Classification and Labelling
with the

Globally Harmonized System

GHS

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The Beginning of GHS

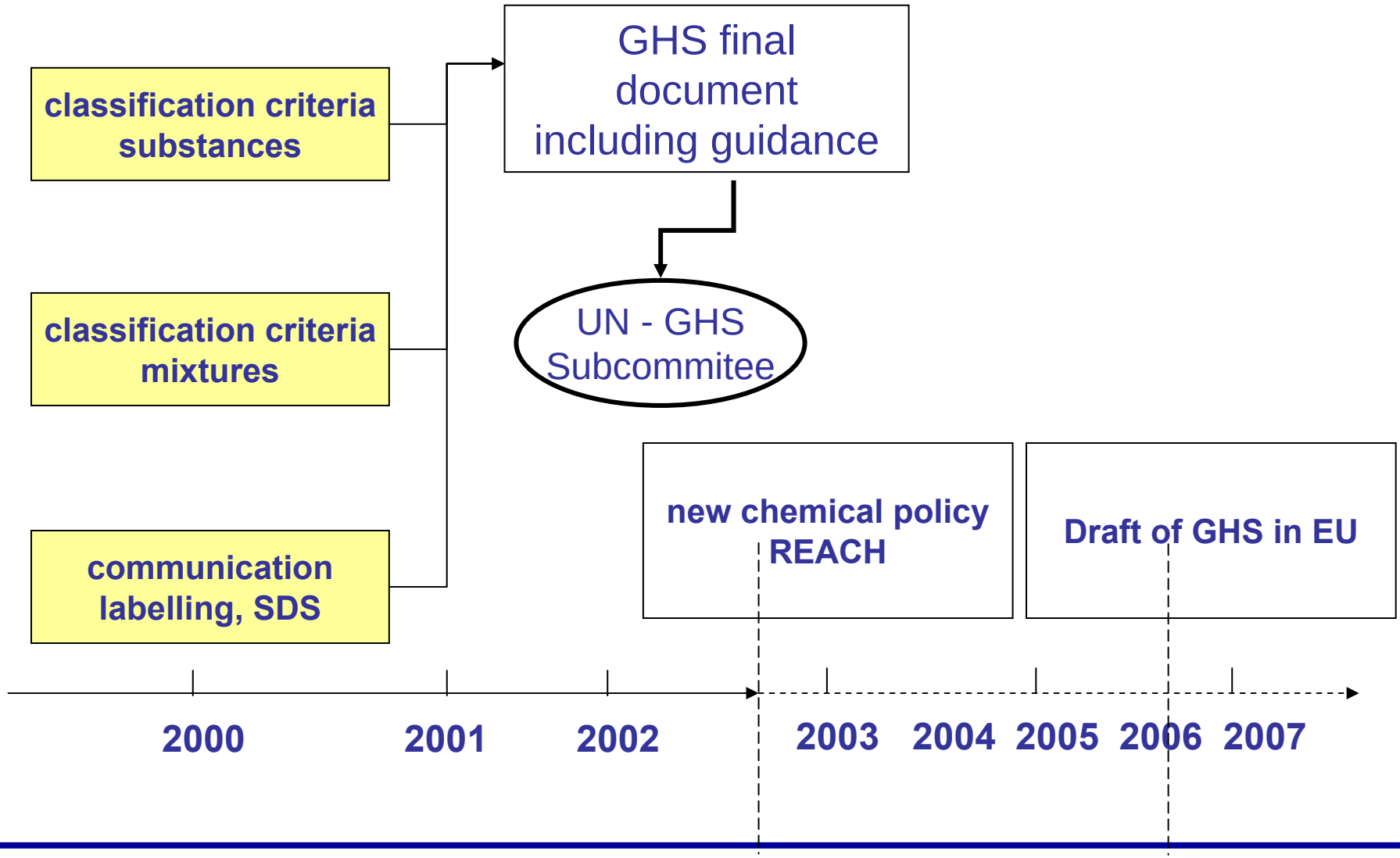
UN summit - Rio de Janeiro 1992

Agenda 21 - Chapter 19.27

„A global system of
- **harmonized hazard classification**
- **compatible labelling**
- **harmonized safety data sheets**
- **easily understandable symbols**

should be available, if feasible, by the year 2000.“

Timeline


classification criteria substances
classification criteria mixtures
communication labelling, SDS
GHS final document including guidance
UN - GHS Subcommitee
new chemical policy REACH
Draft of GHS in EU
2000
2001
2002
2003
2004
2005
2006
2007

