Criteria for environmental hazardousness

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Content of presentation

- Directive 67/548/EEC: environmental classification and labelling, testing methods
- GHS classification and labelling
- Criteria for “hazardous substance” in different frameworks

Classification

- Decide what kinds of hazard the chemical has
  - assign the category of danger
  - describe possible harmful effects by allocating a risk phrase
- Objective
  - to identify all the physico-chemical, toxicological and ecotoxicological properties of substances which may constitute a risk during normal handling and use
- Hazard identification based entirely on the intrinsic properties of the substance

An example

The substance	Strychnine
The category of danger	Very toxic
The risk phrase	Very toxic in contact with skin and if swallowed

These expressions are often abbreviated to letters and numbers, e.g. Strychnine T+, R27/28 (the slash indicates a combined phrase)

Standard criteria in EU

Council Directive 67/548/EEC

of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification. packaging and labelling of dangerous substances

EU Directive 67/548/EEC

- Annex I: List of Dangerous Substances
- Annex II: Symbols and Indications of Danger
- Annex III: Phrases describing the hazards
- Annex IV: Phrases with safety advice
- Annex VI: Guidance to classification and labelling

- Annex V: Test methods for determination of properties
- Annex VII: Notification ‘Base Set’ requirements
- Annex VIII: Post-notification information and tests

Categories of Danger

Health:

- Very toxic
- Toxic
- Harmful
- Corrosive
- Irritant
- Sensitising
- Carcinogenic
- Mutagenic
- Toxic to reproduction

Categories of danger

Environment:

- Classification category “dangerous for the environment” established in the year 1979 (6th amendment of C&L)
- Takes account of the
  - Aquatic toxicity
  - Bioaccumulation potential
  - Persistence

R-phrases for environment

- R50 Very toxic to water organisms
- R51 Toxic to water organisms
- R52 Hazardous to water organisms
- R53 May cause long term adverese effects to the aquatic environment
- R54 Toxic to plants
- R55 Toxic to animals
- R56 Toxic to soil organisms
- R57 Toxic to honey bees
- R58 May cause long term adverse effects to the environment
- R59 Dangerous for the ozone layer

Testing methods

- The legally binding EU standardised Testing Methods to determine the hazardous properties of chemicals are contained in Annex V of Dir 67/548/EEC
  - Part A contains methods for the determination of physico-chemical properties (e.g. melting and boiling point, flash point, flammability, explosivity ...)
  - Part B contains methods for the determination of effects on human health (e.g. acute or chronic toxicity, skin sensitisation, irritancy, corrosivity, carcinogenicity, neurotoxicity ...).
  - Part C contains methos for environmental effects, ecotoxicity and environmental fate (e.g. toxicity to fish, daphnia or algae, bioconcentration, biodegradability, etc.).

List of environmental tests

C.1 ACUTE TOXICITY FOR FISH
C.2 ACUTE TOXICITY FOR DAPHNIA
C.3 ALGAL INHIBITION TEST
C.4 BIODEGRADATION: DETERMINATION OF THE "READY" BIODEGRADABILITY (6 different methods)
C.5 DEGRADATION : BIOCHEMICAL OXYGEN DEMAND
C.6 DEGRADATION: CHEMICAL OXYGEN DEMAND
C.7 DEGRADATION: ABIOTIC DEGRADATION: HYDROLYSIS AS A FUNCTION OF PH
C.8 TOXICITY FOR EARTHWORMS : ARTIFICIAL SOIL TEST
C.9 BIODEGRADATION: ZAHN - WELLENS TEST
C.10 BIODEGRADATION: ACTIVATED SLUDGE SIMULATION TEST

List of environmental tests (2)

