Framework of the Risk Assessment of chemicals
Hazard Assessment and Risk Assessment for the terrestrial compartment in the EU legislation

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The European Chemicals Bureau provides technical and scientific support for implementation of certain EU legislation on dangerous chemicals, such as Directives 67/548/EEC, 93/67/EEC, 98/8/EC, 91/414/EEC, Regulations 793/93, 2455/92 and several other legal provisions.
Chemical Safety

- Testing methods - Implementation and harmonisation
- Classification and Labeling of substances
- Risk assessment of substances
- Co-ordination of EU notification scheme and risk assessment for new chemical substances
- Scientific and technical issues within the approval of active substances in biocidal products
- Information exchange on import and export of dangerous substances
Elements of chemical control

- Data collection 67/548/EEC and 793/93
- Classification and labelling 67/548 and 88/379/EEC
- Risk assessment 67/548/EEC, 793/93 and
- Risk management: worker protection directives, emission control directives, water framework directive
Tools to implement Regulation 793/93

1. Data Collection Step  HEDSET, IUCLID
2. Priority Setting Step  EURAM
3. Risk Assessment Step  TGD - RA, EUSES
4. Risk Reduction Step  TGD - RR
Protecting People and the Environment from Dangerous Chemicals

RISK MANAGEMENT FOR HUMANS AND THE ENVIRONMENT

RISK ASSESSMENT

CLASSIFICATION AND LABELING

HAZARD IDENTIFICATION AND ASSESSMENT

DETERMINATION OF HAZARDOUS PROPERTIES OF CHEMICALS

TESTING METHODS
New chemicals: who is doing what?

- **Industry**: submission of a technical dossier and proposals for classification and labelling (C & L), including recommended precautions relating to safety.
- **Member States**: preparation of dossiers/risk assessments
- **Commission**: policy co-ordination
- **ECB**: co-ordination of technical work and exchange of information among Competent Authorities (CAs)
New chemicals: base set

- Identity: chemical name, formulae, etc.
- Quantity, functions and applications
- Precautionary /emergency measures
- Physical properties
- Chemical properties
- Toxicological properties
- Ecotoxicological properties
- Methods for rendering the substance harmless
Data requirements

**ANNEX VIIa: BASE SET**

1. Identity data, methods of analysis
2. Quantity, functions, applications
3. Precautionary measures, emergency measures
4. Physical properties
5. Chemical properties
6. Toxicological properties:
   a. acute toxicity (2 routes)
   b. skin/eye irritation
   c. sensitization
   d. subacute toxicity
   e. genotoxicity (2 tests)
7. Ecotoxicological properties
   a. acute toxicity (algae, fish, Daphnia)
   b. inhibition bacteria
   c. ready biodegradability
   d. hydrolysis
8. Methods rendering the substance harmless

**ANNEX VIIb**

- Base set minus:
  - 4
  - 5 (partly)
  - 6b,c,d,e
  - 7a-d
  - 8

**ANNEX VIIc**

- Base set minus:
  - 4 (partly)
  - 5
  - 6d
  - 1 genotox test
  - 7a,b,c
  - 8

**ANNEX VIII**

**ANNEX VIIIa**

- Base set plus:
  - Reproductive toxicity
  - Subchronic/chronic toxicity
  - Extended genotoxicity
  - Toxicokinetics
  - Chronic ecotoxicity
  - Terrestrial ecotoxicity
  - Extended fate tests

**ANNEX VIIIb**

- Other tests considered necessary for a full risk assessment

**ANNEX VIIIc**

- 0.1 - 1.0
  - Base set minus:
    - 4
    - 5 (partly)
    - 6d
    - 1 genotox test
    - 7a,b,c
    - 8

- 1.0 - 100
  - Base set minus:
    - 4
    - 5 (partly)
    - 6d
    - 1 genotox test
    - 7a,b,c
    - 8

- 100 - 1000
  - Base set minus:
    - 4
    - 5 (partly)
    - 6d
    - 1 genotox test
    - 7a,b,c
    - 8

- 1000
  - Base set minus:
    - 4
    - 5 (partly)
    - 6d
    - 1 genotox test
    - 7a,b,c
    - 8
Tools to implement Regulation 793/93

1. Data Collection Step      HEDSET, IUCLID
### Data availability in IUCLID (ECB)

<table>
<thead>
<tr>
<th>Exposure information</th>
<th>Availability (%)</th>
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<tbody>
<tr>
<td>Boiling point</td>
<td>69</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>61</td>
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<tr>
<td>Log Kow</td>
<td>58</td>
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<tr>
<td>Water solubility</td>
<td>76</td>
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<tr>
<td>Biodegradation</td>
<td>61</td>
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<tr>
<td>Bioconcentration factor</td>
<td>30</td>
</tr>
<tr>
<td>Ecotoxicity data</td>
<td>Availability (%)</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>LC50 fish</td>
<td>68</td>
</tr>
<tr>
<td>EC50 Daphnia</td>
<td>55</td>
</tr>
<tr>
<td>EC50 algae</td>
<td>46</td>
</tr>
<tr>
<td>EC50 microorganisms</td>
<td>57</td>
</tr>
<tr>
<td>NOEC fish</td>
<td>14</td>
</tr>
<tr>
<td>NOEC Daphnia</td>
<td>18</td>
</tr>
<tr>
<td>LC50 soil-dwelling organism</td>
<td>30</td>
</tr>
<tr>
<td>LC50 plants</td>
<td>32</td>
</tr>
</tbody>
</table>
Tools to implement Regulation 793/93