Implementation of GHS

- New Zealand has implemented so far
- Asia plans to implement in 2006/2007*
- Europe plans to start together with REACH, April 2007
  A transitional period of 3 years for substances and 3 + 4 or 5 years for preparations is being discussed.
  The draft was published 21/08/2006, the internet consultation is until 21/10/2006.
- USA, started a pilot project
- South Africa, Australia, Brazil expressed their wish to participate in the expanded pilot project

***GHS implementation:** APEC (Asia-Pacific Economic Cooperation) aims to implement GHS by the end of 2006 and Japanese ministries are now working together to this end. The Japanese Industrial Standard (JIS) for MSDS and the Industrial Safety and Health Law were amended in this context. Japan is going to implement GHS for certain hazardous substances by 1 December 2006.

Consequences for the current system of Classification and Labelling

In Europe the GHS **Regulation** is going to substitute the:

- Dangerous Substances Directive (67/548/EC)
- Dangerous Preparations Directive (1999/45/EC)

- Safety Data Sheet Directive (1991/155/EC) is subject to REACH

Basic Changes

- new dangers
- new subdivision of dangers
- new ways for classification
- new classification criteria
- new labelling elements
- new safety data sheet
- new philosophy of information

• physical hazards	• health hazards	• environmental hazards

Building Block Principle

... countries are free to determine

which of the building blocks *

will be applied in different parts of their systems **

* See next chart

** Different parts of the system means for example Dangerous Substances / Dangerous Good

Building Blocks *

- SDS (to be handled in REACH)
- Danger
- Danger categorie
  etc.

Physical hazard, flammable liquids **

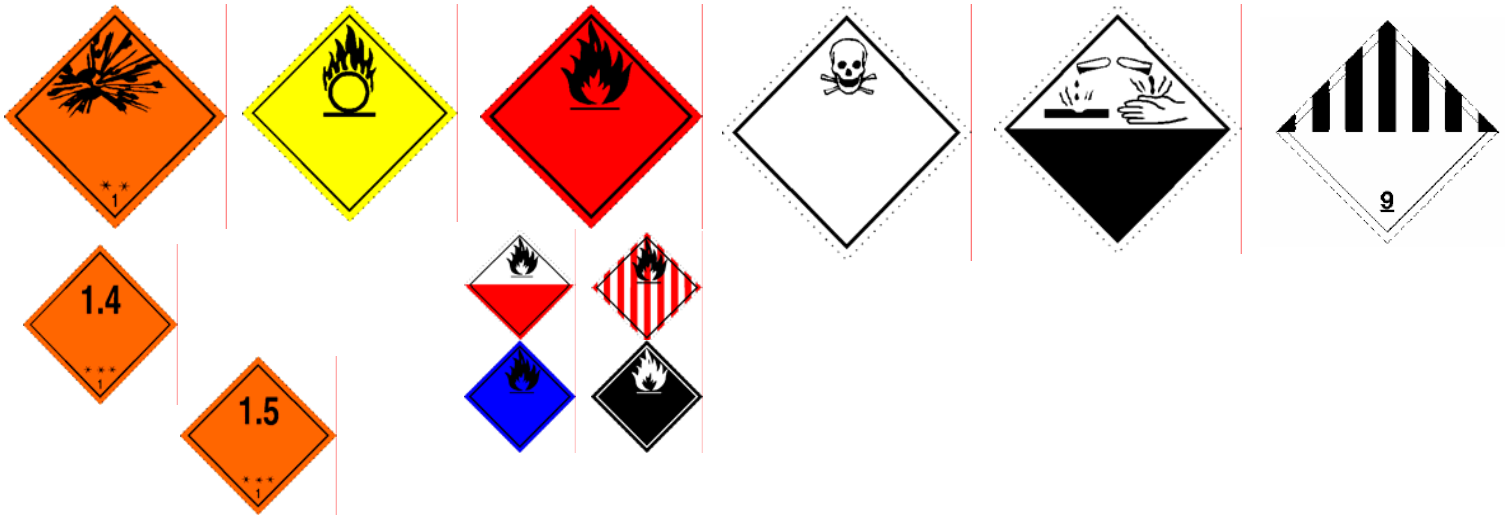
EU	**F+ R-12** $T_{b,i} \leq 35°C$	**F R-11** liquids		**R-10**		
T_{fl}/°C	**< 0**	**0 – 21**	**21 - 23**	**23 – 55**	**55 - 60**	**60 – 93**
GHS	**Flammable Liquids Category 1** $T_{b,i} \leq 35°C$			**Flammable Liquids Category 3**		**Flammable Liquids Category 4**
	Flammable Liquids Category 2 $T_{b,i} > 35°C$					
DG	**Class 3 (no flash point limit) Packaging Group I** $T_{b,i} \leq 35°C$			**Class 3 Packaging Group III**		
	Class 3 Packaging Group II $T_{b,i} > 35°C$					

