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Sent: Thursday, March 25, 2004 7:39 PM
To: Chantal Line Carpentier
Cc: gustavo Alanis Ortega
Subject: timeline for advisory group recommendations

Dear Chantal Line:

It has recently come to our attention that the Advisory Group on Maize and Biodiversity will finalize its recommendations to the CEC Council by 31 March.

As we expressed at the CEC meeting in Oaxaca, if the public comment period lasts until 12 April but the Advisory Group finalizes its recommendations prior to reading these comments, one can only conclude that the exercise of writing those comments is a waste of time.

Could you please inform us of the exact timeline under which the Advisory Group is operating, as well as the procedures that have been developed for their consideration of all the public comments to be submitted?

Thank you for your attention to this matter.

Regards,

Doreen Stabinsky
Greenpeace

Gustavo Alanis
Centro Mexicano de Derecho Ambiental

Comments to the NAFTA Commission for Environmental Cooperation Article 13 report
Maize and Biodiversity: The effects of transgenic maize in Mexic0

Submitted by Greenpeace, 12 April 2004

In chapter 2 of the report, the author suggests that chapter 8 will deal with the precautionary principle. However, nowhere in the chapter is the principle explained. In fact, there is only a single reference listed the precautionary principle – the EC Communication on the precautionary principle. The principle is not addressed in the text at all, except to say that it is being debated. There is some attention given to "scientific uncertainty," but precaution is not the same as uncertainty.

The precautionary principle is a central piece of the Cartagena Protocol on Biosafety, the international legal instrument dealing with trade in engineered organisms. As such, it should be more seriously reflected in the CEC report. This submission is meant to compensate for the sparse coverage of the principle. We hope the authors of the report find our analysis useful as the make their final revisions.

In this document we also provide an analysis of the scientific critiques of ecological risk assessment, both in general and as a methodology for judging risks of GMOs, and we provide a more thorough analysis of scientific uncertainty in this area.

Finally, we discuss specific risks of GMOs and the special case of maize in Mexico, as they relate to the precautionary principle.

The precautionary principle, risks of GMOs, and the specific case of maize in Mexico

1. The Precautionary Principle

introduction

What is this principle that is so politically charged, to the point that the authors of chapter 8 would rather not even mention the words "precautionary principle"? Some simple definitions that have been put forward include "Do no harm" and "Better safe than sorry." A more technical explanation of the Principle is that in the face of serious or irreversible threats to the environment, and in situations of scientific uncertainty, we should take action to minimize or prevent those threats.

Why is the principle so politically charged? One reason is that it allows a serious regulatory challenge to particular industries, such as the genetic engineering industry, where scientific understanding of long-term threats of introducing genetically engineered organisms into the environment is minimal. In defense of their domestic GE industry, countries such as the United States and its allies such as Canada are actively working to impede the use of the principle in environmental decision-making throughout the world. However, the principle is widely accepted, to the point that numerous international

lawyers consider it has already crystallized into a norm of international law. (see for example, McIntyre and Mosedale 1997; Saladin 2000; Sands 2002)

a brief history of The Principle

The history of the precautionary principle varies depending on the teller. Many persons write that the precautionary principle has its roots in German environmental policy. *Vorsorgeprinzip*, the principle of precautionary action, is one of five principles defined in the early eighties as the basis for German environmental policy. (Boehmer-Christiansen 1994) Germany took the lead in introducing the principle of precaution in the international arena in North Sea Ministerial Conferences held throughout the eighties. It became a legally binding principle in international marine law when it was incorporated specifically into the 1992 Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)[1]:

> The Contracting Parties shall apply the precautionary principle, by virtue of which ***preventive measures <u>are</u> to be taken when there are reasonable grounds for concern that substances*** or energy introduced, directly or indirectly, into the marine environment ***may bring about hazards to human health, harm living resources and marine ecosystems***, damage amenities or interfere with other legitimate uses of the sea, ***even when there is no conclusive evidence of a causal relationship between the inputs and the effects***. (emphasis added)

Numerous other treaties and non-binding declarations since then have incorporated a version of the precautionary principle. (These are too numerous to mention here in an exhaustive way. See McIntyre and Mosedale 1997; Saladin 2000; Sands 2002 for further discussion.) The most famous articulation of the principle in international law, at least prior to the conclusion of the Cartagena Protocol negotiations, is Principle 15 of the Rio Declaration on Environment and Development (1992). It reads:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. 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.

