

Frame 2 Research Workshop

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Frame 2 conditions

- Frame 1 conditions must be satisfied for entry into Frame 2
- Discussion about whether standards should be a prerequisite for oversight in Frame 2 – not unanimous

Frame 2 is here – now!

- Any system of regulation that is introduced must be flexible and adaptable.
- There must be feedback loops to which the system could respond, in the light of new knowledge.
- It must not be ‘set in stone’ with fixed standards
- There must be a reporting system (eg yellow card system with drugs)

AGCT + F?

- Extension of the genetic code by use of synthetic nucleotides
- Use of extended DNA templates to manufacture novel polypeptides incorporating amino acids other than the 20 found in life
- Implications for containment, mutation, toxicity, allergy??

Nanobiotech conundrums

“I suspect that, in five years or so, the artificial genetic systems that we have developed will be supporting an artificial life form that can reproduce, evolve, learn and respond to environmental change.”

– Professor Steven Benner,
Chemist, University of
Florida¹⁴⁶

“If biologists are indeed on the threshold of synthesizing new life forms, the scope for abuse or inadvertent disaster could be huge.”

*Philip Ball, Nature, October 7,
2004.¹⁴⁷*

We can learn from:

- Previous work on genetic engineering and GMOs – though this is largely a negative message
- Previous work on IT/WWW/computers/cellphones/sensors - largely a positive message

Discretise Nanotechnology

- **Non-pervasive:** eg nanostructured surfaces, electronic chips
- **Locally pervasive:** use of nano-medicines within patients (life cycle analysis to check final fate)
- **Widely pervasive:** eg free nanoparticles, organisms. Ability to travel in the wider environment, water, food, biota

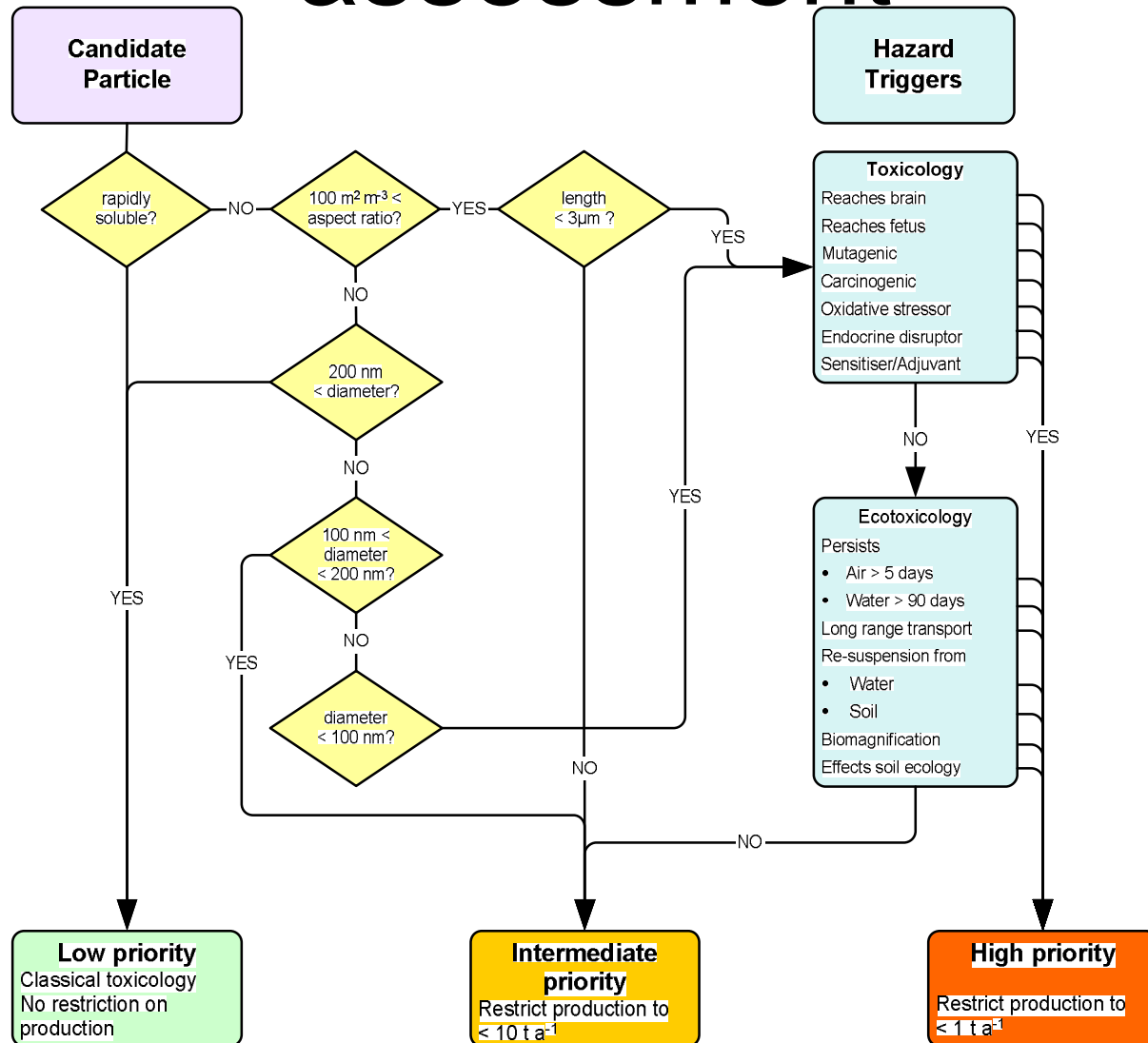
Differing levels of control

- Pre-screening of proposals would have projects allocated to a particular category
- Non-pervasive projects could be fast tracked with a light regulatory touch
- Widely pervasive projects would be heavily regulated

Risk Assessment – 4 phases

- **Hazard identification** – requires insight and understanding of the system in question
- **Hazard assessment** – costs time and money for hard science – positive findings require action
- **Exposure assessment** – can be very expensive and, for human exposure, complex
- **Risk assessment** – depends totally on the 1st three steps

Comparative hazard assessment



NOTE: At decision points, UNKNOWN values should be taken to equal YES.

