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Risk Assessment and Precaution in the Biosafety Protocol

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INTRODUCTION

International trade in genetically modified organisms (GMOs) has become the subject of great debate in recent years. The recent entry into force of the Biosafety Protocol[1] to the Convention on Biological Diversity (CBD),[2] the exponential growth in biotechnological applications, and the differences between the USA and the EU over biotech products[3] mean that the issue will attract even more attention in the coming months and years. A central element in this debate is the extent to which the various regimes or approaches that deal with GMOs promote a scientifically sound basis for decision making. A significant cause for the differences in views is a lack of appreciation of the basic elements and steps associated with risk assessment, precaution and decision making when applied to the regulation of biotechnology and its products.

There has been considerable debate about the respective roles of risk assessment and precaution in environmental decision making.[4] This article explores risk assessment and precaution in the context of the Protocol and demonstrates that, in the context of the Protocol, risk assessment and precaution are entirely compatible, but that they have different roles in the process of decision making. This is important as it is only by a proper understanding of the decision-making procedures of the Protocol that policy makers will be able to assimilate properly or incorporate the instrument into the relatively complex policy environment governing biotechnology. It should be noted that the Protocol also has provisions regarding the role of public participation (Article 23(2)) and the consideration of socio-economic factors (Article 26(1)) in decision making, but these are not considered in this article.

BIOSAFETY CONCERNS REGARDING GMOS

There are numerous types of GMOs that have been developed and approved for release into the environment. To date, the majority are transgenic crops (soybean, maize, cotton and canola) that have been developed to increase yields or to decrease production costs. Herbicide tolerance (in particular for soybean) and insect resistance (in particular for maize) are the most common traits among commercialized crops, but there are many other traits that have been developed, such as virus resistance, disease resistance, altered fruit ripening and drought tolerance.[5] In most cases, transgenic

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[1] Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Montreal, 29 January 2000) (hereinafter 'the Protocol'). The Protocol entered into force on 11 September 2003.

[2] Convention on Biological Diversity (Rio de Janeiro, 5 June 1992).

[3] For example, the ongoing World Trade Organization (WTO) dispute, *Measures Affecting the Approval and Marketing of Biotech Products*, where on 8 August 2003 the USA, Canada and Argentina asked for the establishment of a WTO panel to hear their complaint about the EU control of products of biotechnology (Directive 2001/18 as amended and Regulation 258/97) and national measures in Austria, France, Germany, Greece, Italy and Luxembourg (see documents WT/DS291/23 and WT/DS293/17 and, more generally, *Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291, WT/DS292 and WT/DS293). At its meeting on 29 August 2003, the Dispute Settlement Body established a panel pursuant to the requests of the USA, Canada and Argentina (see document WT/DSB/M/155).

[4] See J.B. Wiener and M.D. Rogers, 'Comparing Precaution in the United States and Europe', 5:4 *Journal of Risk Research* (2002), 317; J. Tait, 'More Faust than Frankenstein: the European Debate about the Precautionary Principle and Risk Regulation for Genetically Modified Crops', 4:2 *Journal of Risk Research* (2001), 175; P. Sandin *et al*., 'Five Charges Against the Precautionary Principle', 5:4 *Journal of Risk Research* (2002), 287; Q. Balzano and A.R. Sheppard, 'The Influence of the Precautionary Principle on Science-Based Decision making: Questionable Applications to Risks of Radio Frequency Fields', 5:4 *Journal of Risk Research* (2002), 351; S. Jasanoff, 'Between Risk and Precaution – Reassessing the Future of GM Crops', 3:3 *Journal of Risk Research* (2000), 277; G.E. Marchant, 'The Precautionary Principle: An "Unprincipled" Approach to Biotechnology Regulation', 4:2 *Journal of Risk Research* (2001), 143; C. Starr, 'The Precautionary Principle Versus Risk Analysis', 23:1 *Risk Analysis* (2003), 1; K.R. Foster, 'The Precautionary Principle – Common Sense or Environmental Extremism?', Winter 2002/2003 *IEEE Technology and Society Magazine* (2002), 8; J. Morris, 'The Relationship Between Risk Analysis and the Precautionary Principle', 181–182 *Toxicology* (2002), 127; A. Klinke and O. Renn, 'A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based and Discourse-Based Strategies', 22:6 *Risk Analysis* (2002), 1071; and G. Conko, 'Safety, Risk and the Precautionary Principle: Rethinking Precautionary Approaches to the Regulation of Transgenic Plants', 12:6 *Transgenic Research* (2003), 639.

