Status Report and Commentary on the International Debate Over the Precautionary Principle

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By

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Status Report and Commentary on the International Debate Over the Precautionary Principle

based on the International Conference on Biotechnology in the Global Economy: Science and the Precautionary Principle, 22-23 September 2000, Kennedy School of Government at Harvard University

1. **Conference Goals**

The following text in sans-serif typeface is the Conference Summary provided by the organizers on their website. I added boldface to one pertinent passage which I will discuss in the next section.

"Harvard University's" **Center for International Development (CID)** and the **Belfer Center for Science and International Affairs (BCSIA)** hosted an "International Conference on Biotechnology in the Global Economy: Science and the Precautionary Principle" on 22-23 September 2000 at the Kennedy School of Government, Harvard University. The conference was part of a series of events aimed at exploring key policy issues related to biotechnology and globalization. The safe use of modern agricultural biotechnology has become one of the most contentious debates worldwide. There is general agreement on the need to ensure the safety of biotechnology products through effective risk assessment, management and communication. However, countries differ on how to reflect these measures in public policy. **Some require that "sound science" is used as a basis for restricting trade in products that pose a threat to the environment and human health. Others, however, argue for "precautionary measures" that allow policy action to be taken in the absence of full scientific certainty.**In 1992, the **United Nations Conference on Environment and Development (UNCED)** adopted Principle 15 which states that "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." A version of this principle was recently incorporated into the **Biosafety Protocol to the Convention on Biological Diversity**. There is considerable controversy on the meaning, scope, context and application of the precautionary principle in international trade and environmental management.The aim of the conference was to explore the policy and practical implications of the use of the precautionary principle in the field of biotechnology. The conference covered: (a) theoretical, historical and cultural aspects of the principle; (b) previous applications in international environmental and trade law (c) the implications of various definitions for the principle''s use in international discussions and negotiations; and (d) social, economic and political implications of the principle in developed and developing countries.The conference was held in two plenary sessions and two parallel discussion sessions. Its results contributed to current efforts to develop research activities, provide training and promote policy dialogue and awareness on the safe use of biotechnology."

[A conference summary (text, pictures and audio) is available at http://www.iisd.ca/sd/biotech/]

2. **Limitations of this Conference**

This conference is the second in a series of highly informative and successful conferences on modern biotechnology. The conference provided a very broad overview of the issues. It was attended by many influential individuals and featured broad international representation. It is

important to note, however, that the debate over the precautionary principle (PP) is very complex and no resolution on this issue can be expected from such a short event.

The debate over the meaning and implementation of the precautionary principle is now so extensive that it has become a profession to some. The flurry of activities encompass a number of dedicated conferences, entire books and countless academic and popular articles. The "Viewpoints" posted to the conference website alone represent approximately 25,000 words and could be bound into a small book (http://www.cid.harvard.edu/cidbiotech/comments/). The materials distributed at the conference further indicate how widespread the debate is. Finally, dedicated conferences on the topic have become frequent. I did not make an effort to track all the recent conferences on the PP, but here is a list of three events I came across by chance within the last few days:

- Four days after the conference the following event took place: "The Precautionary Principle: Agriculture and Biotechnology," a Capitol Hill Briefing sponsored by the International Consumers for Civil Society.
- In the latest newsletter of the Society of Environmental Toxicology and Chemistry, I noted a lengthy discussion on the precautionary principle which was the topic of one of the closing sessions of the Third World Congress of this society (Brighton, UK, May 2000)
- In an electronic newsletter I, received I noted that in June 1999, the Harvard Center for Risk Analysis sponsored a policy workshop on the topic: "The Precautionary Principle: Refine It or Replace It?"

These shall suffice to provide a context in which to view the conference goals stated above.

Another limitation of the conference lies perhaps in the way the issue was framed. The juxtaposition of "sound science" vs. the "precautionary principle," as outlined in the conference description quoted above, may be misleading. It seems to imply that "sound science" is free of the use of the PP and that the PP does not contain sound science. At the conference, however, it was made plain by experts of the contemporary scientific and legal situation in the United States that the precautionary principle has been used for many years within a "sound-science approach" before it became an issue of debate. It was also made plain by advocates of the PP that they are very keen on discussing risk issues in terms of testable hypotheses (which could be addressed by sound science). Therefore, I would argue, the juxtaposition of "sound science" vs. "precautionary principle" does not describe the diverging positions well. Moreover, it may promote the use of rhetoric because neither side wants to be considered "careless" or "unscientific." Instead, all sides aspire to combine accurate facts and reasonable caution.

