Environmental hazard classification and labelling

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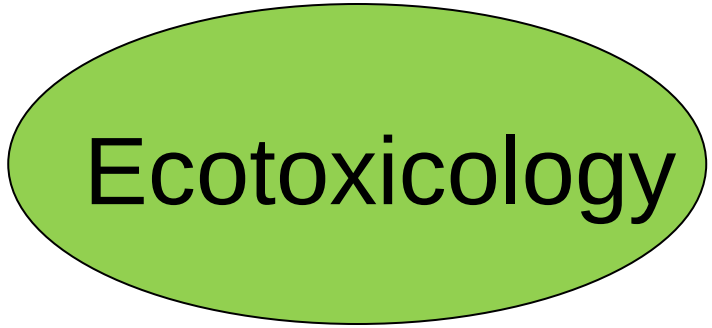
- Background and scope
- The classification scheme
- Criteria for env. hazard classification – substances
- Degradation and Bioaccumulation assessment for classification purposes
- Exercise – substance classification
- Criteria for env. hazard classification – mixtures
- Exercise – mixture classification
  (principle use of the Summation method)

Ecotoxicological concept

- Ecology
- Toxicology
- Environmental Chemistry



➢ Concerned with **adverse effects** of chemical and physical agents on living organisms, especially on populations and communities **within defined ecosystems**.

Environmental hazard classification – Define effects on **ecosystems** rather than on individuals within a species or population. E.g. Hazardous to the aquatci environment

➢ **Short-term (Acute)** and **long-term** adverse effects

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Example of an acute (and obvious) effect

Cyanide in spillage water from a goldmine in Rumania, 2000, caused severe fish death. Also rivers in Serbia were affected.

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Examples of observed long term toxic effects in the environment

- Industrial melanism of moths - 1850s Industrial revolution soot from coal burning

- Eggshell thinning in eagles and brown pelicans - 1950s DDT and organo-chlorines

➢ The classification scheme

- is principally concerned with the aquatic environmental compartment (which for most substances, the majority of data available addresses)

➢ This compartment is

- vulnerable
- receiving environment
- sensitive organisms

Scope

- The classification scheme covers both:
  - short term effects
  - long term effects

  to both

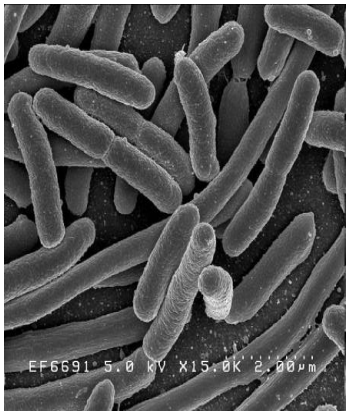
  - aquatic freshwaters
  - marine ecosystems

What about the other compartments?
(E.g. the terrestrial compartment)

- Terrestrial test organisms





Not covered in a hazard classification scheme yet, but many substances hazardous to aquatic ecosystem would also be hazardous to terrestrial ecosys-tems.

Hazardous to the Ozone Layer

Substances

- if the available evidence concerning its properties and its predicted or observed environmental fate and behavior indicate that it may present a danger to the structure and/or the functioning of the stratospheric ozone layer.