[5] Biotechnology Industry Organization, *Agriculture Biotech Products on the Market* (BIO, 2004), available at <http://www.bio.org/er/agri_products.asp>.

crops are engineered with one trait, although a few have more than one trait. Almost all of the land area under production of transgenic crops occurs in just six countries (USA 63%, Argentina 21%, Canada 6%, Brazil 4%, China 4% and South Africa 1%).[6]

Potential risks associated with GMOs, and in particular with transgenic crops, have been discussed extensively. The Ecological Society of America made recommendations regarding environmental considerations as early as 1989,[7] and recently updated these recommendations.[8] Their position paper considered the key ecological effects of concern and argued for a science-based assessment of both the benefits and risks of transgenic organisms that are proposed for release into the environment. There have also been many other reviews of potential risks and descriptions of methods for assessing those risks.[9] It is useful to review a few of the main 'risk pathways' or mechanisms by which GMOs could adversely affect the environment. Here a few key risk pathways are considered, including:

- gene flow to related organisms;
- horizontal gene flow;
- effects on non-target organisms.

This is not a comprehensive review of the types of risks posed by GMOs. There are specific concerns related to transgenic viruses, development of insect resistance, changes to agricultural practices (e.g. herbicide applications), human health effects, socio-economic effects and many other mechanisms, which have been reviewed elsewhere.[10] However, gene flow, horizontal gene flow and non-target effects have been some of the most widely debated mechanisms and are a useful starting point for understanding the types of risks associated with GMOs.

GENE FLOW

A primary concern with some transgenes is that they will spread to unmanaged populations of the same species or to populations of related species.[11] This is sometimes called crop-to-wild gene flow, and is a concern in cases where a transgene confers a fitness advantage such as insect resistance. There may be particular concern in the case of crops that can also behave as weeds or that have weedy relatives, particularly if dispersal of seeds or pollen is such that preventing spread is difficult. A recent review concluded that gene flow between sexually compatible species that occur together cannot practically be controlled.[12] Indeed, many crops are known to hybridize with weedy relatives.[13]

If gene flow can be expected for many transgenic crops, a critical concern is the potential for adverse consequences. Snow *et al.*[14] reviewed some studies on the fitness effects of gene flow and noted that fitness effects will vary on a case-by-case basis, depending on the type of trait and the ecology of recipient populations. For some traits, such as insect resistance, studies have shown that fitness effects occur.[15] For other traits, such as herbicide tolerance, there would be no reason to expect a fitness advantage for wild populations if they would not be subject to herbicide treatments. Interestingly, for fish populations, models

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[6] C. James, *Preview: Global Status of Commercialized Transgenic Crops: 2003*, ISAAA Briefs No 30 (2003).

[7] J.M. Tiedje *et al.*, 'The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations – Special Feature on the Release of Genetically Engineered Organisms: A Perspective from the Ecological Society of America', 70:2 *Ecology* (1989), 298.

[8] A.A. Snow *et al.*, *Genetically Engineered Organisms and the Environment: Current Status and Recommendations*, Ecological Society of America Position Paper (2004), available at <http://www.esa.org/pao/esaPositions/Papers/geo_position.htm>.

