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The Precautionary Principle and Substantial Equivalence

The Precautionary Principle: Implications for Public Policy

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Precautionary Principle

A framework for decision-making in the face of high scientific uncertainty and likelihood of harm

Substantial Equivalence

An approach to risk assessment intended to reduce the degree of scientific uncertainty

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Types of Risk

Risk = f(hazard x exposure)

***Probabilistic** risk: the hazard exists AND has occurred at least once*

Science based

***Hypothetical** risk: the hazard has not occurred **BUT** there is a scientific basis to support its existence*

***Speculative** risk: the hazard has not occurred **AND** there is no scientific line of reasoning to suggest it will*

Realm of Biopolitics

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No Universal Definition of the PP

1992 RIO Declaration on Environment and Development

> *"Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation."*

1998 Wingspread Consensus Statement on the Precautionary Pinciple

> *"When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."*

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Differing Views on Precaution

"Weak" Precaution	"Moderate" Precaution	"Strong" Precaution
Presumption of unfettered market-led development and technological innovation	Underlying presumption of unfettered market-led development and technological innovation **but recognition that this can sometimes be overthrown where there are high levels of societal concern**	No presumption of either market led or technologically driven development
Regulators intervene only where there is positive scientific evidence of risk and intervention demonstrably cost-effective	Presumption of intervention as under 'weak', **but case by case flexibility to shift the onus of proof towards the risk creator**	**Risk creator demonstrates safety of activity**. Little credence in cost effectiveness
Presumption of risk management Banning **very rare**	Underlying presumption of risk management Banning **possible**, but a last resort	Presumption of risk avoidance Banning **likely**
Presumption of free trade on the basis of objective scientific criteria. Individual preferences and **societal concerns given no weight**.	Underlying presumption of free trade on the basis of scientific criteria. Recognition that individual preferences and **societal concerns matter**	No automatic presumption of free trade. Individual preferences and **societal concerns dominant**

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In Practice, the Position Adopted...

- *Should reflect the commitment to sustainable development that gives full weight to economic, social and environmental factors*
- *Should not, therefore, be an obstacle to innovation*
- *Should be a positive, proportionate policy tool to encourage technological innovation and sustainable development by helping to engender stakeholder confidence that appropriate risk control measures are in place*

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Key Point #1

The purpose of the Precautionary Principle is to create an impetus to take a decision notwithstanding scientific uncertainty about the nature and extent of the risk, i.e. to avoid 'paralysis by analysis' by removing excuses for inaction on the grounds of scientific uncertainty.

United Kingdom Interdepartmental Liaison Group on Risk Assessment

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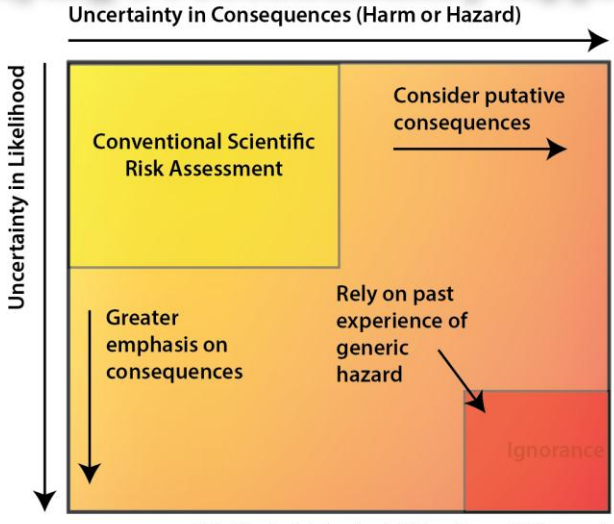
Applying a Precautionary Approach



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Key Point #2

The Precautionary Principle should be invoked when:

- *there is good reason, based on empirical evidence or plausible causal hypothesis, to believe that harmful effects might occur, even if the likelihood of harm is remote; and*
- *a scientific evaluation of the consequences and likelihoods reveals such uncertainty that it is impossible to assess the risk with sufficient confidence to inform decision-making*

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Differentiating between the PP and other Drivers for Caution

Even when there is little scientific uncertainty, regulators may be cautionary where:

- *The hazard is real and known to be serious (e.g., exposure to known carcinogens)*
- *Reliance on individual choice based on information (i.e., warning labels) is not reasonable or possible (e.g., air pollution)*
- *Benefits from tolerating the hazard are not justified, e.g., because there are good alternatives*
- *Common cautionary conventions in risk assessment include -- the use of uncertainty factors for assessing health risks from chemicals; "over-engineering" bridges*

The Precautionary Principle is not relevant when acting to address, for example, hazards from a major chemical plant handling well-known toxic products (i.e., no scientific uncertainty)

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Key Point #3

The Precautionary Principle:

- *is narrower than "being cautionary"; and*
- *is not relevant unless scientific uncertainty is a signficant factor and there is good reason to expect harmful effects.*

