Screening exercise - Chemicals Legislation
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Directive 1999/45/EC

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Objectives of the Directive

establishes provisions for the

- classification,
- packaging &
- labelling

of **dangerous** preparations

- specific provisions for certain preparations not classified as dangerous under the DPD

Scope

applies to

- preparations which contain at least one dangerous substance (what a dangerous substance is, is defined in Article 2)

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- preparations which are considered dangerous within the meaning of Article
  - 5 (physical-chemical),
  - 6 (health) or
  - 7 (environment)

Outside Scope - I

- medical products for human or veterinary use (a.c.b. Dir 65/65/EEC)
- cosmetic products (a.c.b. Dir 76/768/EEC)
- waste (a.c.b. Dir 75/442/EEC & 78/319/EEC)
- foodstuffs & animal feeding stuffs
- preps containing radioactive substances (a.c.b. Dir 80/836/Euratom)
- medical devices which are invasive or used in direct physical contact with the human body

Outside Scope - II

- carriage of dangerous preparations by rail, road, inland waterway, sea or air
- preparations in transit (under customs supervisions) provided they don’t undergo any treatment or processing

Dangerous substances to be considered

- listed in Annex I to Dir 67/548/EEC
- listed in ELINCS (European List of Notified Chemical Substances)
- classified and labelled in accordance with (Dir 67/548/EEC)
  - Article 6 - provisionally self-classification by manufacturer / distributor / importer
  - Article 7 - full notification but not yet in ELINCS
  - Article 8 - reduced notification
  - Article 14 – follow-up information

Possibilities for Hazard Evaluation

- Analysis of the entire preparation (as placed on the market)
  - by the test methods set our for substances (Annex V to Dir 67/548/EEC) or comparable methods (91/414/EEC)
  - classification according to the criteria set out for substances (Annex VI to Directive 67/548/EEC)
- However: discourages animal testing
  - no tests for CMRs endpoints
  - environment – only tests for aquatic toxicity
- Conventional method (only health & environment)
- Account for human experience or studies
- Account for potentiation or antagonism

Classification provisions

Phys-chem	Article 5	Annex I
Human health	Article 6	Annex II Part A – CM Part B – GCLs
Environment	Article 7	Annex III Part A – CM Part B – GCLs

Phys-chem endpoints to be considered

- explosivity
- oxidising properties (includes organic peroxides)
- flammability

based on tests results or read-across with tested preparation of similar composition

Health hazard endpoints to be considered

- Acute Effects
  - acute lethal effects (acute toxicity)
  - non-lethal irreversible effects after a single exposure
  - corrosive effects, irritant effects
  - sensitising effects (contact and respiratory)
- Chronic Effects
  - severe effects after repeated or prolonged exposure
- Specific Effects on Human Health
  - carcinogenic effects
  - mutagenic effects
  - effects on reproduction

based on test results (except CMR!) or by the CM (Annex II Part A or B)

Conventional Method (CM) in general

- is a calculation method (for effects which are assumed to be additive) based on the classification of each substance
- concerns all health (Annex II) and environmental hazards (Annex III)
- applies to preparations containing one or more dangerous substances above a certain concentration limit (either GCLs – Annex II or III to DPD or SCLs in Annex I to DSD)

Conventional method (CM) principles

1. Determination of the quotient (P/L) between the percentage **P** of a substance and the GCL **L**.
2. GCL **L** depends on the substance and on the hazardous effect
3. Examples of GCLs for acute health effects
   - LT+ for the classification as very toxic 7%,
   - LT for the classification as toxic 1% and
   - LXn for the classification as harmful 0,1%,
4. unless individual concentration limits are specified in Annex I to Directive 67/548/EEC.

Classification of the substance	Classification of the preparation		
	T^+	T	Xn
T^+ with R26, R27, R28	$LT^+ \geq 7\%$	$1\% \leq LT \leq 7\%$	$0{,}1\% \leq LXn \leq 1\%$
T with R23, R24, R25		$LT \geq 25\%$	$3\% \leq LXn \leq 25\%$
Xn with R20, R21, R22			$LXn \geq 25\%$

Conventional method (CM) step by step approach 1

- All the values P/L of one hazard category are added.
- If the sum of the quotients is ≥ 1, the preparation has to be classified according to this property.

In the following, the example is given for acute toxicity

Conventional method – step by step approach 2

- For a preparation containing substances with acute lethal effects one has to determine if the preparation itself has to be classified as "very toxic" due to the substance(s) which is/are classified as T^+

  $\sum(\quad P_{T+} / L_{T+}) \geq 1 \quad \rightarrow \quad T^+$

- If this is not the case, it has to be determined if the preparation has to be classified as "toxic" due to the contents of very toxic and toxic substances.

  $\sum(\quad P_{T+} / L_T + P_T / L_T) \geq 1 \quad \rightarrow \quad T$

- If this is not the case either, it has to be calculated if the preparation has to be classified as "harmful" due to its contents of very toxic, toxic and harmful substances.

  $\sum(\quad P_{T+} / L_{Xn} + P_T / L_{Xn} + P_{Xn} / L_{Xn}) \geq 1 \quad \rightarrow \quad Xn$

Concentrations above which dangerous substances have to be taken into account

Danger Category	gaseous preparations	other preparations
	% vol/vol	% w/w
very toxic, toxic, CMR cat 1 & 2	≥ 0,02	≥ 0,1
harmful, irritant, sensitising CMR cat. 3	≥ 0,2	≥ 1
corrosive	≥ 0,02	≥ 1
dangerous for environment N		≥ 0,1
dangerous for environment ozone	≥ 0,1	≥ 0,1

Health hazards – additional remarks

- neither the preparation nor any of its constituents have been tested for a specific effect
  - no obligation to generate the data
  - preparation will not be classified for this effect.
- ranking of available information
  - validated human experience
  - animal experiments as far as accepted by the Directive
  - conventional method
- taking into account of effects such as potentiation or antagonism

Environmental endpoints to be considered

- Acute toxicity to aquatic environment to one or more of the following groups:
  - Fish
  - Aquatic invertebrates (usually *Daphnia spp.*)
  - Algae
- Ozone depleting substances

based on test results or by the conventional method (Annex III Part A or B)

Labelling - I

- Trade name of product
- Name, address, telephone
- Chemical components of the preparation:
  - Very toxic, toxic or harmful
  - Corrosive
  - Sensitizing
  - Carcinogenic, mutagenic
  - Reprotoxic

Labelling - II

- Symbols and indications of danger
- Risk and Safety phrases
- Quantity if sold to public
- Readable size, quality and horizontal

Confidentiality (Article 15)

- Only by direct application of producer / manufacturer / importer to the CA of a Member State
- Only for harmful substances not classified
  - as carcinogenic, mutagenic, reprotoxic, sensitizer

Specific Provisions

- not dangerous within the meaning of Article 5, 6 or 7, but may nevertheless present a specific hazard
  - Article 9 / Annex IV (child-resistant fastenings and tactile warnings)
  - Article 10 / Annex V (additional labelling provisions for certain preparations)
  - Article 14 (Safety Data Sheet)

Packaging / SDSs

- Packaging requirements
  - Quality and suitability of packaging
  - for public: tactile warnings
  - child-resistant fastenings
- Safety Data Sheets (Dir 91/155/EEC as amended)
  - for professional users
  - in electronic or paper form