[9] See K. Ammann *et al.*, *Methods for Risk Assessment of Transgenic Plants III – Ecological Risks and Prospects of Transgenic Plants* (Birkhouser-Verlag, 1999); D.K. Letourneau and B.E. Burrows, *Genetically Modified Organisms – Assessing Environmental and Human Health Effects* (CRC Press, 2002); J. Carpenter *et al.*, *Comparative Environmental Impacts of Biotechnology-Derived and Traditional Soybean, Corn and Cotton Crops* (Council for Agricultural Science and Technology, 2002); A.J. Conner *et al.*, 'The Release of Genetically Modified Crops into the Environment', 33 *The Plant Journal* (2003), 19; National Research Council, *Environmental Effects of Transgenic Plants – The Scope and Adequacy of Regulation* (National Academy Press, 2002); P.J. Dale *et al.*, 'Potential for the Environmental Impact of Transgenic Crops', 20:6 *Nature Biotechnology* (2002), 567; J. Rissler and M. Mellon, *The Ecological Risks of Engineered Crops* (MIT Press, 1996); L.L. Wolfenbarger and P.R. Phifer 'The Ecological Risks and Benefits of Genetically Engineered Plants', 290:5499 *Science* (2000), 2088; and C.R. Roseland, *LMOs and the Environment: Proceedings of an International Conference* (Organization for Economic Cooperation and Development, 2002).

[10] See A.A. Snow *et al.*, n. 8 above; and D.K. Letourneau and B.E. Burrows, n. 9 above.

[11] N. Ellstrand, *Dangerous Liaisons? When Cultivated Plants Mate with Their Wild Relatives* (Johns Hopkins University Press, 2003); N. Ellstrand, 'Going to "Great Lengths" to Prevent the Escape of Genes that Produce Specialty Chemicals', 132:4 *Plant Physiology* (2003), 1770; N.C. Ellstrand *et al.*, 'Gene Flow and Introgression from Domesticated Plants into their wild Relatives', 30 *Annual Review of Ecology and Systematics* (1999), 539; D. Bartsch *et al.*, 'Environmental Implications of Gene Flow from Sugar Beet to Wild Beet – Current Status and Future Research Needs', 2:2 *Environmental Biosafety Research* (2003), 105; Pew Initiative on Biotechnology, *Have Transgenes Will Travel: Issues Raised by Gene Flow from Genetically Modified Crops* (2003), available at <http://pewagbiotech.org/resources/issuebriefs/geneflow.pdf>; J. Messeguer, 'Gene Flow Assessment in Transgenic Plants', 73:3 *Plant Cell, Tissue and Organ Culture* (2003), 201; and A.A. Snow *et al.*, 'A Bt Transgene Reduces Herbivory and Enhances Fecundity in Wild Sunflowers', 13:2 *Ecological Applications* (2003), 279.

[12] National Research Council, *Biological Containment of Genetically Engineered Organisms* (National Academy Press, 2004).

[13] See N.C. Ellstrand *et al.*, n. 11 above.

[14] See A.A. Snow *et al.*, n. 8 above.

[15] See A.A. Snow *et al.*, n. 11 above.

have shown that transgenes could lead to extinction of a recipient population through multiple mechanisms.[16]

Prediction of ecological consequences of gene flow is complex and uncertain. However, it is possible to understand the potential for adverse effects based on an understanding of the likelihood of gene flow and the nature of the trait conferred by a transgene.

HORIZONTAL GENE FLOW

Horizontal or non-sexual gene flow among related or unrelated species is also a biosafety concern. It is known to be common in microbes,[17] and may raise particular concern in the future if transgenic microbes are released into the environment on a large scale, or if there is reason to believe that microbes in the human gut could take up transgenes from modified crop foods as they are digested. Horizontal gene transfer is believed to occur through a number of different mechanisms, all of which depend on the uptake and integration of foreign DNA sequences into the host genome.[18]

As for any gene, horizontal transfer would not imply any particular consequence, since the overall fitness of an organism depends on selective pressures in relation to the entire genome. Nevertheless, specific concerns have been raised with regard to horizontal gene flow. For example, as antibiotic-resistant genes are used as marker genes, there is concern that antibiotic-resistant genes could be transferred horizontally to existing bacteria, including bacteria that are human pathogens, or bacteria that are present in the human gut.