C.11 BIODEGRADATION: ACTIVATED SLUDGE RESPIRATION INHIBITION TEST
C.12 BIODEGRADATION: MODIFIED SCAS TEST
C.13 BIOCONCENTRATION: FLOW-THROUGH FISH TEST
C.14 FISH JUVENILE GROWTH TEST
C.15 FISH, SHORT-TERM TOXICITY TEST ON EMBRYO AND SAC-FRY STAGES
C.16 HONEYBEES - ACUTE ORAL TOXICITY TEST
C.17 HONEYBEES - ACUTE CONTACT TOXICITY TEST
C.18 ADSORPTION/DESORPTION USING A BATCH EQUILIBRIUM METHOD

List of environmental tests (3)

C.19 ESTIMATION OF THE ADSORPTION COEFFICIENT (KOC) ON SOIL AND ON SEWAGE SLUDGE USING HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

C.20 DAPHNIA MAGNA REPRODUCTION TEST

C.21 SOIL MICROORGANISMS: NITROGEN TRANSFORMATION TEST

C.22 SOIL MICROORGANISMS: CARBON TRANSFORMATION TEST

C.23 AEROBIC AND ANAEROBIC TRANSFORMATION IN SOIL

C.24 AEROBIC AND ANAEROBIC TRANSFORMATION IN AQUATIC SEDIMENT SYSTEMS

List of environmental tests (new)

New C.xx Simulation Test: Aerobic Sewage Sludge Plant (=OECD 303).

New C.xx Biodegradation in surface waters (OECD 309?).

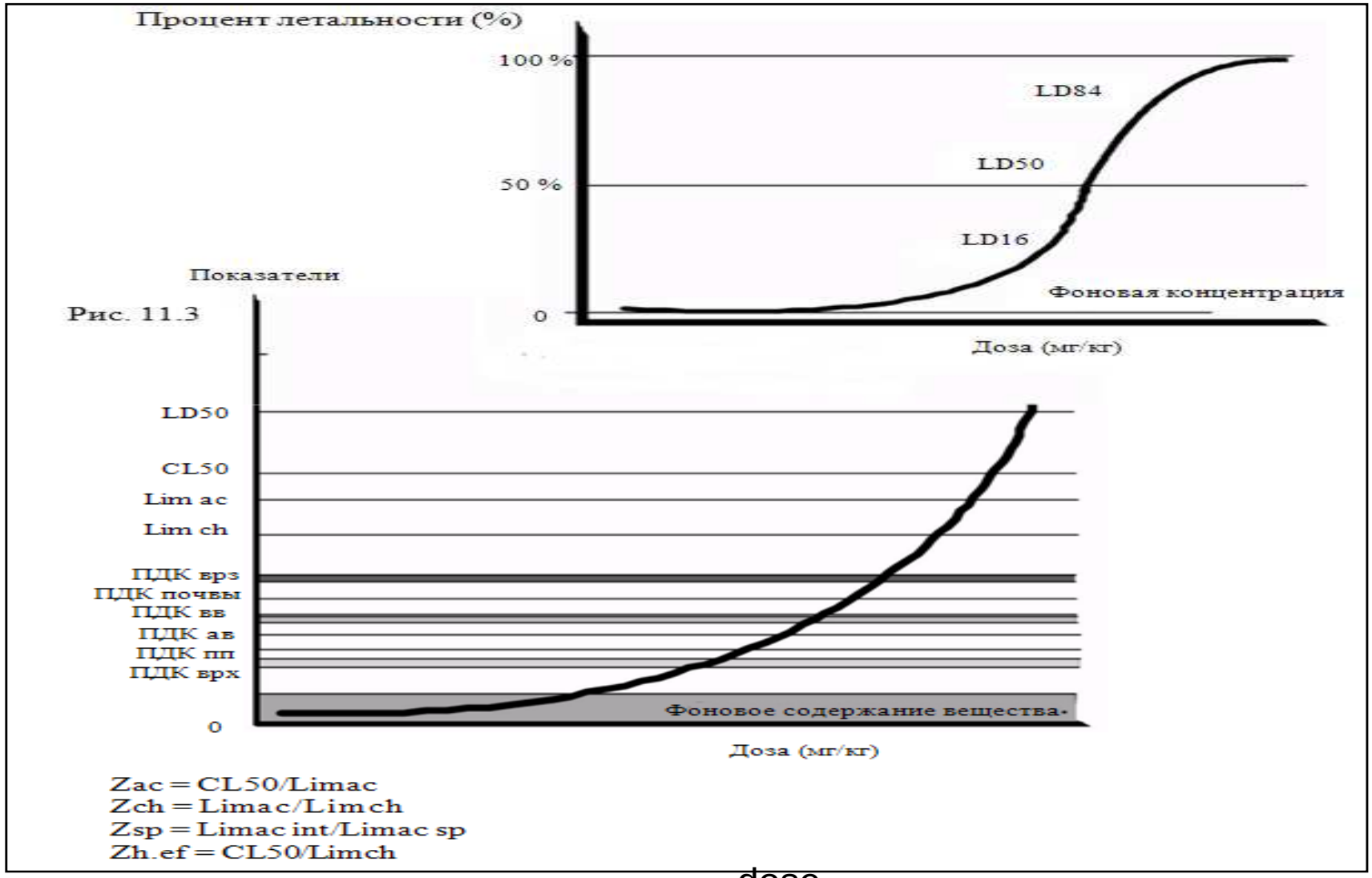
New C.xx Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (= OECD 218).