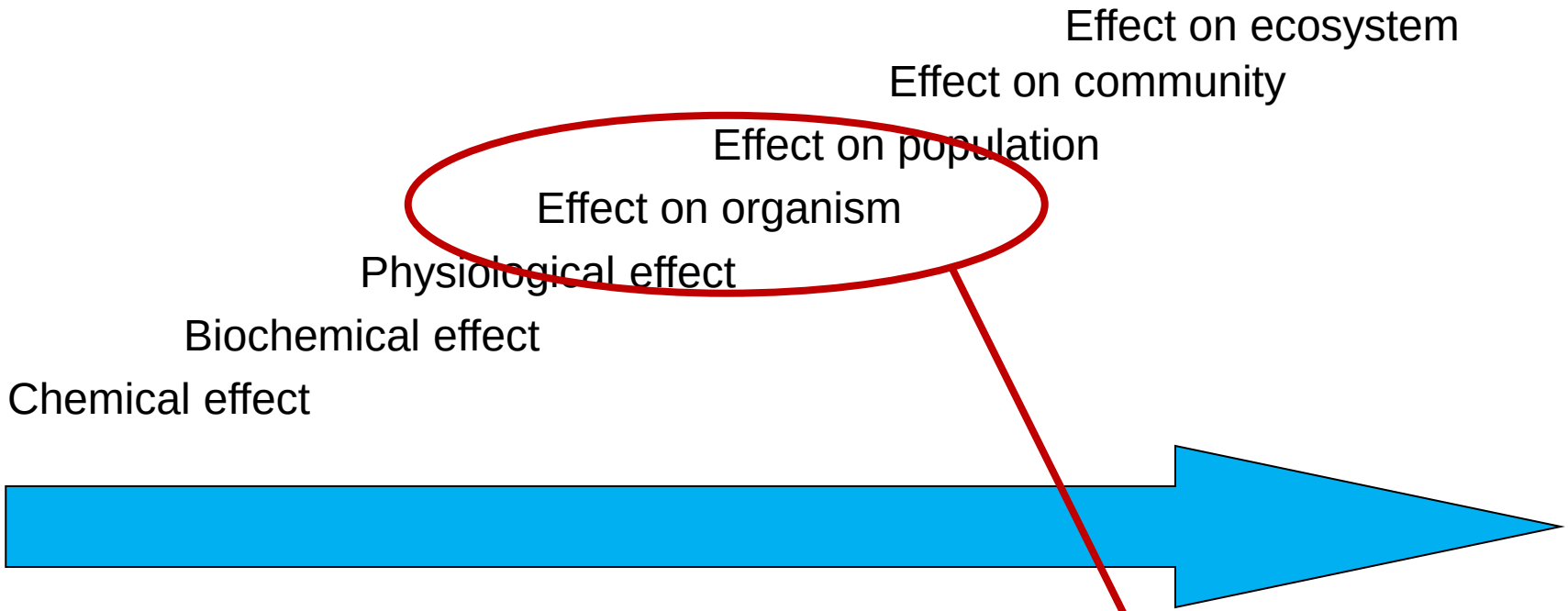
Mixtures

- Concentration limit of 0.1%

WARNING

H420: Harms public health and the environment by destroying ozone in the upper atmosphere

What effects can be observed?



- Increased ecological relevance
- Increased difficulty to relate to a specific chemical
- Increased time from disturbance to effect

pragmatic choice:
- controlled conditions
- low natural variance,
- short time frame
- easy to observe
- cheap
- comparable between substances

For aquatic hazard classification, toxicity data is normally needed on three trophic levels

Fish

Crustacean

Alge/aquatic plants

- The taxa chosen from three trophic levels represent the "base-set" of toxicity test data; a minimum data-set for a fully valid description of toxicity as part of aquatic hazard.

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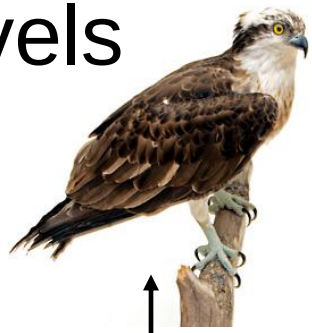
Food chain with different trophic levels

Top-consumers

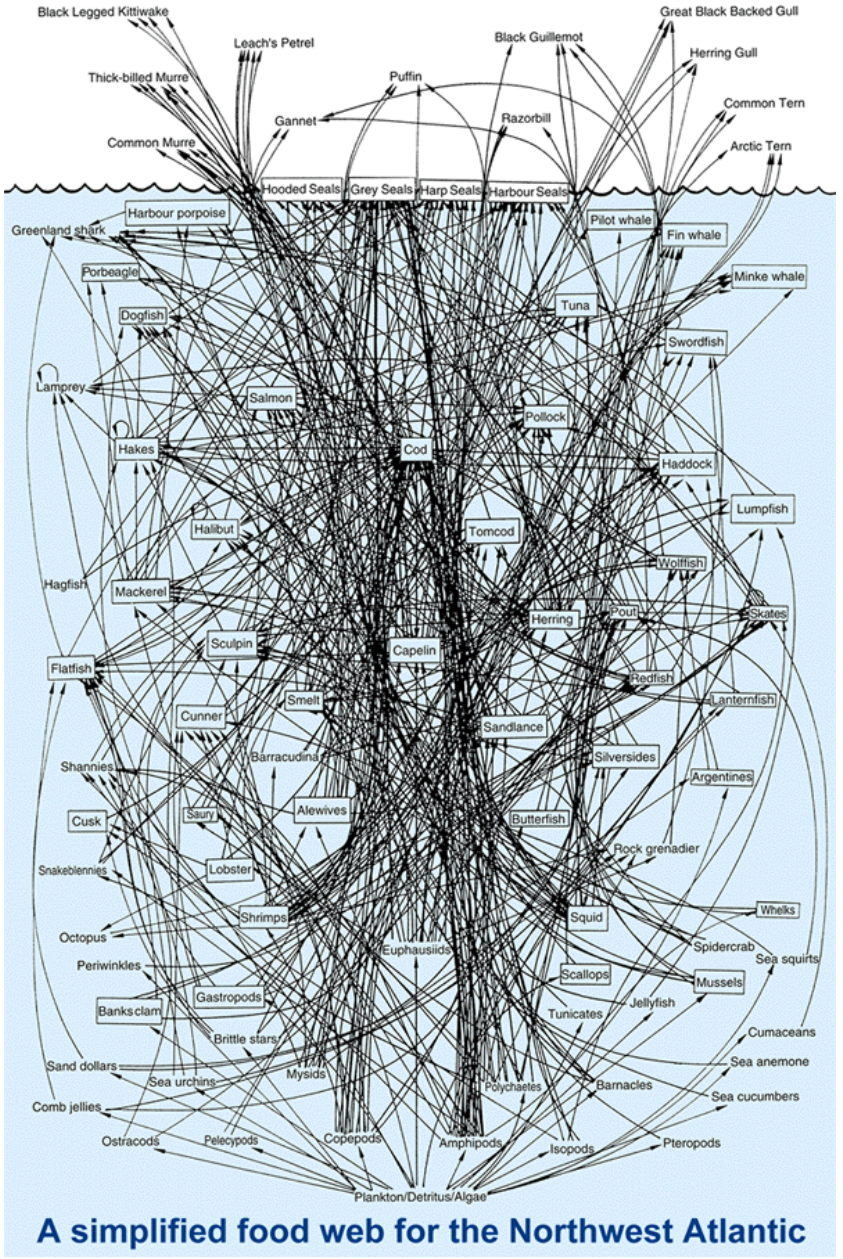


Secondary consumers

Primary consumers

Producers

Food web



A simplified food web for the Northwest Atlantic

Test methods for environmental toxicity and fate

- Test methods are highly standardized.
  - OECD test guidelines
  - EU test methods (Council regulation 440/2008)
  - ISO standards (CEN)
  - National: ASTM (USA), MITI (Japan), SIS (Sweden)
  - IOBC-guidelines and SETAC guidelines regarding arthropods