In general, it is believed that horizontal transfer of genes at the level of plants, animals and fungi is probably rare or insignificant except on an evolutionary timescale.[19] Nevertheless, even at low transfer frequencies, transgenes could become established depending on selection pressures.[20]

EFFECTS ON NON-TARGET ORGANISMS

Transgenic crops that incorporate insect-resistant traits are intended to have adverse effects on target insects. However, such crops may also affect non-target organisms, either directly or indirectly.[21] For example, direct exposure to insecticidal proteins through ingestion may cause lethal or sublethal effects. One well-known case was a widely publicized laboratory study, which showed that high doses of Bt toxins associated with Bt-maize crops are toxic to monarch butterflies.[22] A subsequent risk assessment showed that risks in the field are probably not significant because real exposure levels are much lower than in the laboratory.[23]

Indirect effects may occur when effects on one component of an ecosystem (e.g. soil microbes, pollinators, native plants) lead to changes in ecosystem dynamics. Prediction of indirect effects is generally complex and uncertain.

Risks to non-target organisms are a particular concern when those organisms are beneficial species, such as pollinators or enemies of pests, species of conservation value, or flagship species that are perceived as indicators of ecosystem health.[24]

Given the potential risks associated with GMOs, and in particular the complexity and uncertainty associated with understanding those risks, governments have shown great interest in approaches for assessing risks, and approaches for taking decisions about the use and release of GMOs in light of both potential benefits and potential risks. This was apparent during the negotiation of the Protocol.[25] Ultimately, the Protocol was adopted with provisions related to risk assessment and decision making that recognize the complexity of decision making in the face of uncertain outcomes.[26]

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16 W.M. Muir and R. Howard, 'Assessment of Possible Ecological Risks and Hazards of Transgenic Fish with Implications for Other Sexually Reproducing Organisms', 11:2 *Transgenic Research* (2002), 101.

17 E.V. Koonin *et al*., 'Horizontal Gene Transfer in Prokaryotes: Quantification and Classification', 55 *Annual Review of Microbiology* (2001), 709.

18 K.M. Nielsen *et al*., 'Horizontal Gene Transfer from Transgenic Plants to Terrestrial Bacteria – A Rare Event?', 22:2 *FEMS Microbiology Reviews* (1998), 79.

19 See U. Bergthorsson *et al*., 'Widespread Horizontal Transfer of Mitochondrial Genes in Flowering Plants', 424: 6945 *Nature* (2003), 197; and J.A. Thomson, 'Horizontal Transfer of DNA from GM Crops to Bacteria and to Mammalian Cells', 66:2 *J. of Food Sci* (2001), 188.

20 K. M. Nielsen *et al*., n. 18 above.

21 D.K. Letourneau and B.E. Burrows, n. 9 above.

22 J.E. Losey *et al*., 'Transgenic Pollen Harms Monarch Larvae', 399:6733 *Nature* (2003), 6733.

23 M.K. Sears *et al*., 'Impact of Bt Corn Pollen on Monarch Butterfly Populations: A Risk Assessment', 98:21 *PNAS* (2001), 11937.

24 A.A. Snow *et al*., n. 8 above.

25 C. Bail *et al*., *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment & Development* (Earthscan Publications, 2002); and Secretariat of the Convention on Biological Diversity, *The Cartagena Protocol on Biosafety: A Record of the Negotiations* (SCBD, 2003).

26 R. Mackenzie *et al*., *An Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN Environmental Law Paper No 46 (2003).

