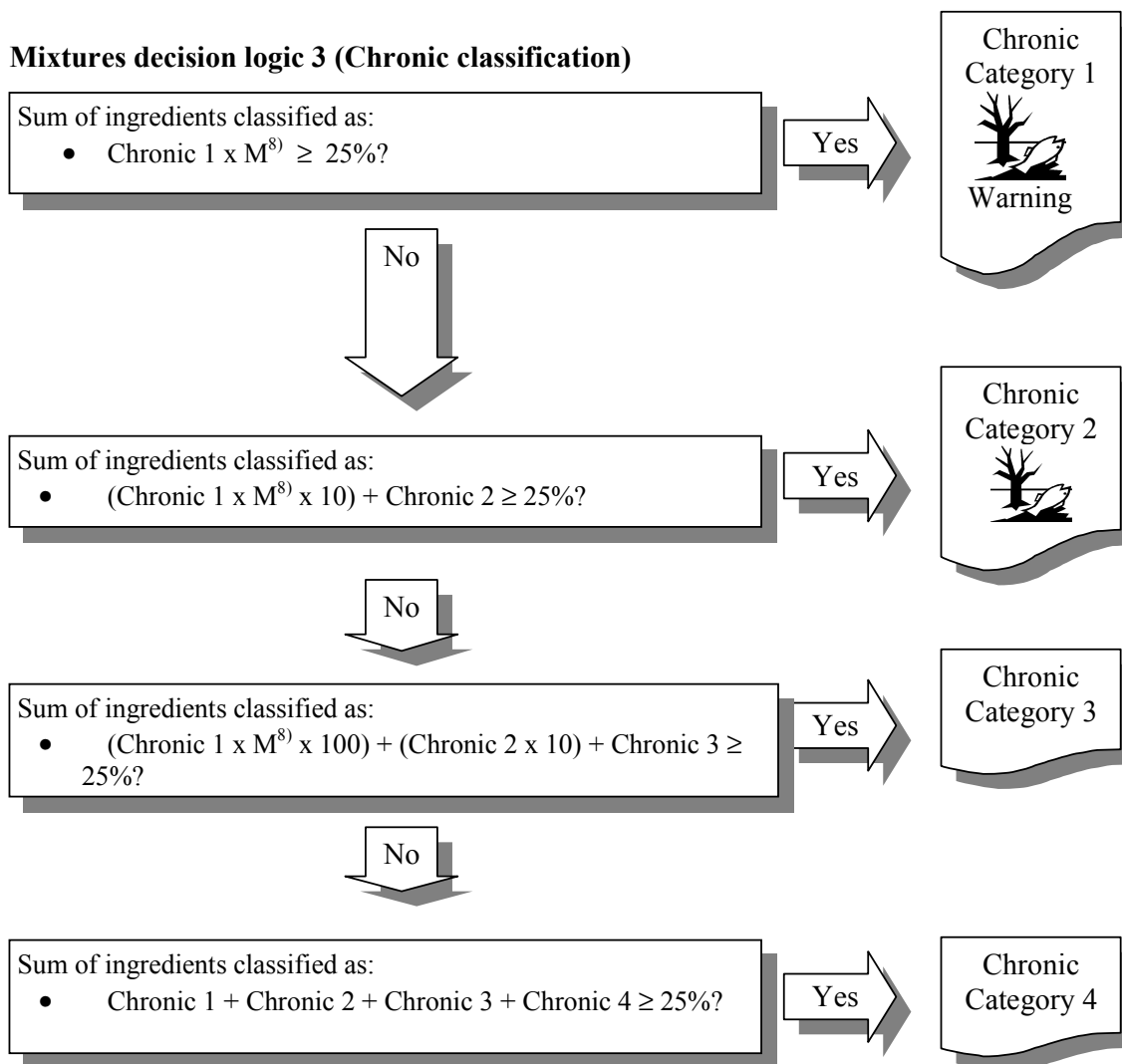
$$\frac{\sum C_i}{L(E)C_{50m}} = \sum \frac{C_i}{L(E)C_{50i}}$$

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



Mixtures decision logic 3 (Chronic classification)



EXAMPLES