T_{fl} = flash point, $T_{b,i}$ = initial boiling point

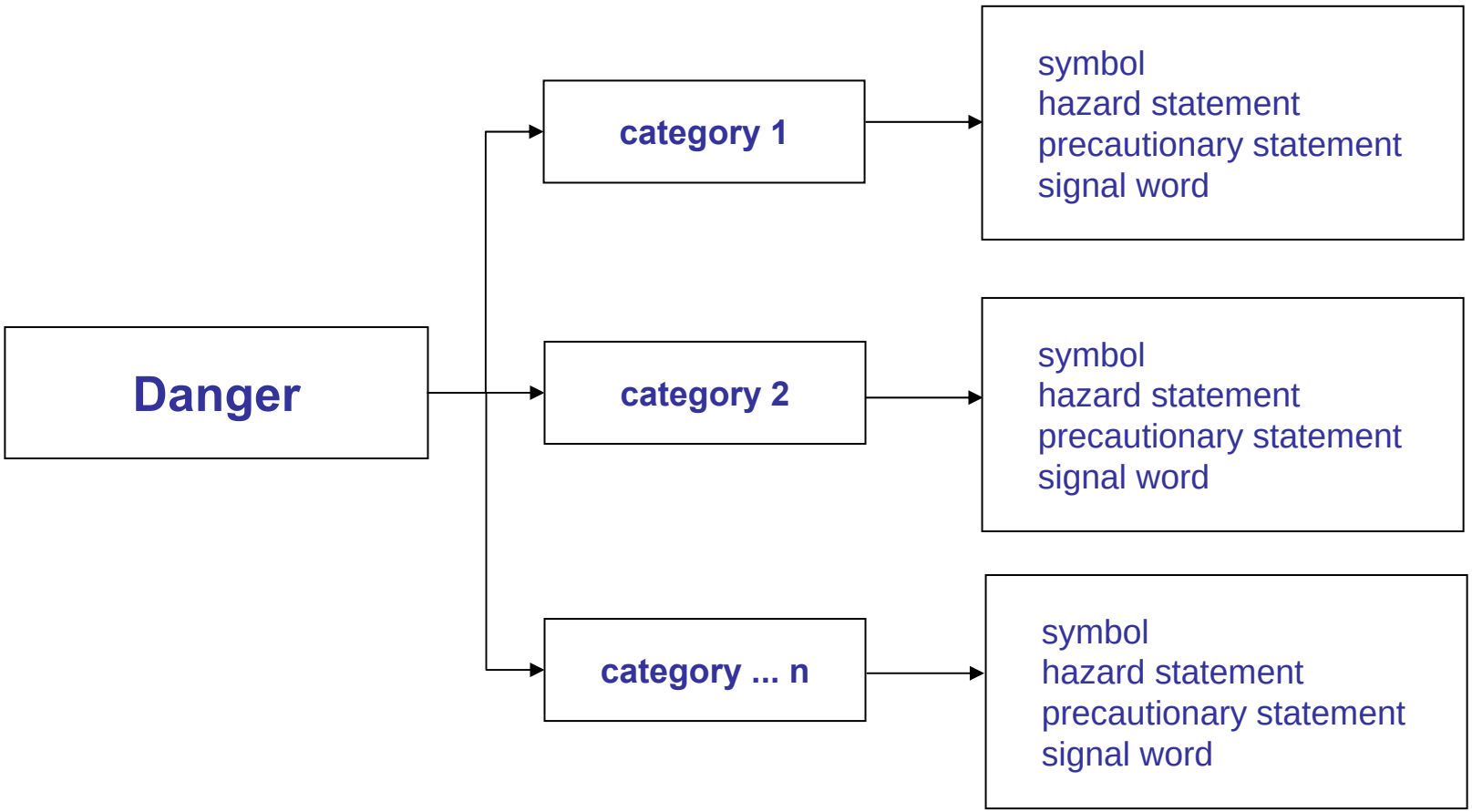
Labelling Elements

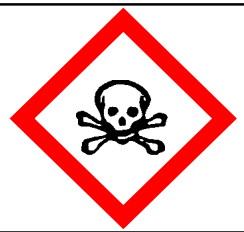
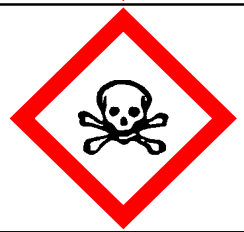
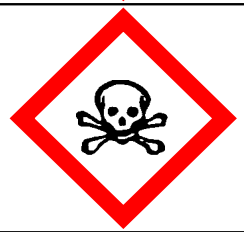
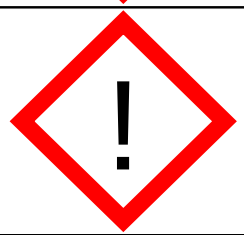
GHS symbol set

Transport symbol set



Allocation of Labelling Elements



Acute tox (oral)	Symbols		Hazard statement	Precautionary statement	Signal word
	Consumer/workplace	Transport			
category 1 ≤ 5 mg/kg			**Fatal if swallowed.**	Precautionary statement must be used. (not yet harmonised.)	Danger
category 2 > 5 ≤ 50 mg/kg			**Fatal if swallowed.**	Precautionary statement must be used. (not yet harmonised.)	Danger
category 3 > 50 ≤300 mg/kg			**Toxic if swallowed.**	Precautionary statement must be used. (not yet harmonised.)	Warning
category 4 > 300 ≤2.000 mg/kg		no symbol	**Harmful if swallowed.**	Precautionary statement must be used. (not yet harmonised.)	Warning
category 5 > 2.000 ≤5.000 mg/kg	no symbol		**May be harmful if swallowed.**	Precautionary statement must be used. (not yet harmonised.)	Warning

SDS Structure

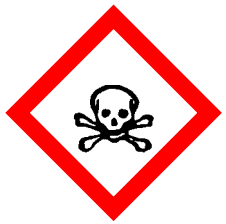
1. Identification
2. **Hazard(s) identification**
3. **Composition/information on ingredients**
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls/personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. **Regulatory information**
16. Other information