RISK ASSESSMENT PROVISIONS IN THE PROTOCOL

The Protocol's operational provisions focus largely on the processes of decision making by parties regarding the import of living modified organisms (LMOs).[27]

The Protocol requires that decisions regarding the import of LMOs for intentional introduction into the environment be taken in accordance with a risk assessment.[28] Annex III of the Protocol provides more detailed guidance on the application of risk assessments, including some general principles, such as the need for risk assessments to be carried out in a scientifically sound and transparent manner; the need to consider risks in the context of risks posed by non-modified parental organisms; and the need to carry out risk assessments on a case-by-case basis. The methodologies for these risk assessments are also described in Annex III, with some generic steps common to risk assessment frameworks,[29] including:

- identification of characteristic(s) of an LMO that may have adverse effects (i.e. hazard identification);
- evaluation of the likelihood of effects (or some other measure of exposure);
- evaluation of the consequences of those effects if they occur;
- characterization of risk based on the likelihood and consequences of effects (i.e. risk characterization).

Although the precise delineation and terminology of the steps in risk assessment vary among frameworks, the guidance provided by Annex III is generally consistent with accepted principles and methodology for risk assessment.

[27] The term 'living modified organism' is specifically defined in the Protocol (Article 3) as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. Although it is commonly assumed that LMOs and GMOs have a similar meaning, there are many different interpretations of both terms.

[28] Biosafety Protocol, Article 15.

[29] See UK Department of the Environment, Transport and Regions, *Guidance on Principles for Risk Assessment and Monitoring for the Release of Genetically Modified Organisms*, DETR/ACRE Guidance Note 12 (2000); European Commission, Commission Decision of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, [2002] OJ L200/22; National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (National Academy Press, 1983); Australian Office of the Gene Technology Regulator, *Risk Assessment Framework for License Applications to the Office of the Gene Technology Regulator* (January 2002); and US Environmental Protection Agency, *Guidelines for Ecological Risk Assessment* (EPA 630/R-95-002F, 1998).

PRECAUTION IN THE PROTOCOL

As the whole idea of the Protocol is based on using a precautionary approach in the management of LMOs, it is difficult to describe comprehensively the nature of precaution in the Protocol. Nevertheless, elements of precaution are reflected in many places. The 'precautionary approach' is explicitly mentioned in the Preamble and the Objective (Article 1) of the Protocol. However, such references are not that important or even new, as references to the precautionary principle and approach are common in international agreements.[30]

What is unique, and of more significance, is that the concept of precaution is also found in the Protocol's operative provisions. The decision-making procedures outlined in Articles 10 and 11 provide that when making a decision about whether to allow an import of an LMO:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate with regard to the import of the living modified organism referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.[31]

Annex III on risk assessment adds an additional element by providing that:

> Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.[32]

Even though the concept, as set out in these operative provisions, is far from clear, particularly since the Protocol allows parties to consider undefined socio-economic considerations, due to the detailed requirements outlined elsewhere in the Protocol about decision making, such decisions must be generally taken in a scientifically sound and transparent manner, taking into account expert advice and relevant international guidelines. Moreover, the Protocol merely sets out a right of parties to take a precautionary import decision in the case of scientific uncertainty – it is not characterized as an obligation.

[30] For example, Rio Declaration, *Report of the UN Conference on Environment and Development* (Rio de Janeiro, 3–14 June 1992), A/CONF.151/26, Vol. 1, Annex I, Principle 15; United Nations Framework Convention on Climate Change (New York, 9 May 1992), Preamble; and Agreement on Straddling and Highly Migratory Fish Stocks (New York, 4 December 1995), Article 6.

[31] Biosafety Protocol, Article 10(6). Article 11(8) contains almost identical wording.

[32] Ibid., Annex III, para. 4.

