The Precautionary Principle, under the HMCS, in light of increasing data availability

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Outline

• The Precautionary Principle
• Examples of application
• Increase in availability of data
• The future for chemical regulation
• Conclusions
History of Precautionary Principle

- **Sweden**: first legal use: Swedish Environmental Protection Act (1969).Introduced reversed burden of proof
- **West Germany**: *Vorsorgungsprinzip*, “cautionary principle”. Emerged from Social/Liberal Democrat election in 1969
- **Europe**: discussed in 1982, at World Charter for Nature
- **North Sea**: unifying principle for regulating discharge of hazardous material into the North Sea since 1980s
- **Maastricht Treaty**: adoption of the principle in the Treaty of the European Union, 1992
The Precautionary Principle

Rio Summit Declaration (1992):
"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."
Application of The Principle

Communication from the European Commission on the precautionary principle, COM/2000/0001

“... should be considered within a structured approach to the analysis of risk”

“...is part of risk management, where scientific uncertainty precludes a full assessment of the risk”
Application of The Principle

Communication states measures must be:

• proportional to chosen level of protection;
• non-discriminatory in their application;
• consistent with similar measures already taken;
• based on assessment of costs and benefits;
• subject to review in light of new scientific data;
• assign responsibility for producing scientific evidence
Application of The Principle

Ragnar Lofstedt (ChemicalWatch, Apr 2014):

• Precautionary Principle was never intended to justify arbitrary decisions

• It should be based on the strongest possible scientific evaluation

In actuality, legislative instruments redefine the principle in the context of each new law.
Harmonised Mandatory Control Scheme

- Pre-screening
- HOCNF
- HMCS
- CHARM
- Minimum Data sets
Company Details

Product 3
Synopsis of information relating to the component(s) in the formulation which is/are responsible for the product's section based hazard quotients

<table>
<thead>
<tr>
<th>Platform Type</th>
<th>Named Sub-Algorithm</th>
<th>HQ</th>
<th>Does a surfactant drive the worst case HQ? (Yes/No) and surfactant type if &quot;Yes&quot;</th>
<th>Percentage of component in formulation</th>
<th>Biodegradation Result</th>
<th>Days taken to reach the max % bio-degradation</th>
<th>Biodegradation Protocol</th>
<th>Min Log Pow Or Koc, Protocol, Org. carbon content of test sediment</th>
<th>Dosage (ppm)</th>
<th>Worst case aquatic tox test</th>
<th>Number of aquatic tox tests</th>
<th>Sediment Reworker (Left blank if no result)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oil</td>
<td>Standard Production Compound</td>
<td>8.810E-04</td>
<td>No</td>
<td>N/A</td>
<td>98.00</td>
<td>18</td>
<td>28</td>
<td>OECD 301D</td>
<td>2.9</td>
<td>10</td>
<td>123</td>
<td>3</td>
</tr>
</tbody>
</table>

Product Warnings - Left blank if none apply:
The Product contains one or more components that are deemed by precautionary principle to be candidates for substitution

Yes

Version Number: 4
DTI Number: 000000001190
Expiry date: 31/12/2006

Product verified by: MIKE TOLHURST
Signature: Mike Tolhurst
Pre-screening

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Pre-screening

EU REACH Reg. check

REACH Annex IV/V PLONOR?

OSPAR Priority Lists

Inorganic?

Biodeg < 20% in 28d

2 out of 3 rule
Biodeg < 60% in 28d
Bioacc BCF >100
Pow ≥3 & MolWt <700
Toxicity L(E)C50 < 10mg/L

SUBSTITUTION
Expected outcome from Pre-screening

- **PLONOR? 30%**
  - Yes: Expert judgement
  - No: Annex 2? 2%

- **Annex 2? 2%**
  - Yes: Inorganic? 6% (rebrands) 20% (products)
  - No: Biodegradation <20%? 31%

- **Inorganic? 6% (rebrands) 20% (products)**
  - Yes: LC/EC\(_{50}\) <1mg/l?
  - No: Biodegradation <20%? 31%