changed order of chapters

complete information on classification and labelling now in chapter 2

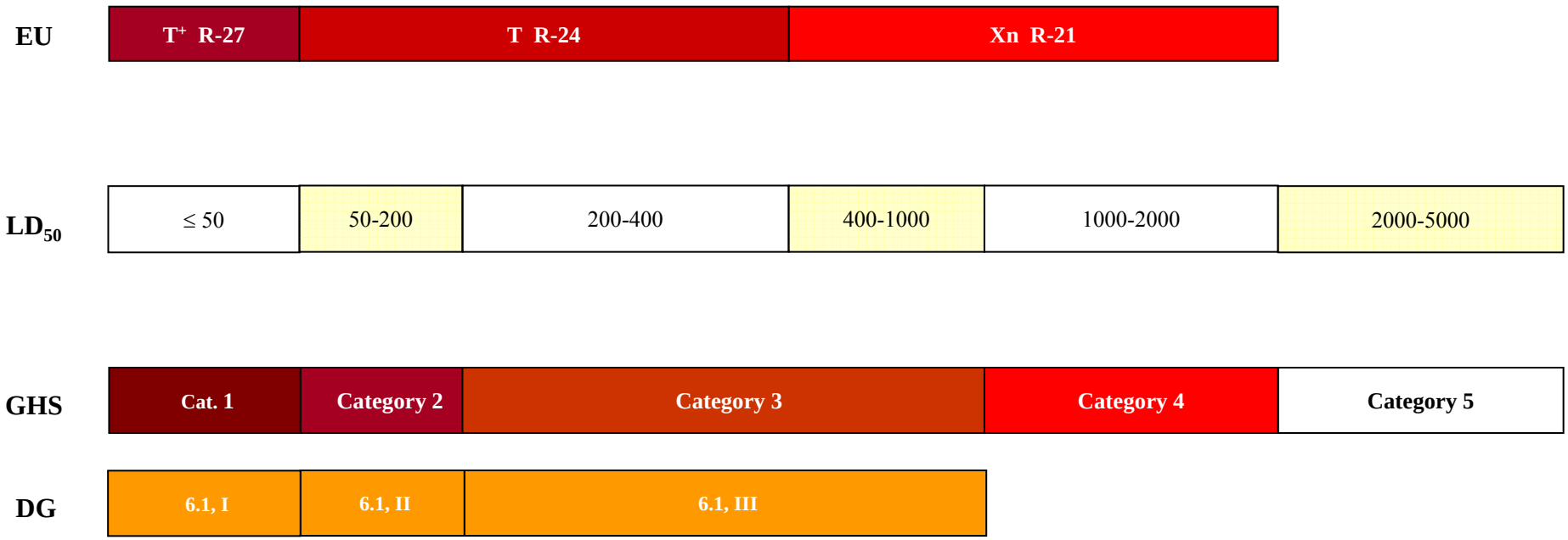
only legal information in chapter 15

Advantages of the GHS

- Harmonized classification criteria – toxic in EU = toxic in the US
- Harmonized labelling elements - EU =  = USA
- Harmonized safety data sheet - 16 chapters
- Central UN expert committee responsible for GHS
- Decreasing trade barriers in global trade

... it is the **first step** in international harmonization of classification, labelling and SDS

Acute toxicity, dermal



Classification of Preparations

- **health hazards**

ATE = acute toxicity estimate = [mg / kg body weight]

ATE_{mix} , if all **LD_{50}** - values of ingredients are known.

$$\frac{100}{ATE_{mix}} = \sum_{\eta} \frac{C_i}{ATE_i}$$

- **C_i**= concentration of ingredient **'i' .**
- **η** = index of ingredients from 1 - **η**
- **ATE_i** = LD_{50} -value of ingredient **'i'** .
- **ATE_{mix}** = calculated LD_{50}- value of mixture.

Classification of Preparations

- **health hazards**

ATE = acute toxicity estimate = [mg / kg body weight]

ATE_{mix} , if **not** all LD_{50} - values of ingredients are known.

$$\frac{100-(C_{unknown})}{ATE_{mix}} = \sum_{\eta} \frac{C_i}{ATE_i}$$

- **C_i**= concentration of ingredient **'i' .**
- **$C_{unknown}$** = concentration of ingredients without LD_{50}
- **η** = index of ingredients from 1 - **η**
- **ATE_i** = LD_{50} -value of ingredient **'i'** .
- **ATE_{mix}** = calculated LD_{50}- value of mixture.

