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EU Workshop: Industrial Chemicals: Burden of the Past, Challenge for the Future

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Hazard vs Risk
Towards more precautionary regulation of chemicals

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Introduction

- **We need a coherent process to deal with**
  - **the need for chemicals**
  - **the protection of human health and the environment**
  - **the pervasive uncertainty surrounding our current and future knowledge of the health and environmental effects of chemicals**
- **The current system is fragmented and inconsistent, and does not adequately protect human health and the environment.**

"[The Environment Council] Welcomes the intention of the Commission to develop in consultation with Member States and other stakeholders a strategy for an integrated and coherent approach in the chemicals policy of the Community" [21st December 1998]

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What does the public want?

1) Safe products.
2) Chemicals used if necessary, then the safest available used.
   - Minimisation of chemical use, and substitution of more toxic by less toxic chemicals.
3) Risk reduction, not profit protection
   - Human health, and the health of the environment, are more important than profit.
   - Narrow sectoral interests should not influence policy (e.g. BSE disaster).
- How can these aspirations be achieved?

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The 'Joint Statement on Chemicals and Health'

- Friends of the Earth, in association with other UK health and environmental groups, has produced a 'Joint Statement on Chemicals and Health', which proposes a more precautionary chemicals policy.
- Signatories include:
  - World Wide Fund For Nature (WWF) UK, UNISON (a union), Scottish Wildlife Trust, Marine Conservation Society, Association for Public Health, Public Health Alliance (Scotland) and The Food Commission
- Relevant elements of this Joint Statement will be highlighted during this presentation

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1. What are the advantages and disadvantages of hazard and risk assessment ?

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The problems with risk assessment

- It ignores the reality of exposure to mixtures
- It is expensive and time consuming
- It does not deal adequately with pervasive uncertainty
- The burden of proof tends to be on the regulator to demonstrate that a substance is dangerous, rather than on industry to demonstrate safety - contrary to the principles laid out in 1989 in the WHO 'European Charter on Environment and Health':

  "New policies, technologies and developments should be introduced with prudence and not before appropriate prior assessment of the potential environmental and health impact. There should be a responsibility to show that they are not harmful to health or the environment"

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Comments on risk assessment (i)

“Whatever one’s view about risk assessment, it is not science in the sense of an attempt to understand the natural world”

“the way that risk assessment is portrayed and the role of scientists in the process lead the public to confuse risk assessment with science and to confuse the risk assessment activities of scientists with other activities that are normally considered scientific”

‘Environmental Health, Risk Assessment, and Democracy’, editorial by Michael A. Kamrin in the US Journal ‘Environmental Health Perspectives’, May 1998

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Comments on risk assessment (ii)

“The dominant analytical difficulty inherent to risk assessment is pervasive uncertainty”

“Up to now, risk is usually assessed on a chemical-chemical approach. Instead, the importance of exposure to a mixture of chemicals needs also to be considered: effects of various substances can be synergistic or antagonistic. These effects are generally not known experimentally.”

“Additionally, risk assessments themselves can be manipulated so that their results emerge above or below the acceptable value according to an assessor’s personal preferences”

DGIII ‘Workshop on Risk Management - Revised Working Paper’ 9/97

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A hazard based approach

- A more precautionary approach, looking at the intrinsic properties of substances.
- More straightforward, with less data required - particularly the hard-to-obtain exposure data.
- An OSPAR commitment for releases (direct or indirect) to the North Atlantic.
- Better able to deal with uncertainties and future advances in toxicology.
  - e.g. Developments in the investigation of genetic susceptibility and resulting genetic screening.

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Genetic susceptibility- The problem for regulators

- Absorption, detoxification and other processes involved in toxicity can vary by more than 100-fold between individuals.
- Much research is now being done, particularly as part of the US Environmental Genome Project, to identify environmentally-relevant genetic variation - at the same time genetic screening is only a few years away from widespread use in health services.
- Such testing will mean that susceptible individuals know who they are, and will want to avoid the chemicals concerned:
  - The chemical may not be listed on labels, or it may even be a persistent or bioaccumulative environmental contaminant.
  - The regulator has little information on what chemicals are used in which products.