For aquatic hazard classification OECD Test Guidelines or equivalent, Ex.:

- **Physico-chemical properties:**
  - 105 (Water solubility);
  - 107 (n-octanol/water partition coefficient (Log K_{ow}))
  - 111 (Hydrolysis as function of pH - Abiotic degradation)
- **Aquatic toxicity:**
  - 201 (Algal Growth Inhibition);
  - 202 Part 1&2, 211 (*Daphnia* sp. Acute Immob. & Reproduction);
  - 203 (Fish, Acute Toxicity Test);
  - 210 (Fish Early Life Stage)
- **Degradation:**
  - 301A-F, 306, 310 (Ready biodegradability);
  - 309 (Aquatic simulation test)
- **Bioaccumulation:**
  - 305 (Bioconcentration factor in fish, BCF);

- Use of non testing methods -

- In absence of experimental data, valid non testing methods can be relied upon:
  - Read across from similar chemicals
  - Information from Chemical Structure - Structure-activity relationship (SAR)

Ex. provide predictions of acute toxicity by use of QSARs for:

– Non-electrolyte, non-electrophilic, and otherwise non-reactive organic substances.

e.g. hydrocarbons, alcohols, ketones and certain aliphatic chlorinated hydrocarbons and otherwise non-reactive substances

The classification and labelling schemes

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Classification categories for Hazardous to the aquatic environment

See GHS, Table 4.1.1

Hazard Class	Hazard Category
Hazardous to the aquatic environment	
• Short-term (acute) hazard	Acute 1 | Acute 2 * | Acute3 *
• Long-term (chronic) hazard	Chronic 1 | Chronic 2 | Chronic 3 + Chronic 4

NOTE!

Acute 1 to 3 + Chronic 1 to 3: The core classification system.

Chronic 4: 'Safety Net' classification when standard criteria are not met, but there is a concern.
Criteria: Not strictly defined, but one example: poorly soluble substances (< 1 mg/l) that are both

- not rapidly degradable and
- Bioaccumulative.

Short-term and **Long-term hazard:** are applied independently.

Classification categories for Hazardous to the aquatic environment

See GHS, Table 4.1.1

Hazard Class

Hazardous to the aquatic environment

- Short-term (acute) hazard
- Long-term (chronic) hazard

Hazard Category

'cut offs'
≤ 1 mg/l

Acute 1	**Acute 2 ***	**Acute3 ***		
Chronic 1	**Chronic 2**	**Chronic 3**	+	**Chronic 4**

Relevant concentrations in the environment

Sypply and use sector: ≤ 1 mg/l

Transport sector: ≤ 100 mg/l

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Labelling elements

- Acute (short-term) aquatic hazard - Categories Acute 1 to 3

	Acute 1	Acute 2	Acute 3
Pictogram		No Pictogram	No Pictogram
Signal word	Warning	No word	No word
Hazard Statement	H400: Very toxic to aquatic life	H401: Toxic to aquatic life	H402: Harmful to aquatic life

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Labelling elements

- Long-term aquatic hazard - Categories Chronic 1 to 3

	Chronic 1	Chronic 2	Chronic 3
Pictogram			No Pictogram
Signal word	Warning	No word	No word
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

Safety net Chronic 4 - H413: May cause long lasting harmful effects to aquatic life.

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Criteria for environmental hazard classification

-

substances

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Acute toxicity determines the short-term hazard

In principle

- Intrinsic property to be injurious in short-term exposure – (hours to days)
- Generally expressed:
  - LC_{50} (50% lethal conc.) or EC_{50} (50% effect conc.),