3. **The Main Issues**

It is a major challenge to frame this debate. I tried hard to give all sides a fair hearing (and feel qualified to do so as both scientist and ethicist, and being both Canadian and European) but I found that the majority of speakers used rhetoric to promote their diverging outlooks on biotechnology. But this is not only an issue of rhetorical communicators. At the conference it became obvious that it is also an issue of biased audiences: their responses were often emotional and not always justified by the content of the presentations.

In many ways, the first session was the most interesting and showed the fundamental conflicts very clearly. It was also controversial with highly animated debates following the presentations.

In the introduction, Calestous Juma, the conference organizer, indicated that his team has identified 14 different definitions of the PP (later speakers argued that this was too low an estimate). As a consequence, agreeing over the precise meaning of the PP did not look like a feasible goal right at the onset of the conference.

Jeffrey Sachs, Director of the Center for International Development at Harvard made a strong case for the use of biotechnology worldwide and for an implementation of the PP in a narrow risk assessment context. He argued that progress in science and technology is *crucially* important for the future of lesser developed countries. Technology transfer and adoption of biotechnology are required, if poor nations are not to stay outside of a new economy. He also predicted that biotechnology will continue in the US, take off in China and India, and be adopted by South America. Africa he sees as undecided. He argued for the autonomy of nations when it comes to risk acceptance and called the PP hopelessly vague if not quantified.

The next speaker, John Holdren of the Belfer Centre for Science and International Affairs, Harvard University, took a very different stance. He argued that not everything can be quantified nor monetized and warned that overstating expectations can be very dangerous (rf. nuclear power). He also mentioned the increasing abundance of industry / academic relationships is a major issue in the context of biotechnology.

Konrad Von Moltke of the International Institute for Sustainable Development looked into the institutional context. He stated that Article 20 of the GATT is inadequate and represents the reason for the inability of the WTO to move on the issue. The international divergence in the use of the PP is a result. He illustrated that we have already many examples where the PP has been operationalized. He also gave historic examples for environmental issues which were successfully addressed despite the use of apparently inadequate management systems. As a consequence he is not in the least worried about the vagueness of the PP. He pointed out that risk assessment is an invention of the United States which is tied to "inconsistencies of the US government structure" and stated that France "needs risk assessment like a hole in the head". His final advice was to refrain from defining the PP in terms of biotechnology only.

Carloyn Raffensperger, Science and Environmental Health Network, provided an NGO perspective. She promoted the widely used "Wingspread Definition" of the PP in which she has a personal stake (from a 1998 conference). She argued for a broader approach to the assessment of risk as outlined in Mary O'Brien's new book (*Making Better Environmental Decisions,* MIT Press, 2000). General principles are to shift questions towards a more holistic approach and to set broad societal goals. She also argued that the PP is not in conflict with science but that it requires more and different science than traditionally used. In her view the PP is an overarching principle that should be used very early in the research agenda.

Further sessions revisited the themes revealed in this first session. Overall, I would frame the main issues as follows:

- Critics of biotechnology and/or the regulatory system attempted to show that the main problem lies in the "narrow approach" of governments to assess risk or in the "unwillingness" of the governments and industry to answer clear questions. The vagueness of the PP is not a major issue.

- Advocates of biotechnology and defenders of the current regulatory systems attempted to show that the main issue is the lack of public understanding (in concert with the misinformation provided by some NGO's). The vagueness of the PP is seen as a major problem. The industry does not like the PP because it makes the regulatory system presently, or perhaps even permanently, less predictable (the PP is difficult to define narrowly and even broad definitions have not yet been fully agreed to).

Two aphorisms, both stated during the conference, may illustrate these positions succinctly:

- Critics of biotechnology: "*Look before you leap.*"
- Advocates of biotechnology: "*Everybody wants progress, nobody wants change.*"

The issues becomes more complex, however, once the international dimension is added. I would summarize the additional concerns as follows:

- Internationally, on the one hand, critics of biotechnology try to show that the risks of biotechnology are real and that producers have a responsibility to do a better job understanding these risks. Further, one participants argued that the proportionally representative democracies in Europe are "more democratic" than the US and that, therefore, controversial issues surface more readily in European politics.