Skin corrosion

EU	**C R-35**	**C R-34**	
	Corrosion = full thickness destruction of skin tissue on at least 1 animal during the *test for skin irritation* cited in Annex V or during an equivalent method or if the results are based on the results of a validated in vitro test or if the results can be predicted: for example from strong alkali or acid reactions indicated by a pH of ≤ 2 or ≥ 11,5		
Exposure	≤ 3 min	> 3 min - ≤ 1 hour	> 1 hour - ≤ 4 hours
GHS	**Category 1**		
	Cat. 1A	**Category 1B**	**Category 1C**
	Corrosion = destruction of skin tissue, namely visible necrosis through the epidermis and into the dermis in at least 1 of 3 tested animals after exposure up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia and scars.		
DG	**8, I**	**8, II**	**8, III**

Skin irritation

EU	**Xi R-38**
	-Significant inflammation of the skin which persists for at least 24 hours after an exposure period of up to 4 hours determined on the rabbit according to the cutaneous irritation test method cited in Annex V to Dir. 67/548/EEC (Publication: SBN 92-828-0076-8) Inflammation of the skin is significant if : (a)the mean value of the scores for either erythema and eschar formation or oedema formation, calculated over all the animals tested, is 2 or more; or (b)in the case where the Annex V test has been completed using three animals, either erythema and eschar formation or oedema formation equivalent to a mean value of 2 or more calculated for each animal separately has been observed in two or more animals. In both cases all scores at each of the reading times (24, 48 and 72 hr) for an effect should be used in calculating respective mean values. Inflammation of the skin is also significant if it persists in at least two animals at the end of the observation time, Particular effects e.g. hyperplasia, scaling, discoloration, fissures, scabs and alopecia should be taken into account. Relevant data may also be available from non-acute animal studies (see comments on R48, section 2.d). These are considered significant if the effects seen are comparable to those described above. -Substances and preparations which cause significant inflammation of the skin, based on practical observations in humans on immediate, prolonged or repeated contact. -Organic peroxides, except where evidence to the contrary is available.

GHS	**Category 2**	**Category 3**
	(1) Mean value of $\geq$ 2.3 -<4.0 for erythema/eschar or for oedema in at least 2 of 3 test animals from gradings at 24, 48 and 72 hours after path removal, or if reactions are delayed, from grades on 3 consecutive days after the onset of dermal reactions, or (2) Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia, hyperplasia, and scaling, or (3) In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above	Mean value of $\geq$ 1.5 - < 2.3 for erythema/eschar or for oedema from gradings in at least 2 of 3 tested animals from grades at 24, 48 and 72 hours or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions (when not included in the irritant Category 2)

Evaluation of Mixtures regarding corrosivity/irritation

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin corrosiv	Skin irritant
	Category 1	Category 2
Skin corrosive Categories 1A, 1B, 1C	>= 5 %	>=1 but < 5 %
Skin irritant Category 2		>= 10 %
10 x Skin corrosive Category 1A, 1B, 1C + Skin irritant Category 2		>= 10 %
Cat. 1A was C, R-35		
Cat. 1B was C, R-34		
Cat. 1C was C, R-34		
Cat. 2 was Xi, R-38		