As an aside, it should be noted that discussions about the difference between the meaning of precautionary approach and precautionary principle seem to be devoid of substance, especially in the context of this Protocol. There are numerous specific definitions of both of these terms in the literature, with a wide variety of interpretations. These have been debated, including the nuances of Rio Principle 15.[33] It is worth recalling that well before the use of such terms, the literature on the analysis of formal decision-making practices referred to this concept in different ways. For example, the acceptability of risks to decision makers or their 'risk attitudes' have been considered at length.[34] Risk attitudes are sometimes categorized as 'risk averse', 'risk neutral' or 'risk prone'. Risk-averse decisions typically put more value or emphasis on negative risks than on benefits and would, therefore, be most likely to be regarded as 'precautionary' in nature. Risk-averse decisions are, generally, most common in cases where potential adverse effects are large or irreversible, or where uncertainty about the magnitude of potential effects is particularly large[35] (i.e. nuclear or hazardous waste). In the case of the Protocol, in the operational provisions of Articles 10 and 11 and Annex III, it is the wording of the provisions that matters and not whether or not one considers the language used as equivalent to a particular definition of the 'precautionary approach' or the 'precautionary principle'. The language of Articles 10(6) and 11(8), in particular, can be said, at the least, to *reflect* the concept of precaution in decision making.

DISTINGUISHING THE ROLES OF RISK ASSESSMENT AND PRECAUTION

Risk assessment is an approach for evaluating and characterizing risks, whereas precaution is an attitude of decision makers, reflecting their values and/or the values of those they represent, in taking a particular decision. The two concepts have different roles in decision making and are in no way incompatible in a general sense. However, there is considerable confusion about how a decision can, in practice, be based both on risk assessment and on precaution at the same time. It is useful, therefore, to explore the rationale for this confusion, in an attempt to clarify the roles of risk assessment and precaution in decision making under the Protocol.

THE MANDATE OF RISK ASSESSORS

One source of confusion about the roles of risk assessment and precaution stems from the mandate given to risk assessors. Usually, risk assessors are scientists with expertise in relevant disciplines, which allows them to characterize risks based on available scientific information. However, inevitably, decision makers also ask for the advice of risk assessors on appropriate risk-management actions, and may even ask for their advice on the acceptability of risks. For example, Annex III on risk assessment in the Protocol contains the following text as part of the methodology of risk assessment:

> A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks.[36]

Risk assessors are entirely capable of commenting on whether risks can be managed. However, their role in determining the acceptability of risks is less clear. Formally, such value judgements are the realm of decision makers.[37] In practice, though, the link between risk assessment and decision making is usually complex, based on an iterative relationship that involves continuing dialogue between risk assessors (who must communicate complicated and uncertain information to decision makers) and decision makers (who must inform risk assessors about what type of information is needed),[38] as well as dialogue with the public and stakeholders affected by the decision.[39] Partly as a result of this process, in many regulatory systems, the scientists responsible for risk assessment are often given some responsibility for decision making as well. Risk assessors are inevitably involved in the broader decision-making process in one way or another. Still, their primary role is assessment, and the Protocol's language clearly asks only for a 'recommendation' from risk assessors on the acceptability of risks.

[33] See R.L. Keeney and D. von Winterfeldt, 'Appraising the Precautionary Principle – A Decision Analysis Perspective', 4:2 *Journal of Risk Research* (2001), 191; Q. Balzano and A.R. Sheppard, n. 4 above; P. Sandin *et al*., n. 4 above; G.E. Marchant, n. 4 above; P.F. Ricci *et al*., 'Precaution, Uncertainty and Causation in Environmental Decisions', 29:1 *Environment International* (2003), 1; J. Morris, n. 4 above; and G. Conko, n. 4 above.

[34] R.L. Keeney, 'Decision Analysis: An Overview', 30:5 *Operations Research* (1982), 803; T. Page, 'A Generic View of Toxic Chemicals and Similar Risks', 7:2 *Ecology Law Quarterly* (1978), 207; and P. Slovic, 'Perception of Risk', 236 *Science* (1987), 280.