- **Biodegradation <20%? 31%**
  - Yes: 2 of 3 criteria:
    1. Biodegradation: <60 or 70% 10%
    2. Bioaccumulation: \(\log P_{ow} \geq 3\) or \(BCF > 100\) (considering mwt.)
    3. Toxicity: LC/EC\(_{50}\) < 10mg/l
  - No: Permission

- **LC/EC\(_{50}\) <1mg/l?**
  - Yes: Is substitute available?
  - No: A. Permission

- **Is substitute available?**
  - Yes: B. Substitution
  - No: D. Refusal

- **Permission**
  - Yes: Ranking CHARM 19%

- **Expert judgement**
  - Yes: A. Permission
  - No: D. Refusal

Source: Cefas
Pre-Screening

- Hazard based assessment
- Tries to align with other legislation (EU REACH)
- Does not consider exposure/probability
- Can lead to unnecessary controls on substances or exceptions to the process

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PLONOR - Example: Disodium tetraborate

- OIC 15/4/3 – Norway: listed on REACH Candidate List of SVHCs, due to reprotoxic properties
- PLONOR criteria clear – C (cat 1 & 2), M (cat 1 & 2) or R (cat 1, 2 & 3) should not be on list
- Borate and sodium ions are constituents of seawater; argument raised in OIC 11/03/08
- OIC 2011 Summary Record, OIC noted: “PLONOR criteria referred to marine environment not human health, therefore naturally occurring substances in seawater should be retained on the PLONOR List...“
PLONOR

• PLONOR List vs REACH Annex IV & Annex V
  Different drivers for each list

• REACH SVHC Candidate List
  Shouldn’t be driver for non-PLONOR

• REACH Authorisation
  Will effectively ban uses that are not Authorised, similar to OSPAR priority list

• REACH Restriction
  Will prohibit applications where safe use not possible, may include Offshore use
Biodegradation

• OECD 306 Test: a biodegradation lottery, “designed to fail”

Test relies on chance of specific degraders present in test system

Small media sample sizes (1L) with small population ($N_T$):

- low chance of specific degraders (red dots)
- high variability in test outcome (false negatives)
Biodegradation

• Marine BODIS – not accepted by Norway for soluble samples!

• NO scientific basis not to accept BODIS for soluble subst.

• Preferred in some cases: ability to readily extend test

• 40% degradation in 28 days does not mean 60% doesn’t degrade (lag, slope/rate)

• Read across, QSARS, T½ half-life values?
Biodegradation

• Update test methods with latest scientific knowledge: decrease variability

• Agree to accept recognised methods: harmonised system, avoid replication of studies

• Ready degradation test, 40% doesn’t mean only 40% “screening biodegradation tests... discriminating between readily degradable materials and other compounds... using the test material as only source of organic carbon... low concentration of a non-adapted inoculum”

• Other data are available and should be considered: Read across, QSARS, $T_{1/2}$ half-life values?
Bioaccumulation

• BCF value – extremely expensive test (≈£100k)
• Approx. from Log Kow (octanol-water partition coef.)

However, Log Kow not a true measure for surfactants
Surfactants assumed to bioaccumulate (<700MW)
“2 out of 3 Rule” becomes “1 out of 2”
Bioaccumulation

• EOSCA putting together a weight of evidence approach that is acceptable to Cefas

• Looking at:
  ▫ Kow alternative methods
  ▫ in-vitro studies,
  ▫ read across
  ▫ QSARs

• Fundamental issue is data ownership and cost sharing!
REACH and other substance data

• In 2018 all substances marked >1T/yr will have basic data set.
  • Freshwater data!
  • Acute-Chronic ratio?
  • Other biodeg. data?

Beware: there are likely to be data ownership issues!
Data Costs & Data Sharing

REACH: registrants pay for the data relevant to their tonnage

• HMCS every company produces own data
  → Variability

• Global Approach
  → data sharing

• Rewarding additional data
  → reduce uncertainty in model

• Can data sharing with cost sharing be introduced?
  LoAs & data use restrictions
Summary

• Precautionary Principle is not new, and has its roots in North Sea activities
• It must not justify arbitrary decisions
• It must be based on strong scientific evaluation
• Increased availability of data: we must be flexible and open
• Caution: we must consider data ownership and costs!
• This can be a positive!
QUESTIONS

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