1. Data Collection Step     HEDSET, IUCLID
2. Priority Setting Step     EURAM
Priority Setting Existing Substances

- > 100,000 EINECS substances
- > 2000 HPVCs
- 140 Priority Substances
Priority lists

- 1st list 25 May 1994: 42 substances
- 2nd list 27 September 1995: 36 substances
- 3rd list 27 January 1997: 32 substances
- 4th list in 2000: 30 substances
Priority lists: factors which should be taken into account

- the effects of the substance to man or the environment;
- the exposure of man or the environment to the substance;
- the lack of data on the effects of the substance on man and the environment;
- work already carried out in other fora;
- other Community legislation and/or programmes relating to dangerous substances.
Framework of the Risk Assessment

Hazard Assessment and Risk Assessment for the terrestrial compartment in the EU legislation
Principles for risk assessment

- Regulation 1488/94 describes the general principles for risk assessment for man and the environment:
  - definitions
  - endpoints of the assessment
  - PEC/PNEC and MOS
  - possible conclusions
Principles for risk assessment

Detailed procedures for risk assessment are given in the Technical Guidance Documents (TGD):

- man
- environment
- QSARs
- emission scenario documents

TECHNICAL GUIDANCE DOCUMENT IN SUPPORT OF COMMISSION DIRECTIVE 93/67/EEC ON RISK ASSESSMENT FOR NEW NOTIFIED SUBSTANCES AND COMMISSION REGULATION (EC) No 1488/94 ON RISK ASSESSMENT FOR EXISTING SUBSTANCES

PART I
Protection targets

• Environment
  – Aquatic ecosystem
  – Terrestrial ecosystem
  – Sediment ecosystem
  – Predators (through worms and fish)
  – Micro-organisms in STP
  – Atmosphere

• Human
  – Direct at the workplace
  – Direct through use of consumer products
  – Indirectly via the environment
Basic framework of risk management

- Hazard identification
- Exposure assessment
- Effects assessment
- Risk characterization
  - Risk classification
  - Risk benefit analyses
  - Risk reduction
  - Monitoring
**General decision scheme**

1. If PEC/PNEC > 1, then:
   - NO: no need for further testing or risk reduction
   - YES: can further info lower PEC/PNEC?

2. If can further info lower PEC/PNEC? is NO, then:
   - NO: risk reduction measures
   - YES: further testing to lower PEC or PNEC
Basic principle

PEC / PNEC

PEC = Predicted Environmental Concentration

PNEC = Predicted No Effect Concentration

• Attempts to protect the function of the ecosystem be ensuring the survival of species in the specific ecosystem.

• Precautionary approach is built in by the use of conservative extrapolations both for exposure and effects.

• Use of relevant site specific data for refine the model-calculations monitoring data and measure for occurrence (PEC)
Risk Assessment for the Terrestrial Environment

Compartments considered (TGD)

- Soil
- Atmosphere
- Birds and mammals as secondary poisoning

Exposure routes

- Soil dwelling organisms
- Atmospheric deposition and exposure through air
- Exposure via food
RISK ASSESSMENT FOR THE TERRESTRIAL ENVIRONMENT

- TGD of new and Existing Chemicals

- Recommendations for RA of
  - Pesticides
  - Veterinary products
  - Biocides

- Toxicity data (microorganisms, earthworms, and plants) and secondary poisoning

- Full set of taxonomic groups (mammals, birds, bees, non-target arthropods, earthworms, and microorganisms)
HAZARD
FOR THE TERRESTRIAL ENVIRONMENT

Identification: Classification & labeling Directive 67/548/EEC

- Symbol of hazard
- Set of risk (“R”) phrases
- Set of Safety (“S”) phrases

Classification criteria [http://ecb.jrc.it/classification-labelling/](http://ecb.jrc.it/classification-labelling/) for the terrestrial environment under development within GHS !!!

R50 Very toxic to aquatic organisms
R51 Toxic to aquatic organisms
R52 Harmful to aquatic organisms
R53 May cause long term effects in the aquatic environment
R54 Toxic to flora
R55 Toxic to fauna
R56 Toxic to soil organisms
R57 Toxic to bees
R58 May cause long term effects in the environment
R59 Dangerous for the ozone layer

S60 This material and its container must be disposed of as hazardous waste
S61 Avoid release to the environment. Refer to special instructions/Safety data sheet
HAZARD
FOR THE TERRESTRIAL ENVIRONMENT

Quantification

Setting environmental quality standards or criteria:

• Aquatic: agreement to estimate safe concentrations

• Terrestrial: No EU harmonized soil quality criteria

*German; Dutch; Swedish; Spanish; others (US-EPA)

EU Scientific Committee CSTEE opinion on “The available scientific approaches to assess the potential effects and risk of chemicals on terrestrial ecosystems”

<http://europa.eu.int/comm/food/fs/sc/sct/out83_en.pdf>
Revised Technical Guidance Documents: Environmental Effects (continuation)

- Terrestrial compartment
  - Calculation of PNEC using statistical extrapolation
- Secondary poisoning
  - Calculation of the predicted no-effect concentration
  - Calculation of predicted environmental concentration in food
  - Assessment of secondary poisoning
  - Assessment of secondary poisoning via the terrestrial food chain
Revised Technical Guidance Documents: Testing Strategies

• Refinement of PEC
  – Degradation testing strategy for the aquatic compartment
• Refinement of PNEC: strategy for further testing
  – Aquatic compartment
  – Soil compartment
• Examples of assays suitable for further testing for soils and sediment organisms