basic elements of the precautionary principle

The precautionary principle, in essence, is about decision-making in the face of uncertainty. As numerous writers have articulated, "precaution is a means to explicitly recognize fundamental, empirical short-comings in science." Sandin (1999) notes that the principle contains four essential points: if there is a 1) threat, 2) even in the face of scientific uncertainty, then 3) some kind of action 4) is mandatory. This is how we might view the formulation of the principle in the OSPAR Convention. Another way the principle is often phrased is: if there is a 1) threat, then 2) actions taken by governments 3) should not be postponed 4) even in the face of scientific uncertainty about the extent of

[1] Convention for the Protection of the Marine Environment of the North-East Atlantic, art. 2(2)(a), September 22, 1992, reprinted in 32 I.L.M. 1069 (1993) (entered into force March 25, 1998)

the potential adverse effects. This latter formulation is similar to the principle as found in Articles 10.6 and 11.8 of the Cartagena Protocol. Article 11.8 (dealing with imports of commodities such as maize) reads as follows (basic elements are highlighted):

> ***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 that living modified organism intended for direct use as food or feed, or for processing, ***in order to avoid or minimize such potential adverse effects***.

For many authors, the precautionary principle exists on several levels. It is, as noted above, a framework for decision-making, for advocating or permitting action in the face of scientific uncertainty if faced with serious or irreversible threats to the environment or human health. It is also seen as:

> a paradigm to resolve some of the tensions inherent in translation of scientific knowledge into policy,… a means explicitly to recognize fundamental, empirical shortcomings in the science applied to decision-making process, … an overarching principle to guide decision making in the absence of analytical or predictive certainty. (Santillo *et al.* 1998)

precaution and risk assessment

Why would governments be interested in invoking the precautionary principle when making decisions about genetically engineered organisms? We are led to believe in chapter 8 that ecological risk assessment is an adequate method for determining the risks of GMOs. Further, decision-makers are assumed to have all the information needed from the risk assessment process in order to weigh benefits and costs and to manage whatever risks might be posed. However, methods currently used to assess risks of GMOs may in fact not be able to provide decision-makers with an adequate amount of information on the impacts of GMOs at this point in time. Certainly this is the conclusion of chapter 4 regarding the impacts of transgenes on Mexico's natural ecosystems.

Risk assessment as a discipline has its roots in the structural and product engineering fields, whereby technocrats sought to determine probabilities of structural collapse or product failure. Risk assessment has since been adapted for a number of purposes, including the impacts of chemicals on human health, and most recently ecological impacts of chemicals and other potential environmental stressors.

There is an ongoing debate in the risk assessment field over whether or not ecological risk assessment is able to provide adequate answers on the magnitude and consequences of risks being studied. (See for example Power and Adams 1997; Adams and Power 1997) Numerous papers over the past decade have been written on the limitations of ecological risk assessment, the majority of which deal with risk assessment of chemicals

in the environment. Santillo and Johnston (1999), for example, take issue with the fact that in the practice of risk assessment, effects are considered predictable, quantifiable and manageable:

> Risk assessments start from the premise that the *likelihood of adverse effects* in the field *can be quantitatively and reliably forecast and* that, subsequently, potential stressors may be *effectively managed* at levels of risk deemed acceptable. (emphasis added)

In the following sections, we provide more detail on critiques of risk assessment found in the scientific literature.

limits of ecological risk assessment

As mentioned above, the criticisms of ecological risk assessment are found predominantly in the literature on the environmental impacts of chemicals in the environment. Much of this literature actually comes from the field of marine pollution (remember the first instances of the precautionary principle in international law concern the prevention of chemical pollution in marine environments). In this large literature, one can find discussion of a number of methodological limitations of ecological risk assessment relevant to our discussion of genetically engineered organisms. The methodological limitations then limit and color the information available for decision-making. The following is not meant to be an exhaustive list:

- In ecological risk assessment, as in chemical risk assessment, the endpoints that can be studied are limited to quantifiable, major effects, such as lethality or cancer, and to effects that can be detected within the experimental time frame of the assessment. Effects that are difficult to measure are often ignored in chemical risk assessment:
    - altered behaviour,
    - reduced learning ability,
    - immune system impacts,
    - reduced fertility,
    - altered development time,
    - species shifts.

  These types of sublethal effects may be very significant at the ecosystem level, and often develop over much longer time frames than a risk assessment can measure. (Suter 1994; Johnston *et al*. 1998) There are, of course, similar kinds of difficult to measure impacts of GMOs that could have ecological significance. (see chapter 4) We could certainly say the same for impacts on landrace and wild relative genetic diversity.