    e.g. immobilization of daphnids, or reduction in growth rate in algae

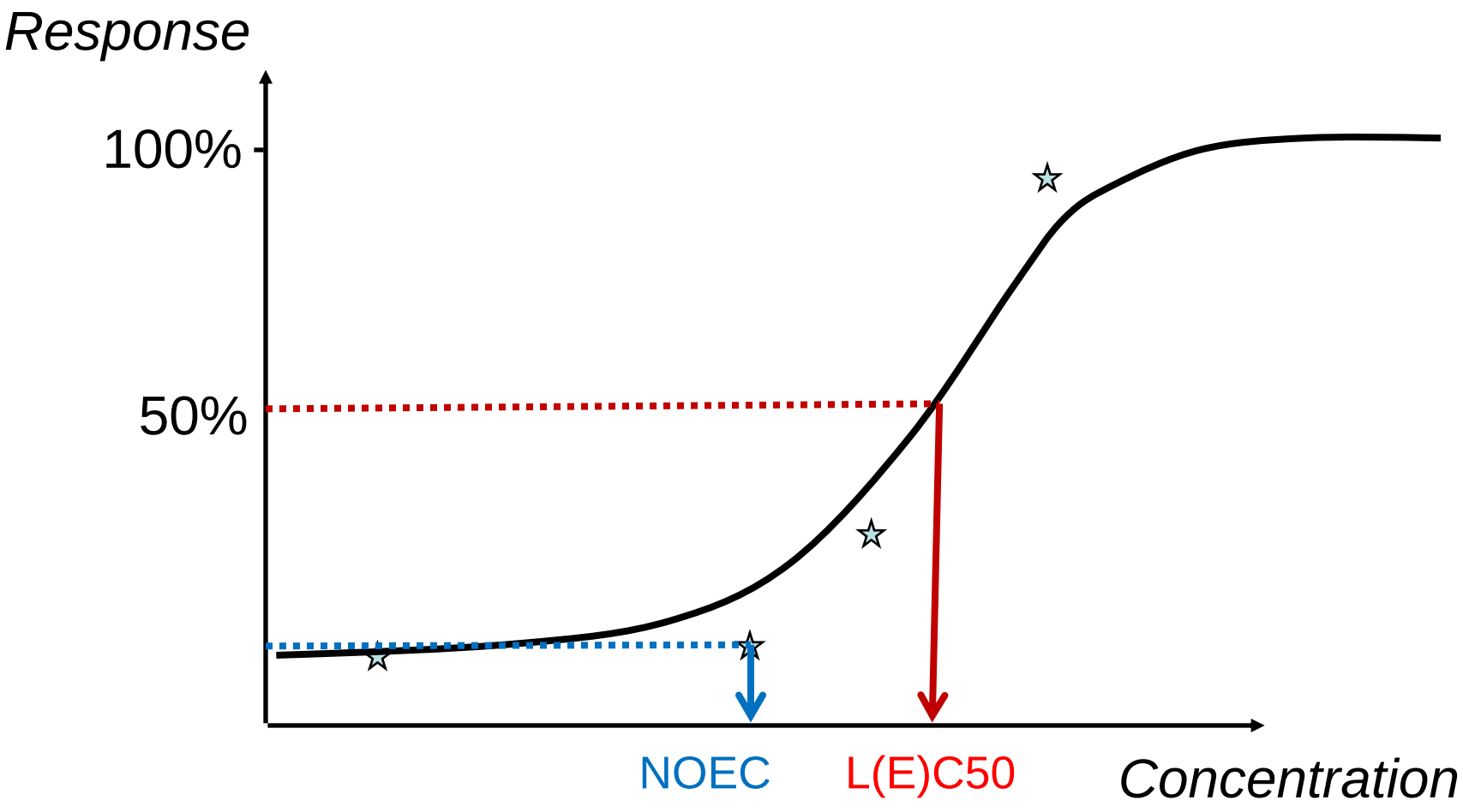
Chronic toxicity determines the long-term hazard

determined by

- Intrinsic property to be injurious during exposures which are determined in relation to the life-cycle of the organism – (days to weeks)
- Generally expressed in terms of:
  - NOEC, LOEC or ECx (Normally EC_{10})

    Sublethal endpoints e.g. Survival, growth and/or reproduction

Dose-response relationship



No Observed Effect Concentration

Concentration causing effect on 50% of test organisms

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Acute (short-term) aquatic hazard

Highest acute toxicity (lowest value) to
●Fish ● Crustacea or ● Aquatic plant ➢ Category

LC_{50} or EC_{50} (or IC_{50}) ≤1 mg/l	**Acute 1**
LC_{50} or EC_{50} (or IC_{50}) >1 to ≤10 mg/l	**Acute 2 ***
LC_{50} or EC_{50} (or IC_{50}) >10 to ≤100 mg/l	**Acute 3 ***

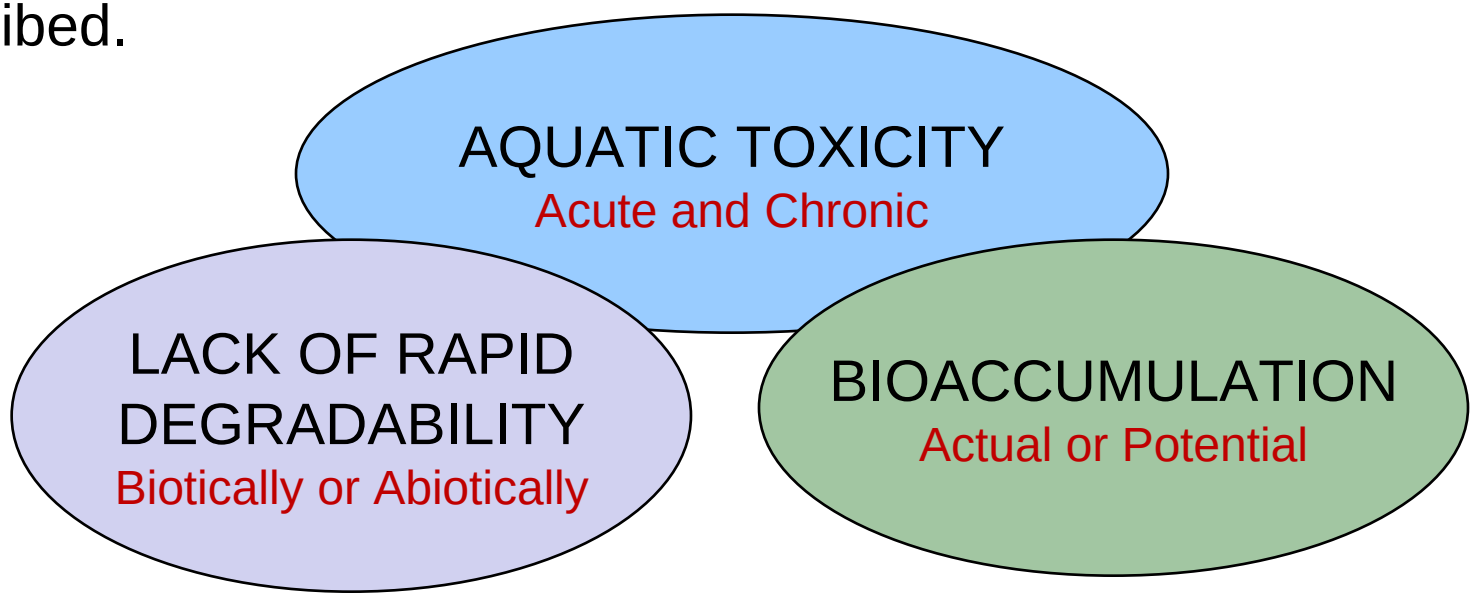
* Categories Acute 2 and 3 were mainly meant for transport of bulk-quantities and therefore normally not implemented for Supply & Use

Basic elements used for Long-term hazard

See GHS, Table 4.1.1

Chronic toxicity data are often expensive to generate and therefore generally less available than acute toxicity data.