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The regulatory impacts of genetic susceptibility

- **Slow and ineffective action by regulators will lead to further loss of public confidence in regulation, and an inability to protect *everyone's* health.**
- **Using the substitution principle to reduce hazards will reduce the risk of harm to humans and the environment.**
- **A more hazard-based approach with positive (permissive) licensing will allow a rapid response to new science.**
- **Any new EU Directive on chemicals regulation will take at least 5 years - genetic testing will probably be widely available by then. There is a real danger of regulations being overtaken by science.**

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2. How can hazard assessment, risk assessment and other approaches (e.g. substitution) be used for risk management

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a) Hazard assessment

1) The phase out of unacceptable hazards of persistence and bioaccumulation:

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(ii) The elimination of persistent or bioaccumulative chemicals

All synthetic chemicals in use should break down rapidly into harmless, natural substances. There should be no accumulation in the human body, wildlife or the environment, unless this is an essential function in a specific application. Phasing out persistent and/or bioaccumulative chemicals will reduce exposures.

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a) Hazard assessment

1) The phase out of unacceptable hazards of persistence and bioaccumulation.
2) Chemicals should be shown to be safe beyond reasonable doubt for the use proposed.

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b) Substitution (comparative assessment)

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(iv) Substitution of toxic chemicals

Where a less toxic chemical is available for an application, it should be substituted for the more toxic chemical. This is the 'substitution principle'.

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Mechanisms of substitution (i)

A system needs to be created where easier substitutions are handled rapidly, whilst less straightforward substitutions go through a more complex comparative assessment.

- **In most cases, a substitute will have similar exposures, allowing rapid substitution on hazard data alone**

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Mechanisms of substitution (ii)

Enforcing substitution will require licensing of chemicals for uses - an extension of positive licensing (or permissioning) to all chemicals

- **Positive licensing already exists for pesticides, biocides, pharmaceuticals and veterinary products**
- **Positive licensing also exists to some extent in the 'New Substances' process, 'Best Available Technology', Ecolabelling and the draft producer responsibility directives, etc.**
- **Liability would remain with industry, not the regulator.**

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(i) A positive licensing system

Chemicals regulation should move towards being a positive licensing system, where chemicals are licensed for different uses, in the same way as already occurs for pesticides and pharmaceuticals. Industry should have to demonstrate that these licensed applications of chemicals are safe beyond reasonable doubt, and that society has a need for them. The potential impacts on the environment of discharges of a chemical should be fully evaluated prior to licensing.

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Mechanisms of substitution (iii)

Substitution will also require easily accessible information on the hazards posed by chemicals, for example through a freely-available on-line chemicals database.

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Other approaches - Right to Know

- **There should be an over-arching right to know what chemicals are present in products, to allow consumers and industry to make their own decisions on which chemicals to use, and to provide exposure and usage information to companies producing chemicals and the regulators.**
- **Comprehensive pollutant release and transfer registers would also add to the information available on exposures to chemicals.**

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(vii) The right to know

The public should have a right to know what chemicals are present in any product they use, including in the packaging of the product. The public should also have access to information on the safety of all chemicals. This information will help individuals to make informed choices.

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3. How should assessment of costs and benefits be included in the process?

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Problems with evaluating costs and benefits

- **Pervasive uncertainty means that cost benefit analysis is never accurate.**
- **Costs of change tend to be more easily calculated than benefits.**
- **Costs frequently impact on one sector; benefits are more widely distributed. The cost of an individual chemical is usually a tiny percentage of the finished product.**

"The health of individuals and communities should take clear precedence over considerations of economy and trade"

'European Charter on Environment and Health', 1989

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Conclusions

- **Risk assessment is costly and inaccurate.**
- **Hazard assessment is easier and more precautionary.**
- **The hazards of persistence and ability to bioaccumulate are unacceptable.**
- **The substitution principle needs to be enforced as a risk reduction measure; this will require licensing of chemicals for uses (an integrated and coherent approach).**
- **A comprehensive right to know is needed to create a transparent and open system.**
- **Protection of human health and the environment is the overwhelming imperative.**

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For FOE's chemicals briefings and related documents:
http://www.foe.co.uk/camps/indpoll/suschem.htm