- On the other hand, participants from lesser developed nations made it very clear that hidden protectionism is a major threat to their economies and that very poor people live a life-style which often requires taking extremely high risks (for example, recycling used syringes from hospitals found on garbage deposits). One industry participant provided the

following challenge: "Does the application of the PP produce an unfair advantage for the developed world in any reasonable use of it?"

4. **Diverging Use of the PP in Different Countries**

The principal conflict in the use of the PP is between Europe and North America. This conference, however, did not focus on how exactly the models differ. A presentation from the Netherlands, for example, presented risk evaluation procedures which looked very reasonable from a North American perspective. However, many participants from the US criticized the European Commission's *Communication from the Commission on the Precautionary Principle* (Brussels, 2 February 2000) but it is not clear to me how the systems will precisely differ once fully implemented. Perhaps the conflict is not so much among regulators of different nations but rather between public representatives and the established regulatory systems. By this I mean that regulatory procedures among OECD countries are already streamlined in a way which does allow for entirely different conceptions of the PP. However, the validity of these regulatory procedures, and the willingness of the public and politicians to call them into doubt, seems to differ among nations. Note that my perception is somewhat speculative, would require more research, and was not explicitly stated at the conference.

Participants from lesser developed countries showed that not only risk-taking may differ among cultures, but that risk assessments may also vary because of different environmental conditions. The autonomy of nations was stressed several times.

5. **Effect on Lesser Developed Nations**

The effect of the use of diverging models for the interpretation and application of the PP on lesser developed nations can only be speculation at this point. Much will depend on the quality of the decisions delivered by competing regulatory systems. The full assessment of who is correct when it comes to the hazards to human health, the environment, and society will require a number of years.

However, it was argued that protectionism could be very harmful to lesser developed nations. The trade official representing Argentina was seriously worried about the possibility that protectionism will surface disguised as precaution (that the PP will override phyto-sanitary regulations under WTO). In the past, Argentina used a form of the PP by not giving registrations while there were on-going international controversies over a given product. He framed the dilemma as follows: (1) there is support for the PP in the sense of an environmental protection regulation but (2) there is distrust of the PP if implemented by trade officials.

In my own presentation I argued for transparency in the debate over and implementation of the PP. This is a moral duty that developed nations should assume because the less developed

nations do not have access to the inside-track of debates under OECD and the detailed workings of our regulatory systems. Lesser developed nations may be capable of assessing and managing risk of products, but they cannot assess the quality of our work if we lack transparency.

6. **Outlook and Recommendation**

I believe there is a real chance that the debate over the precautionary principle will mimic the older debate over "sustainable development." There is a risk of having a counter-productive outcome and, as a consequence, the management of the debate may be very important.

Why is there so much debate over the PP? I would argue that the nature of the debate which involves scientists, policy makers, economists, specialists in international trade and many non-government organizations illustrates that the precautionary principle is *the focal point* of the debate over the role of the World Trade Organization and over the issue of how to deal with *values* in an otherwise *science-based* system.

It would take much work to summarize what already has been done internationally on the conception and application of the PP. We should also note that much is still in movement. Official statements from regulatory bodies have been issued but the trade issues around these statements may lead to modifications in the future or may affect the implementation of the statements. Therefore, a careful summary of the international literature may not be the best approach to the understanding of the important issues.

However, an assessment of the Canadian situation (the perspective from our public, governments and industry) may be necessary in order to be prepared to engage in the on-going global debate. In public consultation, one should be open to suggestions about the regulatory system in general and about how the PP is to be conceived and embedded. However, such comments could only be expected from a small portion of the public familiar with technical issues in risk assessment. A more complete public consultation requires the identification of the fundamental values (and world-views) held by the public. An understanding of what is being valued by the public (who represent the principal risk-bearers) provides guidance for which conception and level of the PP is the most appropriate in the Canadian situation.

Recommendation:

I believe that the core issue is neither scientific in nature nor purely political. In my (biased) opinion, the key to understanding is (1) the analysis of the underlying value-frameworks, (2) the expression of these value-frameworks in a systematic and clear language and (3) the implementation of a dialogue among all stakeholders with the goal to find means of the convergence of policy recommendations. A model for such a dialogue can be found in a paper

recently commissioned by CBAC (Paul Thompson, "Food and Agricultural Biotechnology: Incorporating Ethical Considerations," Draft, June 26, 2000). Such a dialogue, I would argue, should make use of the systematic and clear language developed during the analysis and strive towards *convergence* of policy recommendations rather than *reconciliation* of underlying value-frameworks (the latter, I believe, is too ambitious a goal).