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Principles for Applyng the Precautionary Principle (EC 2000)

- ***Proportionality**: "Measures ...must not be disproportionate to the desired level of protection and **must not aim at zero risk***
- **Nondiscrimination**: *"Comparable situations should not be treated differently and ... different situations should not be treated in the same way, unless there are objective grounds for doing so."*
- **Consistency**: *"Measures ... should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available."*
- ***Examination of the costs and benefits of action or lack of action**: "This examination should include an economic cost/benefit analysis when this is appropriate and feasible. However, othere anlaysis methods ... may also be relevant."*
- ***Examination of scientific developments**: "The measures must be of a provisional nature pending the availability of more reliable scientific data" ... "scientific research shall be continued with a view to obtaining more complete data."*

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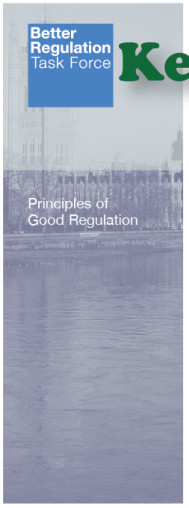

Key Point #4

Action in response to the Precautionary Principle should be in accord with principles of good regulation, i.e., it should:

- *lead to action that is*
  - *proportionate to the required level of protection;*
  - *consistent with other forms of action;*
  - *targeted to the risk; and*
- *be invoked in a process that is*
  - *transparent; and*
  - *accountable to stakeholders and ultimately to the political process.*

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How can we Assess the Safety of a GM Food?

- *How can you prove the safety of any food? -- You can't*
- *Historically, our beliefs about the safety of foods have been based almost entirely on tradition and cultural experience*
- *In practice, very few of the foods we eat today have been subject to any toxicological studies and yet they are generally accepted as safe -- presumption of safety unless a significant hazard identified*
- *At the heart of the risk assessment process is the principle that GM foods can be compared with traditional counterparts that have an established history of safe use*
- *First use of the term "Substantial Equivalence" in OECD 1993 publication on "Safety Evaluation of Foods Derived by Modern Biotechnology"*

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What does a Substantial Equivalence Assessment Involve?

- *knowledge of the composition and characteristics of the conventional comparator*
- *characterization of new components/traits as expressed in the modified organism*
- *transformation technique(s) and molecular characterization (as it relates to understanding the characteristics of the product)*
- *possible secondary effects of the modification*
- *knowledge of the new product/organism with the new component/trait -- compositional analysis and range(s) of expression of the new trait(s)*

OECD (1993). Safety Evaluation of Foods Derived by Modern Biotechnology. Concepts and Principles.

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Applying Substantial Equivalence

- *If SE to an existing food, then further safety or nutritional concerns are expected to be insignificant*
- *Such foods, once SE has been established, are treated in the same manner as their analogous conventional counterparts*
- *Where new foods or classes of new foods or food components are less well-known, the concept of substantial equivalence is more difficult to apply; such new foods or food components are evaluated taking into account the experience gained in the evaluations of similar materials*
- *Where a product is determined not to be SE, the identified differences should be the focus of further evaluations*
- *Where there is no appropriate comparator, then the new food or food component should be evaluated on the basis of its own composition and properties*

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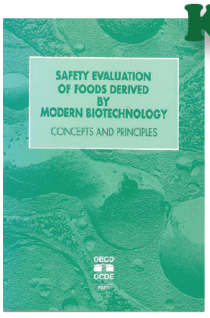

Key Point #5

The concept of Substantial Equivalence is used to:

- *structure the safety assessment relative to the counterpart food;*
- *identify intended or unintended differences on which further safety assessment should focus; and*
- *determine "… as safe as …"*

Substantially equivalent does not mean that two products are identical, but that one can be substituted for the other without affecting the health and/or nutritional status of the consumer

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Are the Precautionary Principle and Substantial Equivalence Still Relevant for GM Crops/Foods?

- *Is the residual scientific uncertainty too high to assess the risk with sufficent confidence to inform decision-making?*
- *Is there good reason, based on the observed evidence, or plausible causal hypothesis, to believe that harmful effects might occur?*
- *Is there a better replacement for the comparative approach to framing the GM food safety assessment?*

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Experience and Learnings

- *More than 25 years of EC-funded GMO research at a cost of > EUR300 million since 1982*
- *2001 – First Overview of 15 years of research (81 Projects, 400 laboratories)*
- *2010 – Sequel overview of subsequent 10 years of research (50 Projects, more than 400 research groups)*
- *The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies*

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Conclusions

- *Based on cumulative experience and totality of research into potential adverse effects of GM crops/foods, there is no justification for invoking the Precautionary Principle for risk management*
- *This does not obviate the need for cautious regulation and risk/safety assessment*
- *When properly applied to frame the safety assessment, some form of Substantial Equivalence, combined with a problem formulation approach, remains a practical solution*

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Thank You!