Eye irritation

EU

Xi R-41	Xi R-36
Substances/preparations when applies to the eye of an animal cause *severe* ocular lesions within 72 hours after exposure which persist for at least 24 hours. Occular lesions are severe if the means of the scores of the eye irritation test in Annex V have any of the values: -cornea opacity equal to or greater than 3 -iris lesion greater than 1.5. The same shall be the case where the test has been completed using three animals if these lesions, on two or more animals, have any of the values : -cornea opacity equal to or greater than 3, -iris lesion equal to 2. In both cases all scores at each of the reading times (24, 48 and 72 hours) for an effect should be used in caculating the respective mean values. Ocular lesions are also severe when they are still present at the end of the observation time. Ocular lesions are also severe if the substance or preparation causes irreversible colouration of the eyes -Substances and preparations which cause severe ocular lesions based on practical experience in humans. Note : When a substance or preparation is classified as corrosive and assigned R34 or R35, the risk of severe damage to eyes is considered implicit and R41 is not included in the label.	Xi R36: Substances/preparations when applies to the eye of an animal, cause *significant* ocular lesions within 72 hours after exposure which persist for at least 24 hours. Ocular lesions are significant if the mean score of the eye irritation test cited in Annex V have any of the following values : -cornea opacity equal to or greater than 2 but less than 3, -iris lesion equal to or greater that 1 but not greater than 1.5, -redness of the conjunctivae equal to or greater than 2.5, -oedema of the conjunctiva (chemosis) equal to or greater than 2, or, in the case where the Annex V test has been completed using three animals if the lesions, on two or more animals, are equivalent to any of the above values except that for iris lesion the value should be equal to or greater than 1 but less than 2 and for redness of the conjunctivae the value should be equal to or greater than 2.5. In both cases all scores at each of the reading times (24, 48 and 72 hours) for an effect should be used in calculating the respective mean values. -Substances or preparations which cause significant ocular lesions, based on practical experience in humans. -Organic peroxides except where evidence to the contrary is available.

GHS

Category 1	Category 2A	Category 2B
At least in 1 animal effects on the cornea, iris or conjunctiva not expected to, or have not fully reversed within an observation period of 21 days and/or at least in 2 of 3 test animals a positive response of: corneal opacity ≥ 3 and/or iritis > 1.5 calculated on the mean scores following grading at 24, 48 and 72 hours after installation of the test material.	At least in 2 of 3 tested animals a positive response of: corneal opacity ≥ 1 and/or iritis ≥ 1 and/or conjunctival redness ≥ 2, and/or conjunctival oedema (chemosis) ≥ 2 calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test material, and which fully reverses within an observation period of 21 days.	When the effects listed in Category 2 A fully reverse within 7 days of observation

Evaluation of Mixtures regarding eye irritation

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Irreversible eye effects	Reversible eye effects
	Category 1	Category 2
Eye effects Category 1 or Skin corrosive Categories 1A, 1B, 1C	>= 3 %	>=1 but < 3 %
Eye effects Category 2		>= 10 %
(10 x eye effects Category 1) + Eye effects Category 2		>= 10 %
Skin corrosive Category 1A, 1B, 1C + Eye effects Category 1	>= 3 %	>=1 but < 3 %
10 x skin corrosive Category 1A, 1B, 1C) + Eye effects Category 1) + Eye effects Category 2		>= 10 %
Cat. 1A was R-35	Cat. 1 was Xi, R-41	
Cat. 1B was R-34	Cat. 2 was Xi, R-36	
Cat. 1C was R-34		

Conclusion

- All chemical substances have to be re-evaluated
- In a second step all mixtures have to be re-evaluated
- All transport classifications have to be re-evaluated

Further Consequences

- New classification
- New labels
- New SDSs
- More dangerous substances (?)
- More dangerous mixtures
- More dangerous goods (esp. mixtures)
- More legal restraints
- Consequences for the following (national) systems
  22 TRGSs, VwVwS, BImSchV, ChemG, GefStoffVO etc.

Sources of Information

- UNECE: Agenda, reports and meetings of the GHS-Sub-committee.
  http://www.unece.org/trans/danger/publi/ghs/ghs_rev01/01files_e.html
- IOMC: Working documents which lead to GHS.
  http://www.ilo.org/public/english/protection/safework/ghs/cghccs.htm
- Europe: Draft and internet consultation
  http://ec.europa.eu/enterprise/reach/ghs_consultation_en.htm

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Vielen Dank für Ihre Aufmerksamkeit !