New C.xx Sediment-Water Chironomid Toxicity Test Using Spiked Water (= OECD 219).

New C.xx Enchytraeid Reproduction Test (= OECD 220).

New C.xx Earthworm reproduction test (= OECD 222).

New C.xx Leaching in soil columns (=OECD 312).


Процент летальности (%)
100 %
50 %
0
LD84
LD50
LD16
Фоновая концентрация
Доза (мг/кг)
Показатели
Рис. 11.3
LD50
CL50
Lim ac
Lim ch
ПДК врз
ПДК почвы
ПДК вв
ПДК ав
ПДК пп
ПДК врх
0
Фоновое содержание вещества
Доза (мг/кг)
Zac = CL50/Limac
Zch = Limac/Limch
Zsp = Limac int/Limac sp
Zh.ef = CL50/Limch

dose

GHS

- **Globally Harmonised System** of classification and labelling of chemicals
- Implemented in EU by Regulation No. 1272/2008
- Relatively long implementation period from 2009

Some terms in GHS

- “Signal word’ means a word that indicates the relative level of severity of hazards to alert the reader to a potential hazard:
  - ‘Danger’ means a signal word indicating the more severe hazard categories;
  - ‘Warning’ means a signal word indicating the less severe hazard categories.
- ‘Hazard statement’ means a phrase assigned to a hazard class and category that describes the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard;

Terms (2)

- ‘cut-off value’ means a threshold of any classified impurity, additive or individual constituent in a substance or in a mixture, above which threshold these shall be taken into account for determining if the substance or the mixture, respectively, shall be classified
- ‘M-factor’ means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present

Generic cut-off values

Hazard class	Generic cut-off values to be taken into account
Acute Toxicity:	
— Category 1-3 — Category 4	0,1 % 1 %
Skin corrosion/Irritation	1 % (1)
Serious damage to eyes/eye irritation	1 % (2)
Hazardous to Aquatic Environment:	
— Acute Category 1 — Chronic Category 1 — Chronic Category 2-4	0,1 % (3) 0,1 % (3) 1 %

(1) Or < 1 % where relevant, see 3.2.3.3.1.
(2) Or < 1 % where relevant, see 3.3.3.3.1.
(3) Or < 0,1 % where relevant, see 4.1.3.1.

GHS environmental classification

Hazardous to the aquatic environment

- The basic elements used for classification for aquatic environmental hazards are:
  - Acute aquatic toxicity;
  - Potential for or actual bioaccumulation;
  - Degradation (biotic or abiotic) for organic chemicals; and
  - Chronic aquatic toxicity.