- For practical reasons a limited set of specific properties (basic elements) has been selected through which the hazard can be best described.



Criteria for Long-term hazard

the "surrogate system"

Adequate chronic toxicity data available		In absence of adequate chronic toxicity data
Non-rapidly degradable (NRD) substance	**Rapidly degradable (RD) substances**	**ACUTE TOXICITY** **+** **NON-RAPIDLY DEGRADABLE** **and/or** **BIOACCUMULATIVE**
Category: **Chronic 1** NOEC or $EC_x \leq$ **0.1**	Category: **Chronic 1** NOEC or $EC_x \leq$ **0.01**	
Category: **Chronic 2** 0.1 < NOEC or $EC_x \leq$ **1**	Category: **Chronic 2** 0.01 < NOEC or $EC_x \leq$ **0.1**	
	Category: **Chronic 3** 0.1 < NOEC or $EC_x \leq$ **1**	

Regulatory acceptance based on relevant concentrations in the environment

Toxicity + degradation and/or bioaccumulation

A/C = 10 and 100

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Long-term hazard in absence of adequate chronic toxicity data

ACUTE TOXICITY TO FISH *CRUSTACEA* OR ALGAE

≤1 mg/l

+

NON-RAPIDLY DEGRADABLE

AND/OR

BIOACCUMULATIVE (measured or potential for bioaccumulation)

