

Istituto superiore per la Ricerca e la  
Protezione Ambientale



Ministero del Lavoro, Salute e  
Politiche Sociali

*In collaborazione con:*

Ministero dell'Ambiente e della Tutela del Territorio e del Mare

Ministero dello Sviluppo Economico

Istituto Superiore di Sanità

## Classification and labelling: the actual system

**Maristella Rubbiani**

ISS

## Summary

- legal base and definition
- the categories of danger
- harmonised classification versus self classification
- criteria for the correct classification

## General provisions:

### Directive 67/548/EEC

#### „Substances Directive“

- notification of New Substances
- list of classified substances
- classification
- packaging
- labelling
- safety data sheets

### Directive 1999/45/EC

#### „Preparations Directive“

- classification
- packaging
- labelling
- safety data sheets
- delivery of information relating to health

Proposal for a  
**Regulation of the European Parliament and  
of the Council**

On classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006

## Dangerous Substance Directive

Objectives and scope:

- Classification
- Labelling
- Packaging
- Classified substances
- SDS
- Notification of new substances

# Dangerous Substance Directive

## Annexes

- I Harmonised classification and labelling
- II Classes of danger symbols
- III R-phrases
- IV S-phrases
- V Testing methods
- VI Criteria for classification, indication of danger, symbols, R- and S-phrases
- VII and VIII: Notification of “new” substances
- IX Child-proof fastenings and tactile warning devices

## Dangerous Substance Directive

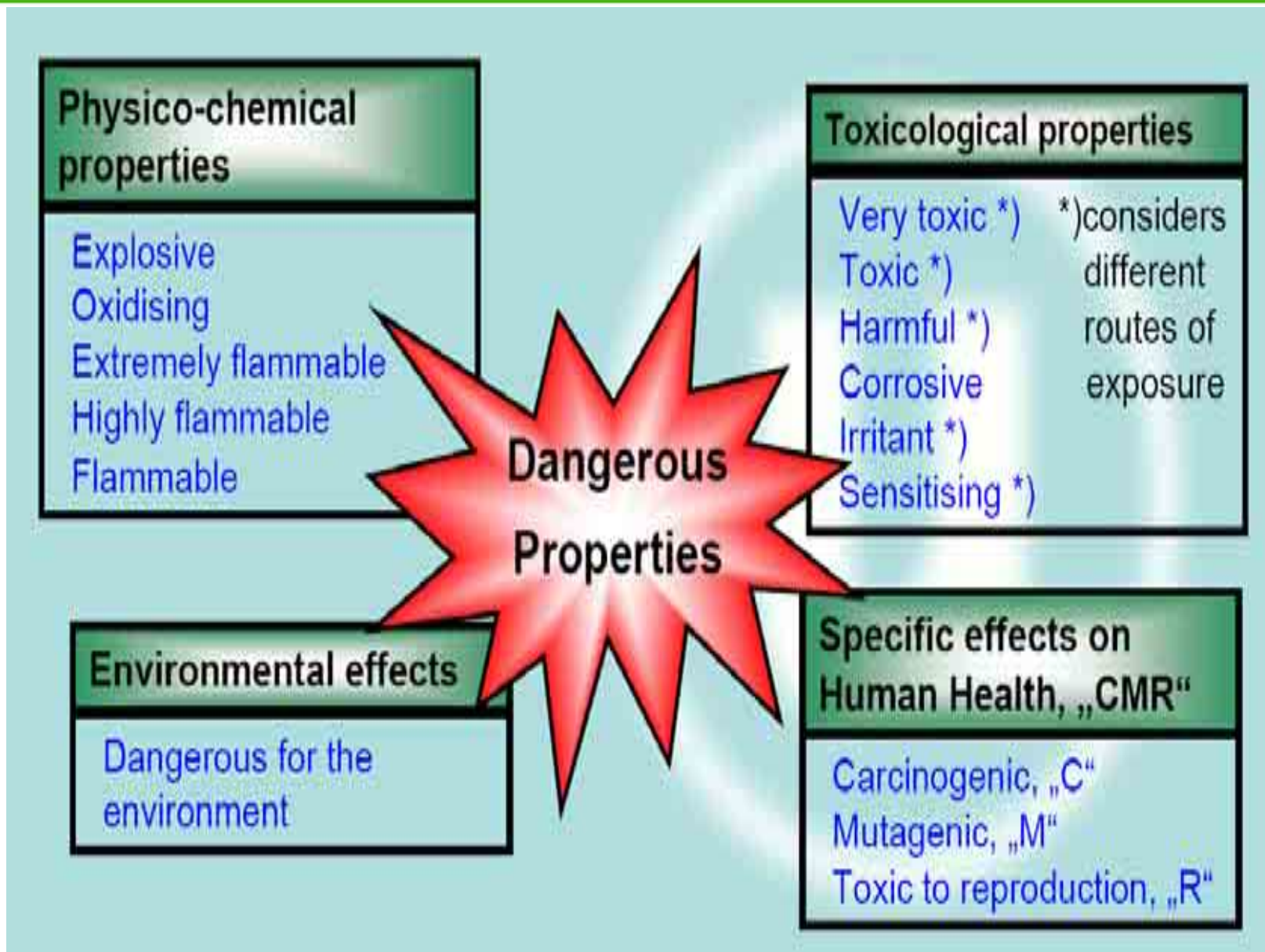
Identification of dangers presented by a chemical:

- assignment of R – phrases
- determination of categories of danger

Aim of classification:

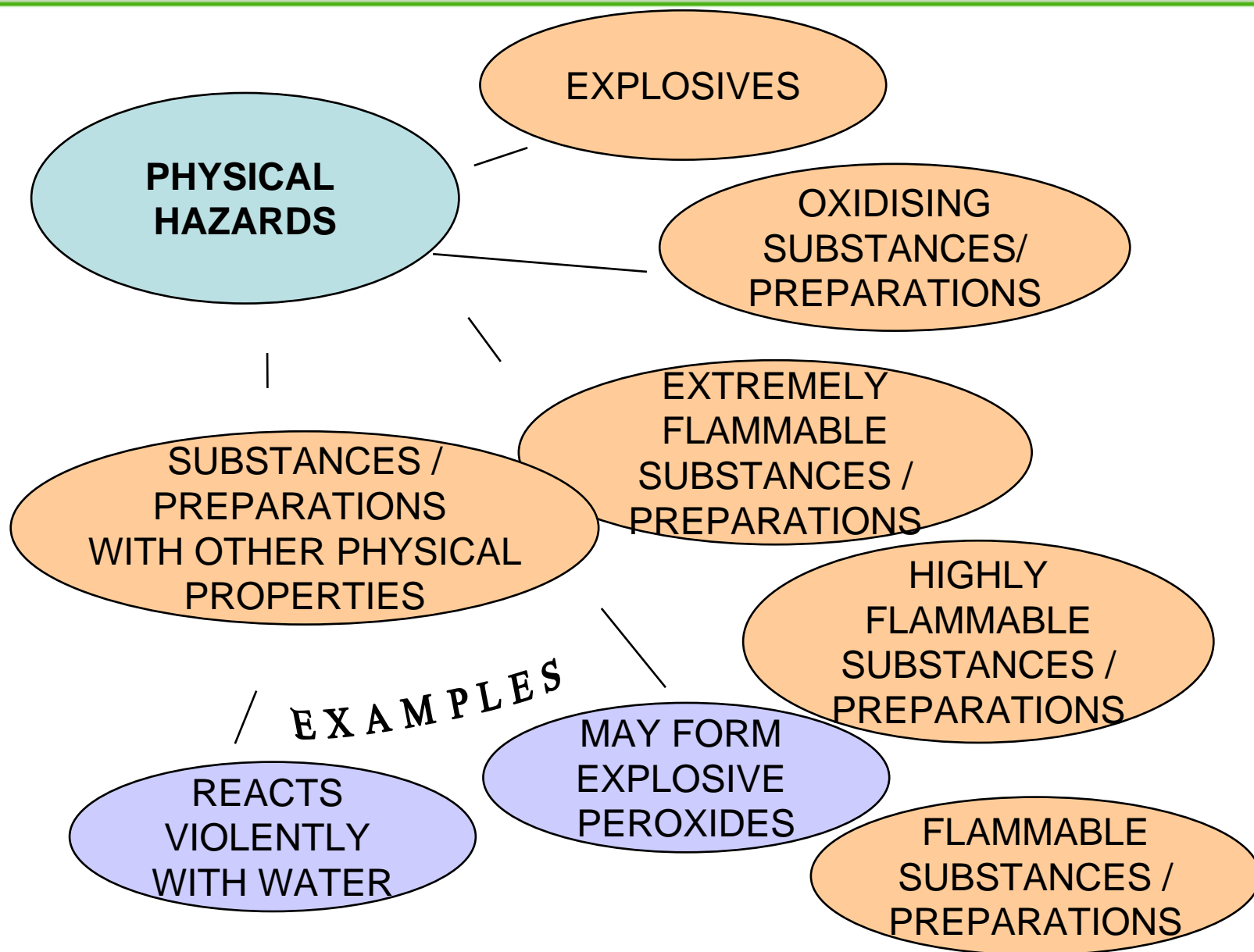
- dangerous properties of the chemical
- comparability between different substances/preparations
- by categorized dangerous properties
- defined criteria for assignment of properties