Complex Systems

- Risk assessment is now being applied to very complex systems - such as ecosystems
- It is impossible to have comprehensive hazard data for such systems
- Missing data is often provided by 'data models', but these can be subjective
- Sometimes the whole risk assessment can be based solely upon data models

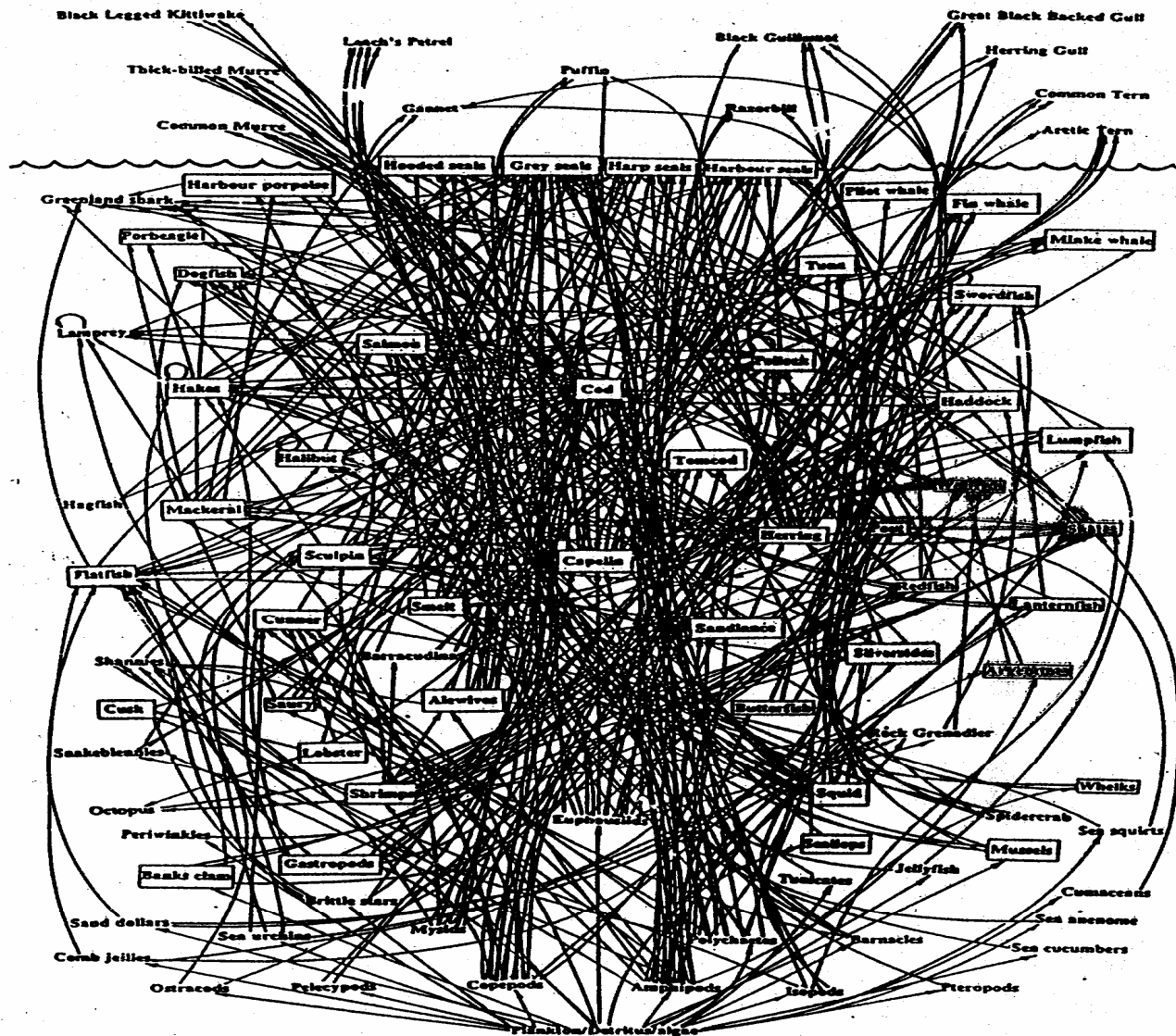


Figure 3.5: The Scotian Shelf food web. This is a well known system with a huge amount of links among species. It is quite obvious that in this ecosystem lacks any hierarchical principle and that a change in a single link may affect some species in an unexpected fashion.

Table 2

- Lacked any reference to benefits of the technology
- Maybe could be framed in terms of risk
 - If you do something
 - If you don't do something

Table 4

Should be more defined – e.g. introduction of specific courses into university education.

Most of recommendations relevant to all categories: Academic, Industry, Government, NGOs etc

Scientists

- Not much benefit/value attached to communicating with the public, undertaking outreach
- When should scientists have to report a particular idea, project
- Lessons from the recombinant DNA sector, ?Osilomar?, hierarchical model of checking: local biosafety cttee etc.

Working model of delegation of responsibility

- Kidney transplantation
- Not enough kidneys to meet demand
- Decisions reached by committees comprising lay members, regulators, health workers
- Decision not taken by the surgeons who will perform the operations

Research proposal formats

- Should develop a widely agreed format for research proposals which include:
 - Type of nanotech methodology
 - Type of application
 - Hazard identification
- Possible problems with confidentiality