→ **CHRONIC 1**

ACUTE TOXICITY TO FISH *CRUSTACEA* OR ALGAE

> 1 to ≤10 mg/l

+

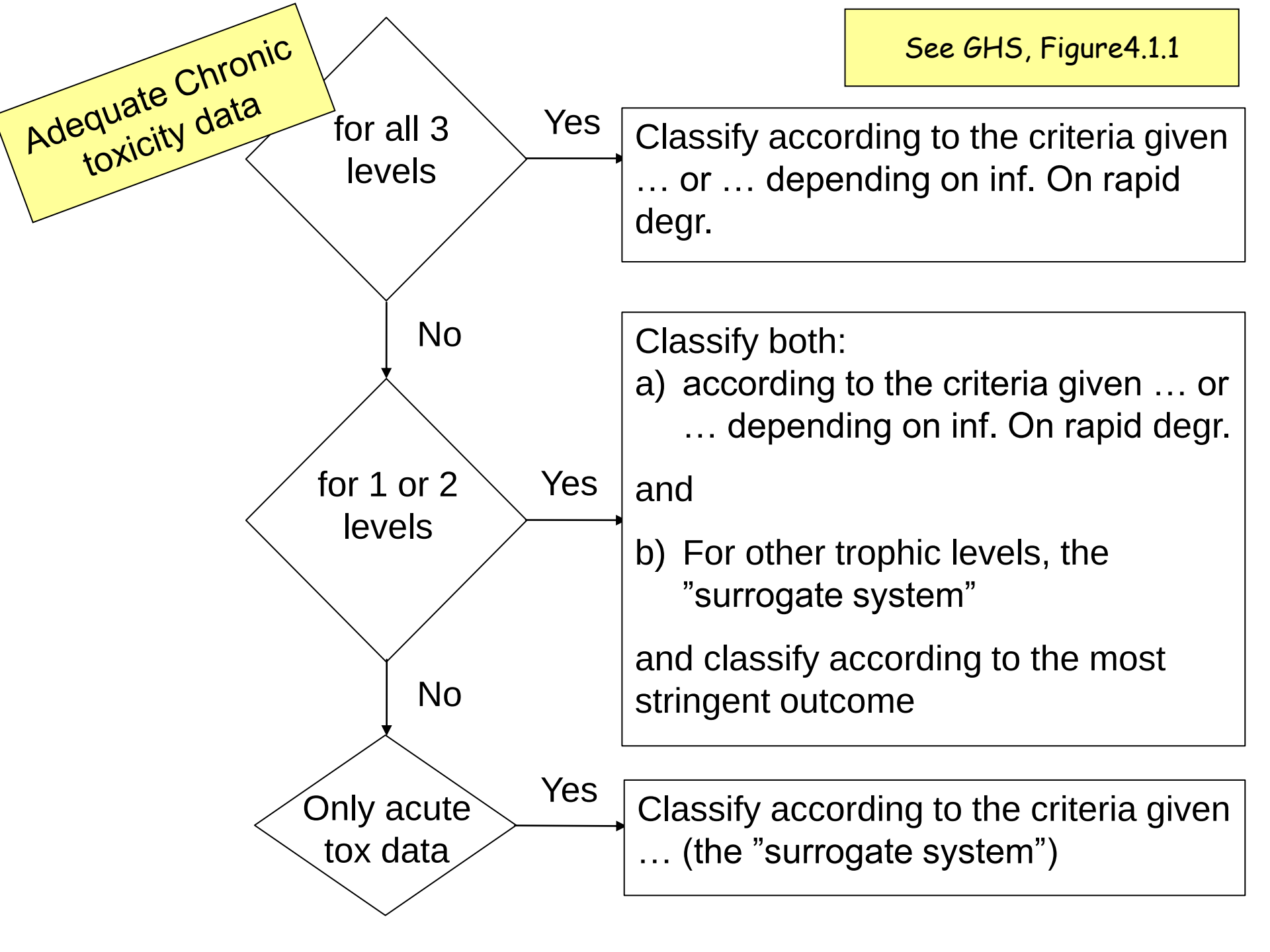
→ **CHRONIC 2**

ACUTE TOXICITY TO FISH *CRUSTACEA* OR ALGAE

> 10 to ≤100 mg/l

+

→ **CHRONIC 3**


See GHS, Figure4.1.1
Adequate Chronic toxicity data
for all 3 levels
Yes
Classify according to the criteria given … or … depending on inf. On rapid degr.
No
for 1 or 2 levels
Yes
Classify both:
a) according to the criteria given … or … depending on inf. On rapid degr.
and
b) For other trophic levels, the ”surrogate system”
and classify according to the most stringent outcome
No
Only acute tox data
Yes
Classify according to the criteria given … (the ”surrogate system”)

Criteria for Long-term hazard

<table>
<tr><th colspan="2">Adequate chronic toxicity data available</th><th rowspan="2">In absence of adequate chronic toxicity data</th></tr>
<tr><th>Non-rapidly degradable substances</th><th>Rapidly degradable substances (RD)</th></tr>
<tr><td>Category: Chronic 1
NOEC or $EC_x \leq 0.1$</td><td>Category: Chronic 1
NOEC or $EC_x \leq 0.01$</td><td rowspan="3">Category: Chronic 1-3

ACUTE TOXICITY
+
BIOACCUMULATIVE
and/or
LACK OF RAPID DEGRADATION</td></tr>
<tr><td>Category: Chronic 2
$0.1 < \text{NOEC or } EC_x \leq 1$</td><td>Category: Chronic 2
$0.01 < \text{NOEC or } EC_x \leq 0.1$</td></tr>
<tr><td></td><td>Category: Chronic 3
$0.1 < \text{NOEC or } EC_x \leq 1$</td></tr>
<tr><td colspan="3">Safety net classification Category: Chronic 4
When standard criteria are not met, but there is a concern. Not strictly defined criteria, but one example: poorly soluble substances (< 1 mg/l) that are not rapidly degradable and are bioaccumulative</td></tr>
</table>

M-factors must be set for highly toxic substances

See GHS, Note 2 to Table 4.1.1

Hazard Class	Hazard Category
Hazardous to the aquatic environment	
• Short-term (acute) hazard	Acute 1 | Acute 2 * | Acute3 *
• Long-term (chronic) hazard	Chronic 1 | Chronic 2 | Chronic 3 + Chronic 4

- 'M-factor' means a multiplying factor. It is applied to substance as part of the substance classification as Categories Acute 1 and/or Chronic 1.
- It is used to derive by the summation method the classification of a mixture in which the substance is present.

Setting M-factors for highly toxic substances
(Acute 1 and Chronic 1)

Acute toxicity	M factor
$L(E)C_{50}$ value (mg/l)	
$0.1 < L(E)C_{50} \leq 1$	1
$0.01 < L(E)C_{50} \leq 0.1$	10
$0.001 < L(E)C_{50} \leq 0.01$	100
$0.0001 < L(E)C_{50} \leq 0.001$	1000
$0.00001 < L(E)C_{50} \leq 0.0001$	10000
(continue in factor 10 intervals)	

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Setting M-factors for highly toxic substances
(Acute 1 and Chronic 1)

Acute toxicity	M factor	Chronic toxicity	M factor	
$L(E)C_{50}$ value (mg/l)		NOEC value (mg/l)	NRD[a] components	RD[b] components
$0.1 < L(E)C_{50} \leq 1$	1	$0.01 < NOEC \leq 0.1$	1	-
$0.01 < L(E)C_{50} \leq 0.1$	10	$0.001 < NOEC \leq 0.01$	10	1
$0.001 < L(E)C_{50} \leq 0.01$	100	$0.0001 < NOEC \leq 0.001$	100	10
$0.0001 < L(E)C_{50} \leq 0.001$	1000	$0.00001 < NOEC \leq 0.0001$	1000	100
$0.00001 < L(E)C_{50} \leq 0.0001$	10000	$0.000001 < NOEC \leq 0.00001$	10000	1000
(continue in factor 10 intervals)		(continue in factor 10 intervals)		

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Degradation
and
Bioaccumulation
assessment
for classification purposes

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Rapid degradation

- biotic or abiotic
  - degradation of organic substances; or
  - transformation of inorganic substances
- Either
  - full mineralisation or
  - primary degradation / transformation to non hazardous species ($t_{½}$ < 16 days)

Rapid degradation - Decision scheme

GHS Annex 9
A9.4.4

A substance is considered to be **not** rapidly degradable **unless** at least one of the following is fulfilled:

a) Ultimately degraded in biodegradation screening test (≥ 60/70% in 28days);

b) Ultimately degraded in a surface water simulation test ($t_{½}$ < 16days);

c) Primarily degraded (or transformed) to non hazardous species ($t_{½}$ < 16 d)

When these **preferred data** types are **not available** rapid degradation may be demonstrated if one of the following criteria is justified:

a) Ultimately degraded in an aquatic sediment or soil simulation test;

b) If only BOD5 and COD available, then if BOD5/COD ≥ 0.5;

c) A weight of evidence approach based on read-across

If none of the above types of data are available then the substance is considered as **not** rapidly degradable.