# Il rischio delle sostanze chimiche e il regolamento REACH

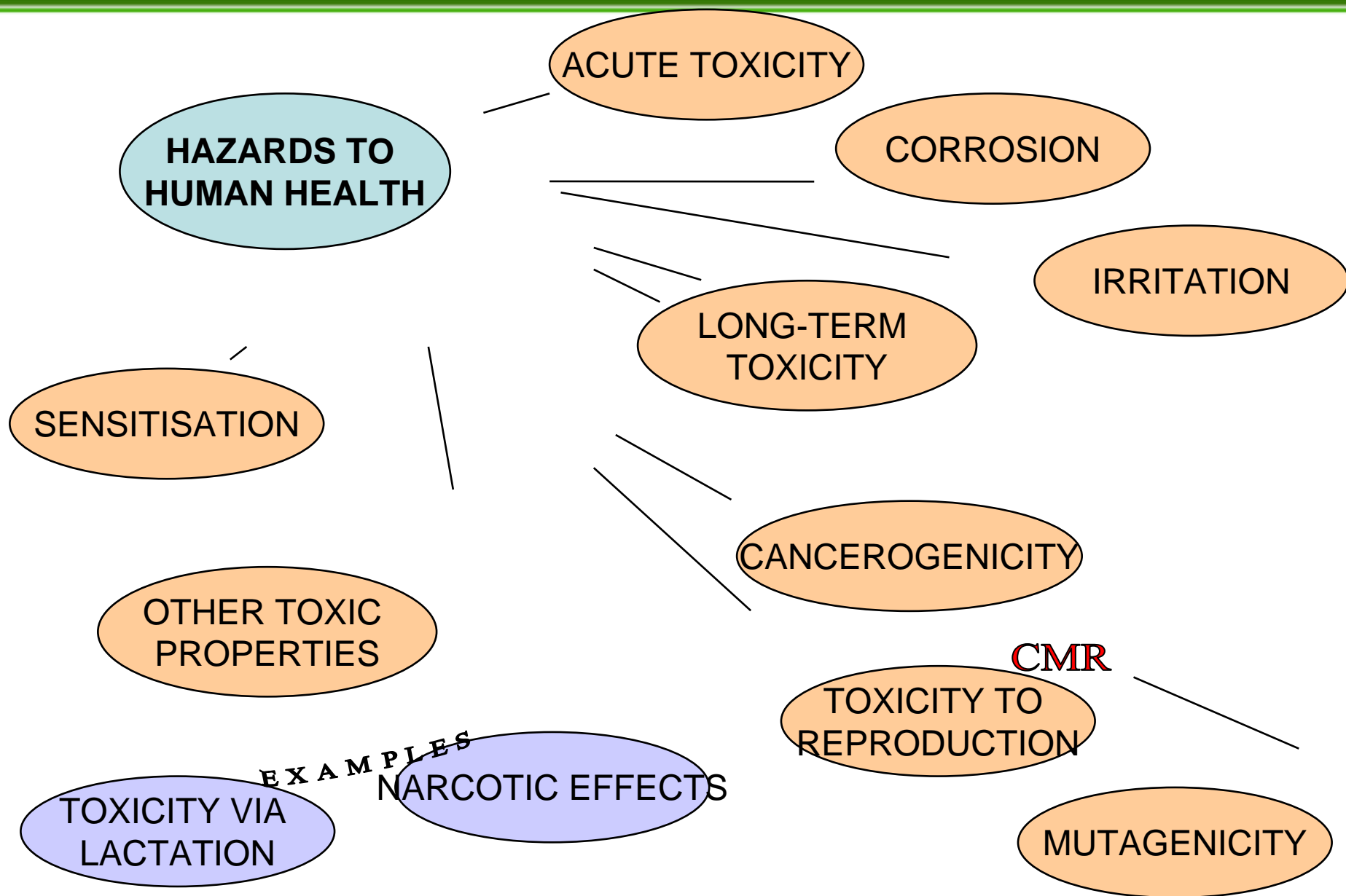




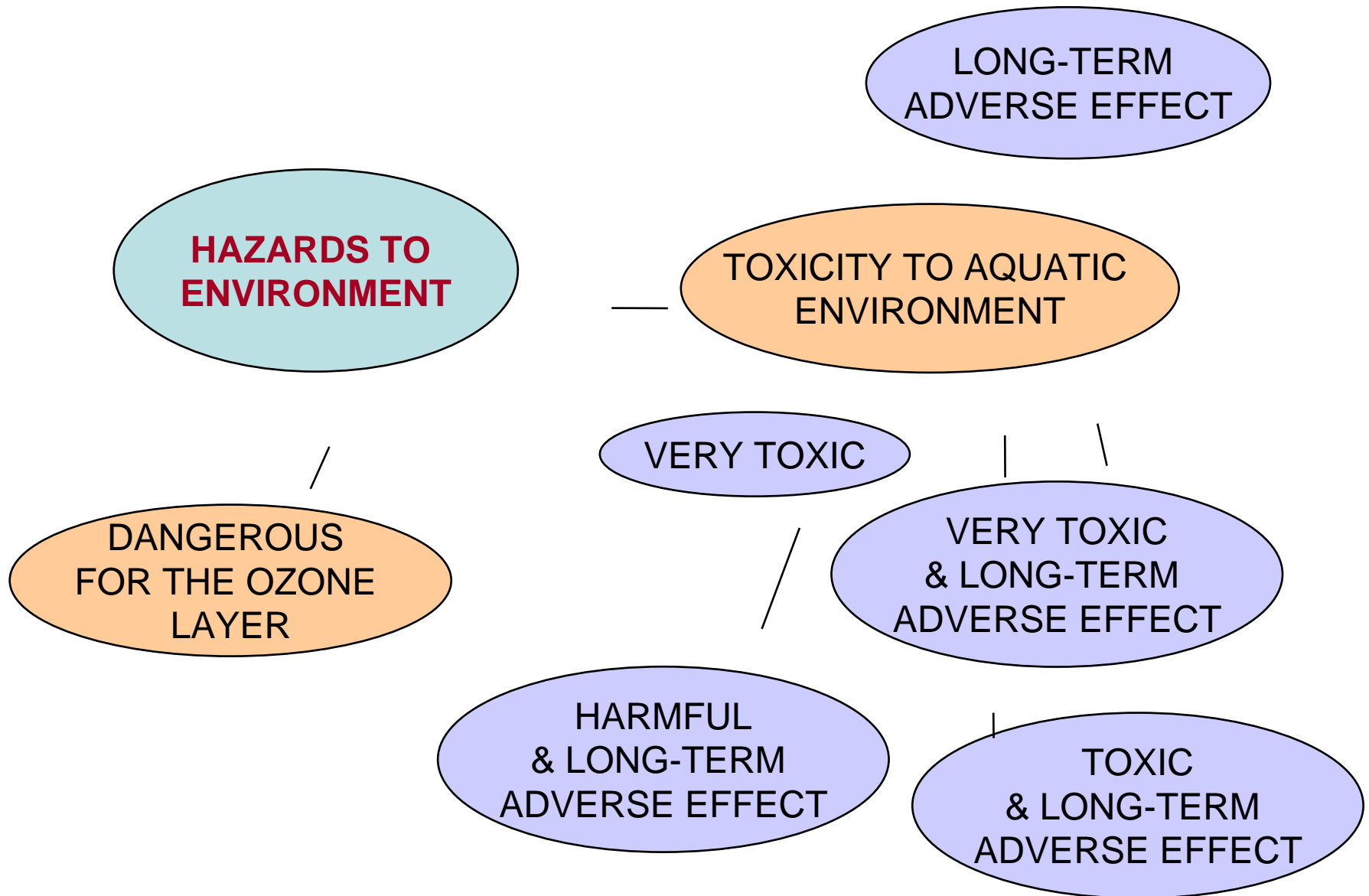
# Il rischio delle sostanze chimiche e il regolamento REACH