[35] M.L. Dekay *et al*., 'Risk-Based Decision Analysis in Support of Precautionary Policies', 5:4 *Journal of Risk Research* (2002), 391.

[36] Biosafety Protocol, Annex III, para. 8(e).

[37] European Commission, Communication of 2 February 2000 from the Commission on the Precautionary Principle, COM (2000) 1.

[38] R.A. Hill and C. Sendashonga, 'General Principles for Risk Assessment of Living Modified Organisms: Lessons from Chemical Risk Assessment', 2:2 *Environmental Biosafety Research* (2003), 81.

[39] A. Amendola, 'Recent Paradigms for Risk Informed Decision Making', 40:1 *Safety Science* (2002), 17; and National Research Council, *Understanding Risk – Informing Decisions in a Democratic Society* (National Academy Press, 1996).

BIAS IN THE SCIENTIFIC METHOD

A second source of confusion about the compatibility of risk assessment and precaution is related to the nature of the scientific approach to data analysis. Conventionally, scientific analysis of data assumes that there is no relationship between two variables (null hypothesis = no relationship), unless there is convincing evidence that the relationship exists. In practice, relationships linking environmental effects to environmental stressors, such as LMOs or chemicals, even when they exist, are difficult to discern due to confounding factors and various sources of uncertainty. When the ability to detect a relationship (i.e. statistical *power*) is low, failure to detect a relationship that exists (a type II statistical error or false negative) is a common problem.[40]

Not surprisingly, it is commonly assumed that a 'scientific' risk assessment would be biased towards concluding that an LMO does not produce adverse environmental effects, and would therefore bias against the use of precaution.[41] However, it is important to view a risk assessment not as a purely scientific exercise, but as a characterization of information for use in analysing a decision.[42] The consequences of erroneously concluding that a relationship does not exist (false negative) can be large, but so can the costs of erroneously concluding that a relationship exists (false positive).[43] This realization is part of the basis for paragraph 4 of Annex III of the Protocol on risk assessment (see earlier section), which cautions risk assessors against drawing particular conclusions based on uncertain information. When risk assessment is an input to decision making, scientific uncertainty should be fully characterized and communicated, so that decision makers are as informed as possible.

VALUES AND RISK ATTITUDES IN DECISION MAKING

A third source of confusion about the compatibility of risk assessment and precaution is the misunderstanding that decisions based on risk assessment cannot reflect value judgements. As referred to above, there is considerable debate in the literature about whether the use of risk assessment might preclude precautionary decision making. Decision makers inevitably base their decisions, in part, on their values or risk attitudes, or those of the constituencies they represent.[44] Two different decision makers, faced with the same decision, may make different choices because one is less willing than the other to accept the risks.

Differences were clearly evident during the negotiations of the Protocol, where the governance cultures of the opposing groups significantly contributed to a different understanding about the need for, and role of, the Protocol. On the one hand, the Miami Group (comprising the USA, Canada, Argentina, Australia, Uruguay and Chile) believed that the precautionary approach might not lead to decisions based on sound science. They were concerned that it could be applied in an arbitrary manner and could lead to distortions of trade. On the other hand, the other governments could not understand the reluctance of the Miami Group to accept rules that would allow a prudent approach to this new technology. These different views were, in part, a reflection of the different cultures of risk assessment that existed in each country. For example, the type of risk assessment favoured by the USA is a highly formalized method that is to the greatest possible extent based on quantitative data. This formalized process has evolved in response to a regulatory environment where decisions based on ambiguous scientific findings are liable to be contested. Most other countries do not have such a complex and adversarial system of governance.

It is important that policy makers recognize such differences as legitimate. Insistence upon, or careless translation of, one approach to risk management into an international context will not resolve deep-seated cultural differences regarding risk management of new technologies. In fact, attempts to harmonize these differences out of existence are liable to be resisted as attacks on types of governance rather than a dispute about science.