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Biodegradation Screening test vs. Simulation tests

Screening tests

- **Tests conducted in the laboratory with relatively high concentrations of test substance (2-100 mg/l).**
- All organic substances that degrade to a level higher than the pass level in a standard ready biodegradability test (OECD 301 A-F, 306 and 310 or similar test) should be considered rapidly degradable.

- ≥ 70 %, 28-day test, based on dissolved organic carbon

  ≥ 60 %, 28 day test, O_2-depletion or CO_2-generation

Biodegradation Screening test vs. Simulation tests

Simulation tests

- **Tests conducted in the laboratory, but simulating environmental conditions and employing natural samples as inoculum.**
- An environmental simulation test would normally be conducted according to one or more of the standard procedures of OECD Guidelines:
  - 307 (soil),
  - 308 (aquatic sediment), or
  - 309 (water)

Biotic vs. abiotic degradation

Hydrolisys (abiotic degradation)

- Data on hydrolysis might be considered for classification purposes to measure the longest half-life t½ determined within the pH range 4 - 9.
- E.g. OECD 111.

Degradation data not used for classification

- Inherent biodegradability (e.g. OECD 302)
- Sewage treatment plant (STP) simulation tests (e.g. OECD 303)
- Anaerobic degradation data
- Field investigations
- Monitoring data

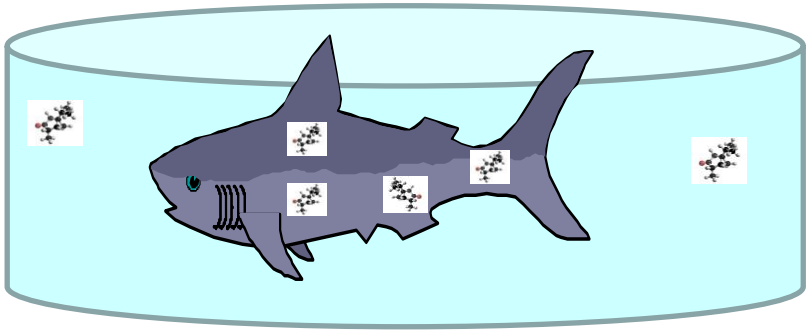
- Photochemical degradation
- Volatilisation

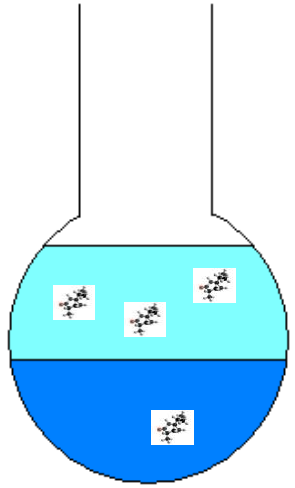
Bioaccumulation

Def.: The net result of uptake, transformation and elimination of a substance in an organism

- Generally expressed in terms of:

- Bioconcentration factor (BCF ≥ 500),
  (The ratio between the conc. in biota and the conc. in surrounding medium, pref. whole fish/water, and
- in absence of BCF, the Octanol-water-partitioning coefficient (log Kow ≥ 4)





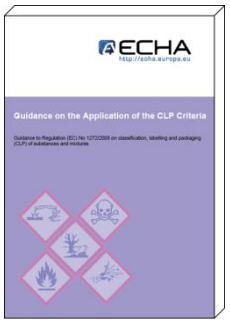
ECHA guidance documents

➢ Introductory Guidance on the CLP Regulation

- Basic guidance for inexperienced classifiers and managers;

Explains the system (roles and obligations) and why we have it.

➢ Guidance on the Application of the CLP Criteria



- Detailed guidance “for experts”;
- On the application of the CLP criteria for physical, health and environmental hazards.

Enable industry to self-classify chemicals and to provide appropriate hazard communication information to the target populations.

Guidance on the Application of the CLP Criteria

- Detailed guidance “for experts” -

PART 1: GENERAL PRINCIPLES FOR CLASSIF. AND LABELL.

PART 2: PHYSICAL HAZARDS

PART 3: HEALTH HAZARDS

PART 4: ENVIRONMENTAL HAZARDS

PART 5: ADDITIONAL HAZARDS

ANNEX I: AQUATIC TOXICITY

ANNEX II: RAPID DEGRADATION

ANNEX III: BIOACCUMULATION

ANNEX IV: METALS AND INORGANIC METAL COMPOUNDS

See GHS, Annex 9, Ch. 7

ANNEX V: COLLECTION OF INTERNET LINKS FOR THE USERS OF THE GUIDANCE

ANNEX VI: BACKGROUND TO GUIDANCE FOR SETTING SCLs FOR REPRODUCTIVE TOXICITY

Criteria for environmental hazard classification

-

mixtures

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Substance ingredients

- It is important to get a clear picture on which substances are contained in a mixture.
- Basic information would include: (i) the substance identity, (ii) its classification (iii) any applied M-factor, and (iv) concentration in the mixture.
- Where an ingredient in a mixture is itself a mixture, it is genereally necessary to get information on the ingredient substances of the first mixture.

NOTE! Further dialogue with the supplier may be necessary to obtain additional information.

Suppliers in a supply chain shall cooperate to meet the requirements for classification, labelling and packaging – CLP, Art. 4.9

Testing of mixtures must be avoided !

- Testing of mixtures is highly complex. Both in conduct of the test, and in interpretation of data.