# Il rischio delle sostanze chimiche e il regolamento REACH



# Il rischio delle sostanze chimiche e il regolamento REACH



## Dangerous Substance Directive

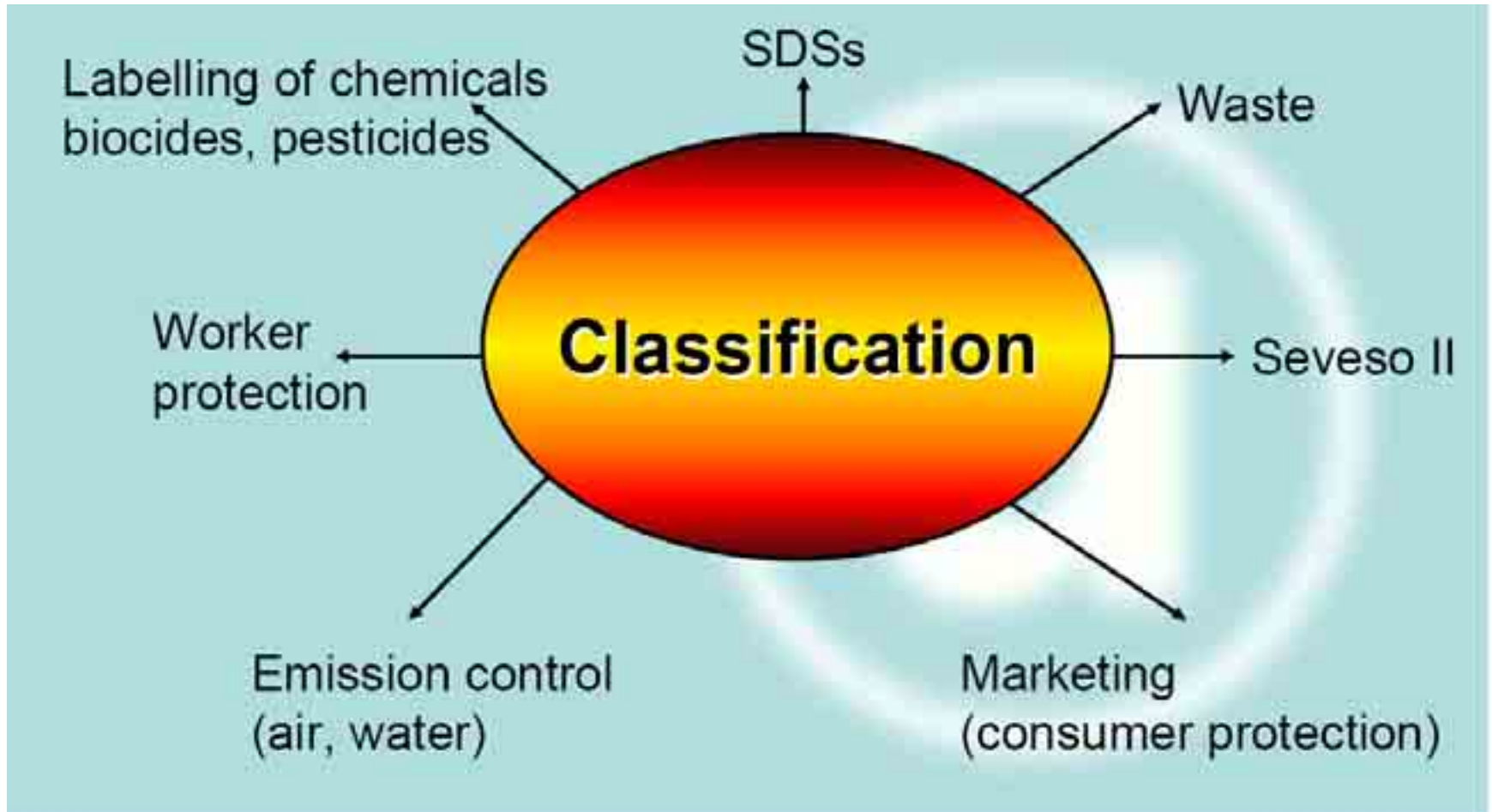
All **15 categories of danger** need to be considered

- determination of intrinsic properties, no risk assessment

When **test studies** are performed: mandatory test methods prescribed in Annex V

- according to the principles of Good Laboratory Practice (GLP), Directive 87/18/EEC
- alternative methods may be acceptable on a case-by-case basis

## Dangerous Substance Directive



## Physico-chemical properties

Indication of danger	R-Phrases	Symbol
Explosive	R2 R3	E
Oxidising	R7 R8 R9	O
Extremely flammable	R12	F+
Highly flammable	R11 R15 R17	F
Flammable	R10	
Other properties – phys.-chem.	R1 R7 R19 R4 R14 R30 R5 R16 R44 R6 R18	

## Acute toxicity

Indication of danger	R-Phrases	Symbol
Harmful by inhalation Harmful in contact with skin Harmful if swallowed Possible risk of irreversible effects R65 May cause lung damage if swallowed	R20 R21 R22 R68/20,21,22 R65	Xn
Toxic by inhalation Toxic in contact with skin Toxic if swallowed Danger of very serious irreversible effects	R23 R24 R25 R39/23,24,25	T
Very toxic by inhalation Very toxic in contact with skin Very toxic if swallowed Danger of very serious irreversible effects	R26 R27 R28 R39/26,27,28	T+

## Repeated dose toxicity

Indication of danger	R-Phrases	Symbol
Danger of serious damage to health by prolonged exposure	R48/20,21,22	Xn
Danger of serious damage to health by prolonged exposure	R48/23,24,25	T



## Corrosive, irritant and sensitisation

Indication of danger	R-Phrases	Symbol
Causes severe burns Causes burns	R35 R34	C
Irritating to skin Irritating to eyes Risk of serious damage to eyes Irritating to respiratory system	R38 R36 R41 R37	Xi
May cause sensitisation by skin contact	R43	Xi
May cause sensitisation by inhalation	R42	Xn

## Specific effects on human health

Indication of danger	R-Phrases	Sym.
<u>Carcinogenic Cat.1 + Cat.2</u> May cause cancer May cause cancer by inhalation <u>Mutagenic Cat.1 + Cat.2</u> May cause heritable genetic damage <u>Toxic to reproduction Cat.1 + Cat.2</u> May impair fertility May cause harm to the unborn child	R45 R49 R46 R60 R61	T
<u>Carcinogenic Cat.3</u> Limited evidence of a carcinogenic effect <u>Mutagenic Cat.3</u> Possible risk of irreversible effects <u>Toxic to reproduction Cat.3</u> Possible risk of impaired fertility Possible risk of harm to the unborn child	R40 R68 R62 R63	Xn
Other toxicological properties	R29,R31,R32 R33,R64,R66,R67	