Classification categories for hazardous to the aquatic environment

Acute (short-term) aquatic hazard		
Acute Category 1	(Note 1)	
96 hr LC_{50} (for fish)	≤ 1 mg/l and/or	
48 hr EC_{50} (for crustacea)	≤ 1 mg/l and/or	
72 or 96 hr ErC_{50} (for algae or other aquatic plants)	≤ 1 mg/l	(Note 2)
Chronic (long-term) aquatic hazard		
Chronic Category 1	(Note 1)	
96 hr LC_{50} (for fish)	≤ 1 mg/l and/or	
48 hr EC_{50} (for crustacea)	≤ 1 mg/l and/or	
72 or 96 hr ErC_{50} (for algae or other aquatic plants)	≤ 1 mg/l	(Note 2)
and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log K_{ow} ≥ 4).		
Chronic Category 2		
96 hr LC_{50} (for fish)	> 1 to ≤ 10 mg/l and/or	
48 hr EC_{50} (for crustacea)	> 1 to ≤ 10 mg/l and/or	
72 or 96 hr ErC_{50} (for algae or other aquatic plants)	> 1 to ≤ 10 mg/l	(Note 2)
and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log K_{ow} ≥ 4), unless the chronic toxicity NOECs are > 1 mg/l.		

Chronic Category 3

96 hr LC_{50} (for fish)	> 10 to ≤ 100 mg/l and/or
48 hr EC_{50} (for crustacea)	> 10 to ≤ 100 mg/l and/or
72 or 96 hr ErC_{50} (for algae or other aquatic plants)	> 10 to ≤ 100 mg/l (Note 2)

and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log K_{ow} ≥ 4) unless the chronic toxicity NOECs are > 1 mg/l.

'Safety net' classification

Chronic Category 4

Cases when data do not allow classification under the above criteria but there are nevertheless some grounds for concern. This includes, for example, poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility (note 3), and which are not rapidly degradable and have an experimentally determined BCF ≥ 500 (or, if absent, a log K_{ow} ≥ 4), indicating a potential to bioaccumulate, will be classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence includes chronic toxicity NOECs > water solubility or > 1 mg/l, or evidence of rapid degradation in the environment.

Label elements for hazardous to the aquatic environment

ACUTE	
	Category 1
GHS Pictogram	
Signal Word	Warning
Hazard Statement	H400: Very toxic to aquatic life

ACUTE	
	Category 1
Precautionary Statement Prevention	P273
Precautionary Statement Response	P391
Precautionary Statement Storage	
Precautionary Statement Disposal	P501

CHRONIC

	Category 1	Category 2	Category 3	Category
GHS Pictograms			No pictogram is used	No pictogram is used
Signal Word	Warning	No signal word is used	No signal word is used	No signal word is used
Hazard Statement	H410: Very toxic to aquatic life with long lasting effects	H411: Toxic to aquatic life with long lasting effects	H412: Harmful to aquatic life with long lasting effects	H413: May cause long lasting harmful effects to aquatic life
Precautionary Statement Prevention	P273	P273	P273	P273
Precautionary Statement Response	P391	P391		
Precautionary Statement Storage				
Precautionary Statement Disposal	P501	P501	P501	P501

PBTs/vPvBs

	EU PBT	EU vPvB
P	Not inherently degradable or $DT_{50,\ water}$ [60] 40d $DT_{50,sed}$ [180] 120d $DT_{50,\ soil}$ 120d	Not inherently degradable or $DT_{50,\ water}$ > 60d $DT_{50,sed}$ > 180d $DT_{50,\ soil}$ > 120d
B	BCF > 2000	BCF > 5000
T	NOEC < 0.01 mg/l or C or M (cat 1&2) or R (cat 1,2 &3) Long term exposure could cause damage to health (R48)	Not applicable