- The measurable time frame of a risk assessment is necessarily short-term, but impacts show up over much longer time scales. For example, scientists have looked through records of plant introduction and weed development and note that this process occurs on time scales of 30-150 years. (Johnston *et al*. 1998 ; ESA 2004)

- Test organisms are limited to those that are easily culturable or measurable; quite often these organisms are of limited ecological significance. Not all organisms can be cultured in the laboratory, nor can endangered species easily be tested for obvious reasons. This means that for chemical impacts on a soil ecosystem, effects on a small number of soil-dwelling organisms – earthworms and collembola – might be measured. These organisms are expected to serve as proxies for the entire ecosystem, as other organisms cannot be tested. Of greater ecological relevance would be an examination of impacts on soil microbial and fungal populations, because of the essential roles they play in the soil processes of nutrient cycling, decomposition, and making nutrients bioavailable for other organisms. (However, even if we could measure the changes in soil microbial diversity, our understanding of soil ecosystems is minimal – we know a minute fraction of the microorganisms that live in any particular soil – and current techniques are inadequate to provide meaningful data for assessing the significance of such population changes.) (Berg and Scheringer 1994; Cairns and Pratt 1989; Holdway 1997; Power and McCarty 1997)

- It is impossible to extrapolate to an entire ecosystem from effects shown through tests on single organisms. As a simple example, food web effects that might result from a reduction in the population of soil predators such as carabids cannot be predicted, nor longer term, downstream consequences of alterations in the food web. (Holdway 1997; Power and McCarty 1997)

- Uncertainty and ignorance are the dominant conditions in dynamic ecological systems.

general epistemological problems of ecological risk assessment

- **The complexity of ecosystems can't be taken into account.** There are parameters of ecosystems that are fundamentally unknowable because of webs of interdependency, multiple causalities, and feedback loops. (Berg and Scheringer 1994; Calow 1994; Calow and Forbes 1997)

- **What you can measure is not necessarily what's relevant**. The organizational levels of relevance – population, community, and ecosystem – are least understood. With risk assessment techniques, scientists can measure changes at the organismal and sub-organismal levels – but we want to be able to predict and prevent changes at the higher organizational levels. In many instances we may not be able to determine *a priori* what end points are even relevant for assessing impacts on these higher levels of organization, nor will the endpoints necessarily be conveniently measurable parameters. (Johnston *et al.* 1998; Power and McCarty 1997; Santillo *et al.* 1998; Santillo *et al*. 2000)

- **Lack of statistical power.** Type II errors – not detecting an effect when there actually is one – in ecological assessments can be common. Take, for example, the laboratory experimental evidence that showed a 30% reduction in fecundity

for lacewings feeding on Bt-crop-fed prey. Field experiments would not be able to provide enough statistical power to detect such a reduction. Statistical power for manageable field studies would limit you to seeing deviations of 200-300%. Sub-lethal effects with potential long-term consequences would routinely go undetected; lack of evidence of impact cannot be considered evidence of safety. From Underwood (1992): "Type-II errors are a serious problem for environmental management – and much more so than Type I errors. … not detecting impacts (Type II) is not precautionary." (Andow 2003; Holdway 1997; Marvier 2001, 2002; Peterman and M'Gonigle 1997; Underwood 1992)

- **Assumes that you can quantify risks**, now or sometime in the future. This is problematic with chemicals, where you can apply a measurable amount of a chemical to an organism to find a dose-response relationship (only with particular endpoints like cancer; exposure assessments are difficult). There is, of course, the added problem with GMOs in that you cannot establish any sort of dose-response relationship. It is impossible to derive quantitative relationships for many parameters of ecological importance. It is also impossible to quantify risks for those hazards that are completely unpredictable, or that derive in a complex, non-linear way. (Santillo *et al.* 1998)

    - A corollary to the assumption that risk can be objectively quantified is that non-quantitative, subjective factors only enter into the discussion at the risk management phase. This is clearly incorrect – for example, the choice of endpoints is not an objective, technical decision. Someone, based on subjective parameters, decides that cancer is an appropriate endpoint to test for and that developmental abnormalities are not.