## Environmental effects

Indication of danger	R-Phrases	Symbol
Very toxic to aquatic organisms	R50	N
Toxic to aquatic organisms	R51	
Dangerous for the ozone layer	R59	
Harmful to aquatic organisms	R52	
May cause long-term adverse effects in the aquatic environment	R53	

## Classification of substances

- Annex I of Directive 67/548/EEC:
  - ⇒ Published list of substances with a **harmonised classification and labelling**
  - ⇒ **Legally binding** classification, established in Commission working groups of MS experts
  - ⇒ ...2550 existing substances, 700 new substances
- Self classification by industry
- REACH: Title XI C&L inventory
- GHS: Annex I – Tables 3.1 and 3.2

## Entries in Annex I

Index No	Chemical name	*	EC No	CAS No	Classification	Labelling	Concentration Limits	**
601-013-00-X	1,3-butadiene buta-1,3-diene	D	203-450-8	106-99-0	F+; R12 Carc. Cat. 1; R45 Muta. Cat. 2; R46	F+; T R: 45-46-12 S: 53-45		
601-041-00-2	dibenz[a,h]ant hracene		200-181-8	53-70-3	Carc. Cat. 2; R45 N; R50-53	T; N R: 45-50/53 S: 53-45-60-61	C ≥ 0.01 %; T; R45	
602-027-00-9	trichloroethylene trichloroethene		201-167-4	79-01-6	Carc. Cat. 2; R45 Muta. Cat. 3; R68 R67 Xi; R36/38 R52-53	T R: 45-36/38-52/53-67 S: 53-45-61		6

## Dangerous Preparations Directive (I)

### Objectives and scope:

- Classification (physico-chemical properties, human health hazards, environmental hazards)
- Packaging
- Labelling
- Safety data sheets

of dangerous preparations

## Dangerous Preparations Directive (II)

### Annexes:

- I Methods for evaluation of physico-chemical properties
- II Methods for evaluation of health hazards
- III Methods for evaluation of the environmental hazards
- IV Provisions for preparations offered to the general public
- V Provisions concerning labelling of certain preparations
- VI Confidentiality for the chemical identity of a substance
- VII – IX ... currently not relevant

## Classification of preparations

- by the “conventional method”  
calculation method, using substance-specific  
concentration limits
  - based on practical experiences
  - on the basis of test studies according to Annex V of  
67/548/EEC
- ⇒ all 15 dangerous properties have to be evaluated!



## “Dilution effect” (I)

<b>very toxic, T+</b>	→	<b>toxic, T</b>	→	<b>harmful, Xn</b>
R 26 (inhalation)	→	R 23 (inhalation)	→	R 20 (inhalation)
R 27 (skin)	→	R 24 (skin)	→	R 21 (skin)
R 28 (oral)	→	R 25 (oral)	→	R 22 (oral)
R 39/26 (inhalation)	→	R 39/23 (inhalation)	→	R 68/20 (inhalation)
R 39/27 (skin)	→	R 39/24 (skin)	→	R 68/21 (skin)
R 39/28 (oral)	→	R 39/25 (oral)	→	R 68/22 (oral)
		R 48/23 (inhalation)	→	R 48/20 (inhalation)
		R 48/24 (skin)	→	R 48/21 (skin)
		R 48/25 (oral)	→	R 48/22 (oral)

## “Dilution effect” (II)

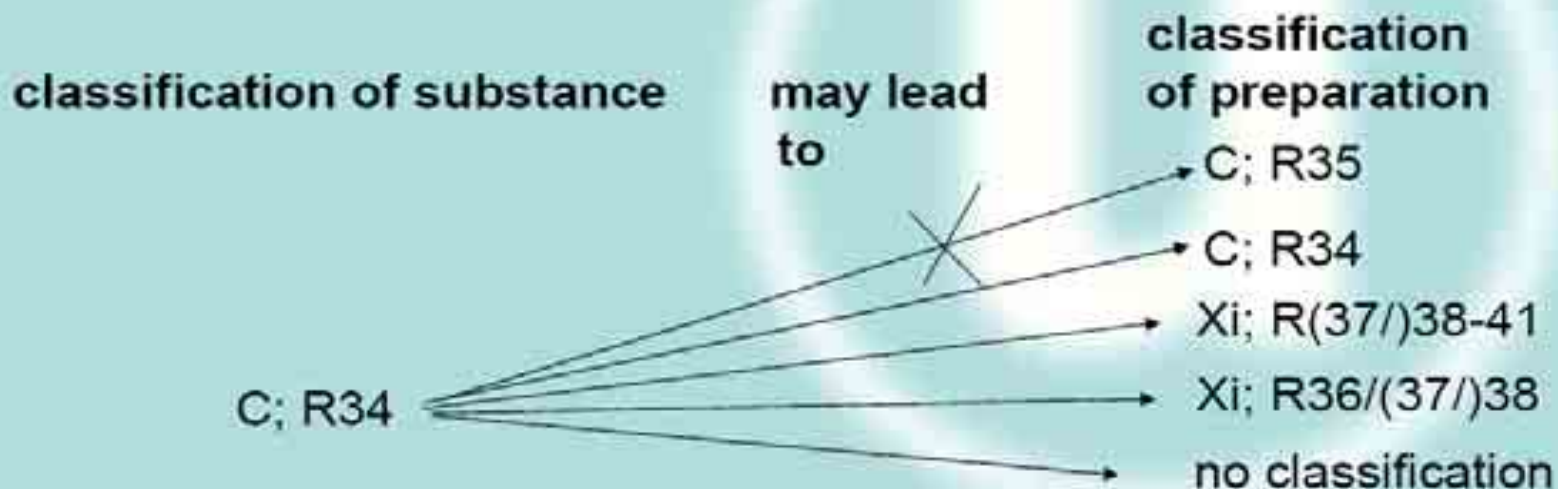
<b>causes severe burns, C</b> →	<b>causes burns, C</b> →	<b>irritating, Xi</b> →	<b>irritating, Xi</b>
R 35	R 34	-	R 38 (skin)
R 35	R 34	R 41 (eye)	R 36 (eye)

<b>very toxic to aquatic organisms, N</b> →	<b>toxic to aquatic organisms, N</b> →	<b>harmful to aquatic organisms</b>
R 50-53 →	R 51-53 →	R 52-53

## Additivity and “Dilution effect”

A dangerous substance may contribute to the classification of a preparation

- of the same severity
- of a lower severity (dilution effect !)
- but NOT of a higher severity !