- Alternative approaches such as the summation method, should be considered, particularly where testing would involve the use of vertebrate animals such as fish.

NOTE! *Degradability* and *bioaccumulation* tests for mixtures are not used as they are usually difficult to interpret, and such tests may be meaningful only for single substances.

Classification of mixtures

- The approach used is dependent upon the type of information available for the mixture itself and for its components.
  - Criteria as for substances – Using data on the mixture itself;
  - Bridging principles - Data on similar tested mixtures; or
  - The Summation method – Classification based on individual ingredients.

However: Testing of mixtures must be avoided !

It is generally the summation of the quantities of the hazardous components that should be used to determine a specific hazard classification of the mixture.

Summation method

- Short-term (acute) hazard:

Summation of components:	Mixture is classified as:
∑(Acute 1 x M) ≥ 25 %	Acute 1

- Long-term aquatic hazard (**a stepwise procedure**):

Summation of components:	Mixture is classified as:
∑(Chronic 1 x M) ≥ 25 %	Chronic 1
∑(Chronic 1 x M x 10) + ∑(Chronic 2) ≥ 25 %	Chronic 2
∑(Chronic 1 x M x 100) + ∑(Chronic 2 x 10) + ∑(Chronic 3) ≥ 25 %	Chronic 3
∑(Chronic 1) + ∑(Chronic 2) + ∑(Chronic 3) + ∑(Chronic 4) ≥ 25 %	Chronic 4 (Safety-net)

Exercise

–

mixture classification

(principle use of the Summation method)

Summation method, example on Long term effects step 1:

Mixture classified as Category Chronic 1 if
∑(Chronic Category 1 x M) ≥ 25%

Ingr. A	Ingr. B	Ingr. C
1%	10%	10%

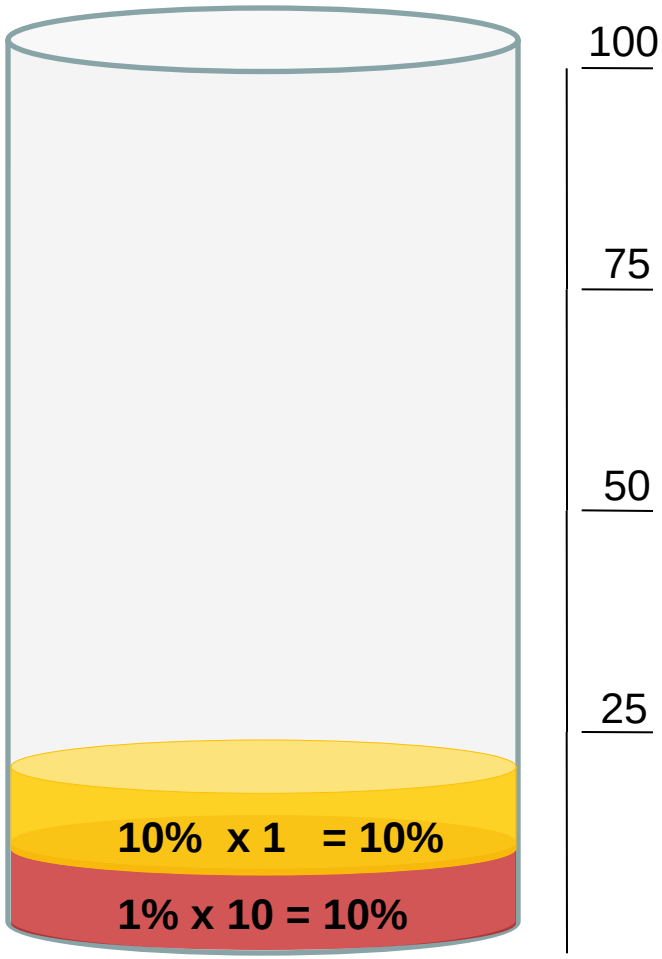
Chronic 3

Chronic 2

Chronic 1, M1

Chronic 1, M10

Chronic 1, M100

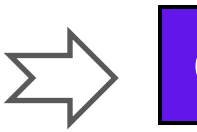


10% + 10% = 20%, which is < 25%.
Hence, mixture not classified as Chronic 1.

Summation method, example on Long term effects step 2:

Mixture classified as Category Chronic 2 if
∑(Category Chronic 1 x M x 10) + ∑(Category Chronic 2) ≥ 25%

Ingr. A	Ingr. B	Ingr. C
1%	10%	10%



CHRONIC 2

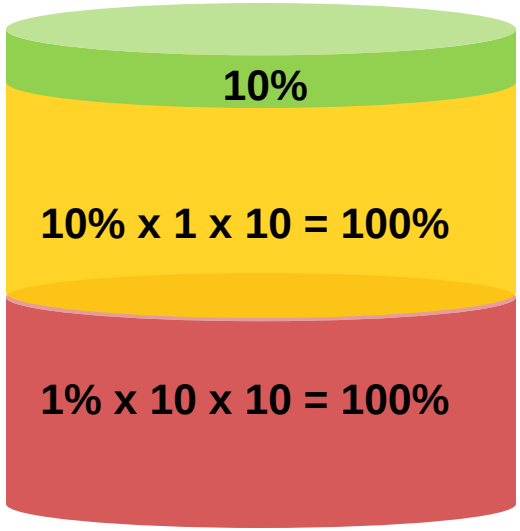
Chronic 3

Chronic 2

Chronic 1, M1

Chronic 1, M10

Chronic 1, M100



100% + 100% + 10% = 210%, which is ≥ 25%.
Hence, mixture classified as Chronic 2.

Thank You
for Your Attention