- **Reduces risk to two dimensions – hazard and exposure.** Risk is, in fact, multidimensional. Sterling and his colleagues have explored this in some depth in their study for the European Science and Technology Observatory (1999). Appraisal of technological risk should be able to examine risk across multiple dimensions, moreover, the evaluation of diverse aspects of risk should not be relegated to the management phase of the process. Multiple dimensions of risk according to ESTO include: severity, immediacy, gravity, reversibility, spatial distribution, balance of benefits and burdens, fairness, public or worker exposure, intergenerational equity, voluntariness, controllability, familiarity, trust. These multiple dimensions are incommensurable – "they cannot be readily or unambiguously be reduced to a single measure of performance," a single articulation of "hazard." (ESTO 1999)

  Most importantly, "the relative priority attached to the different dimensions of risk is intrinsically a matter of subjective value judgment. These properties of multidimensionality and incommensurability are crucial and intractable features of technological risk." (ESTO 1999)

further thoughts on "uncertainty"

As should be clear from both the above discussion as well as the various chapters of the CEC report, "uncertainty" is the norm in evaluations of risks of GMOs. We can add to our understanding of this topic with a more nuanced look at types of uncertainty identified in the literature on risk. A very common approach to risk (Wynne 1992) identifies useful a taxonomy of uncertainty: risk, uncertainty, ignorance and indeterminacy (we do not address indeterminacy here).

> ***Risk*** is the condition under which it is possible both to define a comprehensive set of all possible outcomes and to resolve a discrete set of probabilities across this array of outcomes. This is the domain under which the various probabilistic techniques of risk assessment are applicable.
>
> ***Uncertainty*** is the condition under which there is confidence in the completeness of the defined set of outcomes, but no valid theoretical or empirical basis for assigning probabilities to these outcomes.
>
> In a situation of ***ignorance***, there not only exists no basis for the assigning of probabilities, but the definition of a complete set of outcomes is also problematic, that is, an acknowledgement of the possibility of surprises. (after ESTO 1999)

From ESTO (1999): "the unprecedented nature of genetic modification technology [is] such as to render ignorance and uncertainty (in their formal senses) the dominant condition in the management of … risk … The curious thing is that these are routinely treated in the regulatory appraisal of technology by using the probabilistic techniques of risk assessment."

If not risk assessment, then what?

This discussion is not meant to advocate tossing the baby out with the bath water. Ecological risk assessment, for better or worse, is an important tool in our toolbox to evaluate impacts of GMOs and to inform regulatory decision-making. But risk assessment is only a tool, and the decision-making process is ultimately a political process. As numerous authors have mentioned, the more transparent scientists are about the limits of their knowledge, the better informed decision-makers, including the general public, can be. And if indeed they are faced with the prospect of severe and irreversible consequences, decision-makers may well decide to take precautionary action, even in the face of significant uncertainty.

If not risk assessment, then what? How do you make your technological appraisal robust and useful, if you can't rely completely on methods of risk assessment? According to the European Science and Technology Observatory (1999): more humility, more scientific disciplines involved, more types of information and knowledge, more constituencies, and use of other systematic approaches to analysis, for example, multicriteria analysis and consensus conferences. As well, they include as essential to the evaluation process the

placing of the proof of burden on the advocate, and an openness to alternatives, a consideration of multiple options, rather than a single option in isolation. (see also Kriebel *et al.* 2001)

Given that at the end of an ecological risk assessment we are inevitably left with a great deal of uncertainty, decision-makers (or risk managers) are left somewhat in the dark. A risk assessment will hardly ever provide a decision-maker with unambiguous information for how to proceed. At that point, politics must prevail. The decision to undertake a particular risk, or to undertake unknown or unknowable risks, is always political – informed by science, but nothing more. For science can never determine how much risk is acceptable to any particular set of people, and the unknowability of ecological impacts means science provides much less technical information than a decision-maker would desire or require.

In the face of substantial uncertainty, decision-makers may look to specific characteristics of a particular technology that may cause them more caution. In the case of chemicals, decision makers around the world have identified several characteristics of concern: irreversibility, persistence, bioaccumulation, ubiquity. Persistent organic pollutants, that is, organochlorines and other chemicals that are long-lived, accumulate in body tissues, and have properties that allow them to be transported around the globe and to the far reaches of the Arctic and Antarctic have attracted the most attention; recently negotiations concluded on the Stockholm Convention on Persistent Organic Pollutants (POPs), where twelve such chemicals were targeted by the international community for eventual phase-out, and where an entire class of chemicals (POPs) singled out for concern. Under OSPAR, hazardous substances are defined as those that are toxic, persistent and liable to bioaccumulate. Governments have agreed to continually reduce discharges of hazardous substances to the North Sea, with the goal of eliminating discharges within one generation.