## Labelling of chemicals

- legal base
- aim of the labelling
- responsibility for the labelling
- general labelling requirements
- general labelling elements
- labelling elements:
  - substances
  - preparations
  - implementation
  - symbols of danger

### LABELLING ELEMENTS:

1. SYMBOLS
2. RISK PHRASES
3. SAFETY PHRASES

## Labelling of chemicals

### **Legal basis**

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

### **Aim of the labelling**

- identification of dangers arising from the chemicals
- reference to additional and more detailed information available
- standardised information system: allows comparability between chemicals

## Labelling of chemicals

### Responsibility

- manufacturer
- importer
- domestic retailer declared in the label
- any person placing the chemical on the market

## Labelling of chemicals

- labelling elements:
  - risk phrases (R-phrases)
  - safety advice phrases (S-phrases)
  - declaration of ingredients
  - small packages
  - additional requirements

## General labelling requirements

### **step 1:**

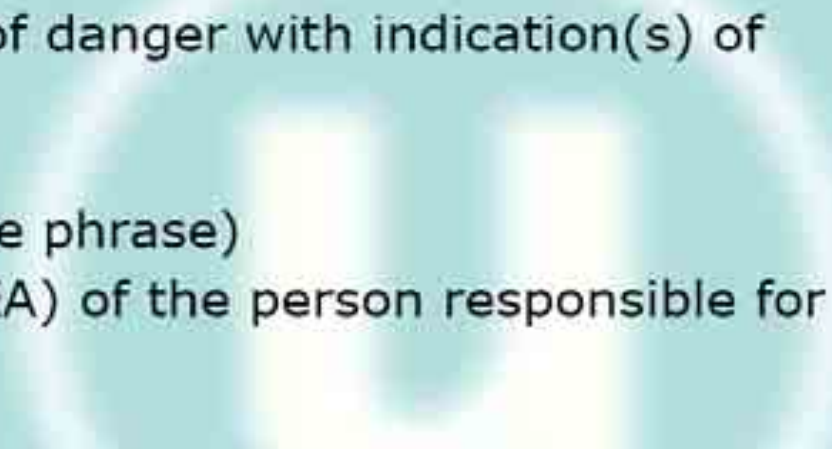
- proper classification of the substance/preparation with danger symbol(s), indication(s) of danger and R-phrase(s)
- identification of specific / relevant ingredients

### **step 2:**

- deduction of the proper labelling elements depending on step 1



## General labelling elements

- orange-yellow symbol(s) of danger with indication(s) of danger
  - R-phrase(s) (risk phrase)
  - S-phrase(s) (safety advice phrase)
  - name / address (within EEA) of the person responsible for placing on the market
  - telephone number
- 

### Specific labelling elements: SUBSTANCES

- name of the substance
- EC number (EINECS, ELINCS) of the substance
- “EC labelling” in case of substances from the list of classified substances
- indication in case of New Substances without complete testing
- special cases

### Specific labelling elements: PREPARATIONS

- trade name
- declaration of dangerous substances present (ingredients)
- nominal quantity of package
- indication for presence of New Substance(s) without complete testing
- special cases

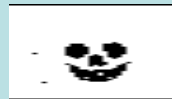
## Labelling elements: IMPLEMENTATION

- minimum size of label, of symbol, of text
- presentation of the label (colour)
- labelling of a single package – of a outer package