DEFINITIONS OF PRECAUTION

A final and important source of confusion about the compatibility of risk assessment and precaution is the use of particular, usually extreme, interpretations of precaution. For example, if one pre-determines that precautionary decision making means not approving an import of an LMO unless there is 100% certainty

[40] D.A. Andow, 'Negative and Positive Data, Statistical Power, and Confidence Intervals', 2:2 *Environmental Biosafety Research* (2003), 75. R.M. Peterman, 'Statistical Power Analysis Can Improve Fisheries Research and Management', 47:1 *Canadian Journal of Fisheries and Aquatic Sciences* (1990), 2.

[41] See G.E. Marchant, n. 4 above; and R.M. M'Gonigle *et al.*, 'Taking Uncertainty Seriously: From Permissive Regulation to Preventative Design in Environmental Decision Making', 32:1 *Osgoode Hall Law Journal* (1994), 99.

[42] See R.L. Keeney and D. von Winterfeldt, n. 33 above; and D. Santillo *et al.*, 'The Precautionary Principle: Protecting Against Failures of Scientific Method and Risk Assessment', 36:12 *Marine Pollution Bulletin* (1998), 939.

[43] See J.B. Wiener and M.D. Rogers, n. 4 above.

[44] See R.L. Keeney and D. von Winterfeldt, n. 33 above; R.L. Keeney, n. 34 above; and M.G. Morgan and M. Henrion, *Uncertainty – A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis* (Cambridge University Press, 1990).

that there are no adverse effects, then there is really no point in conducting a risk assessment – the choice is pre-determined because 100% certainty is generally impossible.

Such extreme views of precaution exist,[45] but they are neither reasonable nor appropriate in the context of the Protocol, since they would negate the relevance of much of the operational provisions concerning decision making, by concluding, *a priori*, that it is impossible for the benefits of biotechnology to outweigh the risks in any circumstance. As others have noted,[46] precaution is only operational if it is applied in a balanced way in the context of evaluating the positive and negative impacts of a decision. Indeed, the notion of decision making based on full consideration of benefits and risks, including their uncertainties, is simply common sense.

CONCLUSION

In summary, risk assessment and precaution as contained in the Protocol are entirely compatible. Risk assessment plays a key role in characterizing the potential adverse effects of LMOs, while precaution is an attitude in decision making that reflects a particular aversion to risk in the face of uncertainty. Risk assessment does not, *a priori*, condone or preclude a precautionary attitude in decision making. Similarly, whether decision-making attitudes are precautionary or otherwise, risk assessment provides an important input by characterizing potential adverse effects of LMOs based on available information.

Importantly, future efforts to elucidate the application of risk assessment and precaution to decision making on imports of LMOs should not be overly prescriptive, recognizing that decision making is, ultimately, based not only on scientific information but also on value judgements and other considerations that may vary widely among countries and regions. Attempts rigidly to standardize decision making in this area will inevitably be resisted as attacks on a way of doing things rather than a dispute about science. Sufficient flexibility to allow differences to manifest themselves, while at the same time insisting upon a certain rigour, is inherent in the provisions of the Protocol.

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The opinions presented in this article are those of the authors and in no way represent the views of the Secretariat of the Convention on Biological Diversity, the parties to the Convention or to the Biosafety Protocol, or the United Nations University.

[45] See M.D. Rogers, 'Scientific and Technological Uncertainty, the Precautionary Principle, Scenarios and Risk Management', 4:1 *Journal of Risk Research* (2001), 1; C. Starr, n. 4 above; K.R. Foster, n. 4 above; and J. Morris, n. 4 above.

[46] See R.L. Keeney and D. von Winterfeldt, n. 33 above; J. Tait, n. 4 above; P. Sandin *et al.*, n. 4 above; P.F. Ricci *et al.*, n. 33 above; and European Commission, n. 37 above.