PHYSICAL  
CHEMICAL  
HAZARDS



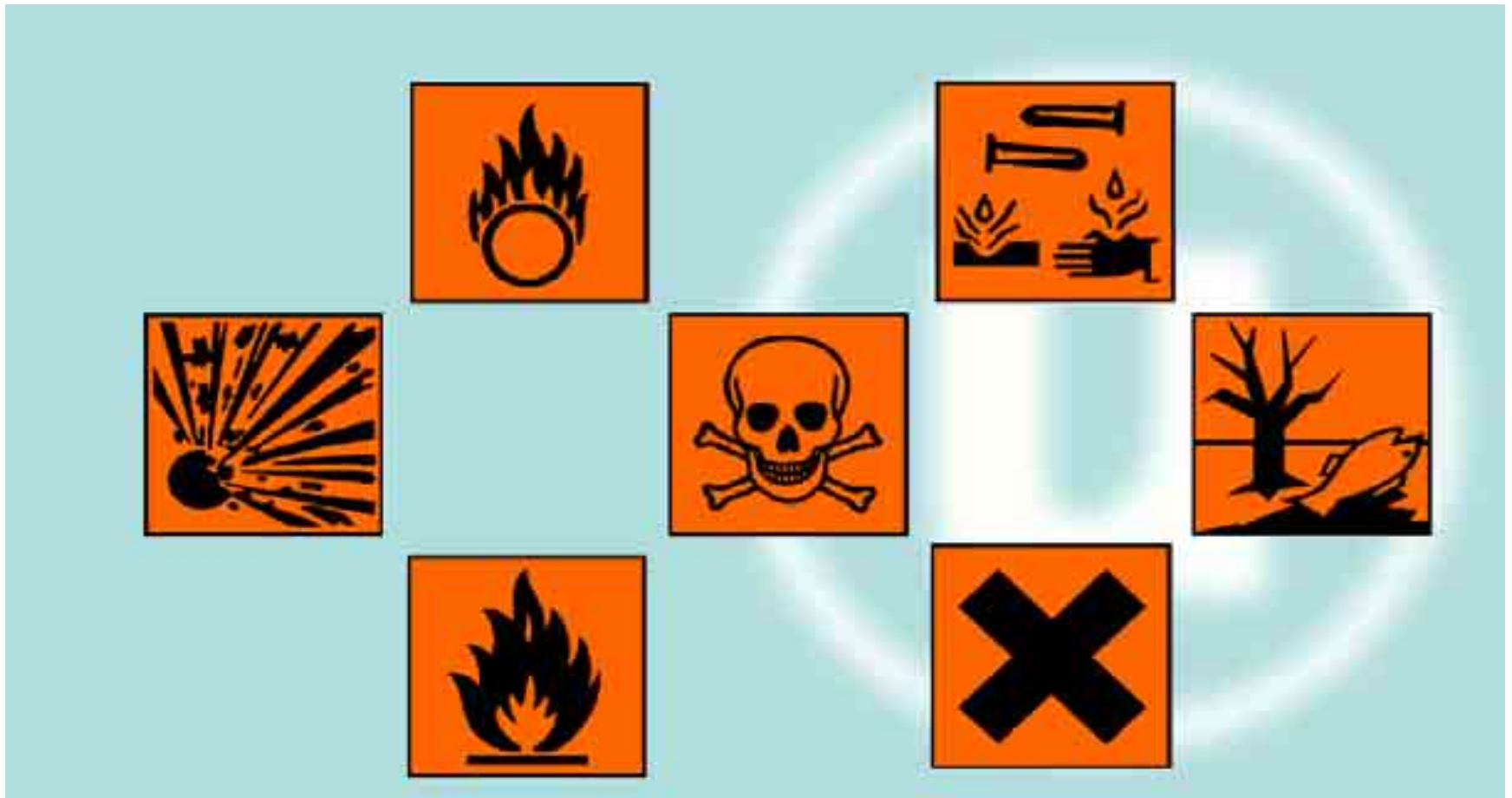
HAZARDS TO  
HUMAN HEALTH



HAZARDS TO  
ENVIRONMENT








## Labelling elements: SYMBOLS OF DANGER

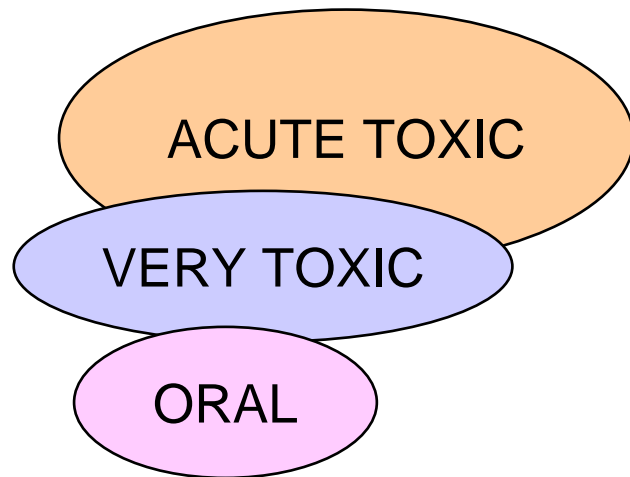


## Labelling elements: “HIERARCHY” OF SYMBOLS

The diagram illustrates the hierarchy of GHS hazard symbols and their corresponding hazard statements. A large, faint 'U' symbol is visible in the background.

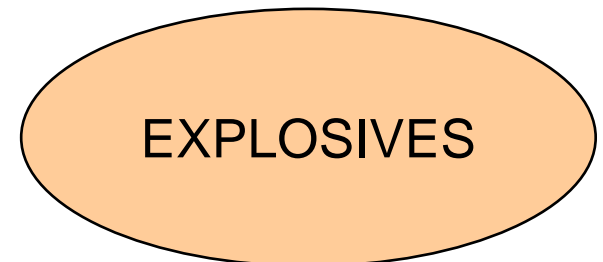
 T+	<del>T; Xn; C; Xi</del>	 E	<del>F+; F; O</del>
 T	<del>Xn; C; Xi</del>	 Xn	<del>Xi</del>
 C	<del>Xi, Xn</del> (not in case of Xn because of CMR Cat. 3)		

## Risk Phrases



R28: Very toxic if swallowed

R2: Risk of explosion by shock, friction, fire other sources of ignition





## Safety Phrases

**NOW**

ACUTE TOXIC

VERY TOXIC

ORAL

S36/37: Wear suitable protective clothes and gloves

S2: Keep out of reach of children

EXPLOSIVES

## Labelling elements: R- and S- phrases

### **R- and S-phrases**

- unchangeable standard text phrases
- cover the principle hazards with R-phrases
- both obligatory and recommended S-phrases
- usually no more than 6 R-phrases/6 S-phrases
- special provisions for omission of specific R-phrases

### **Declaration of ingredients**

### **Small packages**

### **Additional requirements**

## Labelling elements: Special provisions

Preparations classified as dangerous:

Example: sold to the general public: additional S-phrases



Preparations irrespective of their classification

Example: not classified as sensitising but containing at least one sensitising substance

Preparations not classified but containing at least one dangerous substance

Example: preparations not intended for the general public  
"Safety data sheet available for professional user on request"

## Example for labelling: SUBSTANCE

<b>Pentachloroethane</b> EC-Nr: 200-925-1	Name of substance EC-No	
		Symbols of danger
<b>Toxic</b>	<b>Dangerous for environment</b>	Indications of danger
Limited evidence of a carcinogenic effect. Toxic: danger of serious damage to health by prolonged exposure through inhalation. Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. In case of accident or if you feel unwell seek medical advice. Do not breathe vapour. Avoid release to the environment.		R-phrases and S-phrases
<b>Example Company, Examplestreet 1, A 1111 Exemptown</b> Tel: +43 (00)1234 56789 EC Labelling	<b>Responsible person</b>  <b>EC labelling</b>	

## Practical control aspects (SUBSTANCE)

- Ask for label, SDS and substance identity
- Check of classification:
  - listed in Annex I? if not ⇨
  - use information in SDS (physchem., tox., ecotox....)
  - Databases
  - ask responsible person for further data
- Check of labelling elements (general and specific)
- Comparison classification – chapter 2 of SDS  
(former chapter 3)
- Comparison label - chapter 15 of SDS

### Practical control aspects (preparations)

- Ask for label, SDS and composition (substances)
- Check of classification:
  - Check substances relevant for classification (cut-off-values)
  - Dilution effect for dangerous properties?
  - Additivity, non-additivity for substances in the preparation?
  - Concentration limits (general - specific)?
- Check of labelling elements (general and specific)
- Comparison classification - chapter 3 of SDS
- Comparison label - chapter 15 of SDS

## Appearance of Annex I (I)

	A	B	C	D	E	F	G	H	I
1	Index No	Chemical name	Notes related to substances	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes related to preparative
2234	613-049-00-3	benzoyl (ISO), methyl 1-(butylcarbamoyl)benzimidazol-2-ylcarbamate		341-775-7	17804-35-2	Muta. Cat. 2, R46 Repr. Cat. 2, R60-61 Xi, R37/38 R43 N, R50-53	T, N R: 46-60-61-37/38-43-50-53 S: 53-45-60-61	C ≥ 20 %: T, N, R46-60-61-37/38-43-50-53 2,5 % ≤ C < 20 %: T, N, R46-60-61-43-50-53 1 % ≤ C < 2,5 %: T, N, R46-60-61-43-51-53 0,5 % ≤ C < 1 %: T, N, R46-60-61-51-53 0,25 % ≤ C < 0,5 %: T, N, R46-61-53 0,1 % ≤ C < 0,25 %: T, R46-52-53 0,025 % ≤ C < 0,1 %: R52-53	
2235	613-050-00-9	carbadox (INN), methyl 3-(quinoxalin-2-ylmethylene)carbazate 1,4-dioxide, 2-(methoxycarbonylhydrazonomethyl)quinoxaline 1,4-dioxide	E	229-878-0	6804-07-5	F, R11 Carc. Cat. 2, R45 Xi, R23	F, T R: 45-11-22 S: 53-45		
2239	613-054-00-0	thiabendazol (ISO), 2-(thiazole-4-yl)benzimidazole		205-725-8	148-79-8	N, R50-53	N R: 50/53 S: 60-61		
2242	613-058-00-2	permethrin (ISO), m-phenoxycarbonyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate		258-067-9	52645-53-1	Xn, R20/22 R43 N, R50-53	Xn, N R: 20/22-43-50/53 S: (2-)13-24-36/37/39-60-61	C ≥ 25 %: Xn, N, R20/22-43-50-53 1 % ≤ C < 25 %: N, R43-50-53 0,025 % ≤ C < 1 %: N, R50-53 0,0025 % ≤ C < 0,025 %: N, R51-53 0,00025 % ≤ C < 0,0025 %: R52-53	
2243	613-059-00-8	profenalin (ISO), N-(cyclopropylmethyl)-4,8-difluoro-2,6-dinitro-N-propyl-p-toluidine		247-656-6	26399-36-0	Xi, R36 N, R50-53	Xi, N R: 36-50/53 S: (2-)60-61		
	613-060-00-3	resmethrin (ISO), 5-benzyl-2-bis(2-methyl-1-hydroxyethyl)phosphorothioic acid triethyl ester		293-940-7	10450-06-0	Xn, R22 N, R50/53	Xn, N R: 22-50/53 S: 22-50/53		

## HARMONISED CLASSIFICATION & LABELLING vs SELF-CLASSIFICATION & LABELLING

### SUBSTANCES:

SOME SUBSTANCES HAVE A COMPLETELY HARMONISED AND LEGALLY BINDING CLASSIFICATION THROUGH ANNEX I TO DIRECTIVE 67/548 SUBSTANCES NOT LISTED IN ANNEX I ARE SUBJECT TO 'SELF-CLASSIFICATION' IN ACCORDANCE TO THE SAME CRITERIA

### PREPARATIONS:

ALL PREPARATIONS ARE SUBJECT TO 'SELF-CLASSIFICATION' IN ACCORDANCE TO THE CRITERIA IN DIRECTIVE 67/548 AND ADDITIONAL PROVISIONS FOR PREPARATIONS IN DIRECTIVE 1999/45



### WHO IS RESPONSIBLE IN THE SUPPLY CHAIN

THE ONE PLACING THE SUBSTANCE OR MIXTURE ON THE MARKET MUST CLASSIFY AND LABEL IN ACCORDANCE WITH DIRECTIVE 67/548

‘PLACING ON THE MARKET’ MEANS MAKING AVAILABLE TO THIRD PARTIES. IMPORTATION INTO THE COMMUNITY CUSTOMS TERRITORY SHALL BE DEEMED TO BE PLACING ON THE MARKET FOR THE PURPOSES OF THIS DIRECTIVE

# Il rischio delle sostanze chimiche e il regolamento REACH

## DOWNSTREAM LEGISLATION

PREPARATIONS  
(1999/45/EC)

... and  
others

RESTRICTIONS ON  
MARKETING AND USE  
(76/769/EEC)

PLANT  
PROTECTION  
PRODUCTS  
(91/414/EEC)

WORKPLACE  
PROTECTION  
(98/24/EC)

SEVESO –  
MAJOR ACCIDENT  
HAZARDS  
(96/82/EC)

BIOCIDES  
(98/8/EC)

HAZARDOUS  
WASTE  
(91/689/EC)

COSMETICS  
(2003/15/EC)

EXPORT-IMPORT  
(304/2003)