Persistence, environmental accumulation, potential for serious harm, and irreversibility – these are characteristics that the international community has singled out for concern – all characteristics that GMOs share with POPs.

implementing the Precautionary Principle: the Cartagena Protocol, the EC white paper, and the WTO

In its most simple form, the precautionary principle states what should be done in the situation of scientific uncertainty. Recognizing a lack of information is key, and so is taking precautionary action in the face of uncertainty, particularly when risks are long-term, serious, or irreversible. This of course entails a political decision that society values the preservation of the environment.

The principle in its purest form – consider Article 15 of the Rio Declaration – leaves out much of what has been frequently ascribed to the principle. For example, many writers also consider an alternatives assessment as part of the precautionary principle. An alternatives assessment may be key to decision-making that affords the greatest amount of environmental protection, and we certainly would not argue against its necessity, but

this is not part of any currently existing legal formulations of the principle. Another ascribed component of the principle is the reversal of burden of proof – that is, under the precautionary principle it is up to the proponent of the technology to provide *prima facie* evidence of safety. Again, no international legal formulation of the precautionary principle contains this requirement. However, in the implementation of the protocol within national decision-making apparatuses, this could certainly be incorporated as a regulatory requirement. It does not mean, though, that this is an essential element of the Principle.

To conclude this section, we look at three different international legal regimes that have something to say about when precautionary action might be taken: the European Union, the Cartagena Protocol, and the World Trade Organization.

operationalizing precaution: The European Commission's communication on the precautionary principle

In 2000, the European Commission published a white paper on the precautionary principle, laying out guidance to member states, and to the rest of the world, on how to operationalize the principle within the EU. (Commission of the European Communities 2000) We do not analyze the white paper at all here, but merely provide some statements from that communication relevant to our discussion:

> A decision to take measures without waiting until all the necessary scientific knowledge is available is clearly a precaution-based approach.
>
> An analysis of the precautionary principle reveals two quite distinct aspects: (1) **the political decision to act or not to act as such**, which is linked to the **factors triggering** recourse to the precautionary principle; (ii) in the affirmative, **how to act, i.e.,** the **measures** resulting from application of the precautionary principle. (emphasis in the original)
>
> The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible identifying at each stage the degree of scientific uncertainty.
>
> Judging what is an "acceptable" level of risk for society is an eminently political responsibility. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers.
>
> Whether or not to invoke the Precautionary Principle is a decision exercised where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection.

Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

- Proportional
- Non-discriminatory
- Consistent with similar measures already taken
- Based on an examination of the potential benefits and costs
- Subject to review
- Capable of assigning responsibility for producing the scientific evidence

The dimension of the precautionary principle goes beyond the problems associated with a short or medium-term approach to risks. It also concerns the longer run and the well-being of future generations.

risk assessment and precaution in the Cartagena Protocol on Biosafety

One of the obligations imposed on Parties by the Cartagena Protocol is the obligation to carry out a risk assessment prior to taking a decision. This obligation is found in Article 10, paragraph 1: Decisions taken by the Party of import shall be in accordance with Article 15 (the article dealing with risk assessment). This is in keeping with obligations under at least one other treaty, the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) – a side-agreement of the World Trade Organization.

But as we have described in a previous section, the results of an ecological risk assessment for a particular GMO (living modified organism – LMO – in Protocol language) may be extremely inconclusive. What then is a government to do? It clearly depends on the tolerance of a particular government to the potential risks posed by the GMO. As noted above, the Protocol provides guidance on the application of the precautionary principle in this situation.[2]

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[2] **The Precautionary Principle and the Cartagena Protocol**

It is instructive to look at the wording of the precautionary principle in the Cartagena Protocol. Relevant text is found in four places throughout the protocol:

> Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development. (preamble)
>
> In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements. (Article 1)
>
> 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,

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 in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects. (Article 10, paragraph 6)

In lay terms, the Protocol legitimizes actions to avoid or minimize such potential adverse effects, including a ban on the importation of certain GMOs.

the World Trade Organization and zero risk

In some situations of potential damage to the environment or human health, societies will decide to accept zero risk. Nothing in international law prevents a country from establishing a zero risk standard, as long as certain procedural requirements are carried out, such as undertaking a risk assessment and notification of trading partners in the case of a ban on imports of the risky product. The articulation of the right of states to set zero risk standards is found in recent jurisprudence of the Appellate Body of the dispute settlement framework of the World Trade Organization (WTO).

In *EC – Asbestos* (WTO 2001), the Appellate Body clearly stated that States have the right to determine the level of risk they consider appropriate. The issue at hand was whether France could ban the use of asbestos, which included banning imports of asbestos from Canada, based on health considerations. Canada challenged this action of the French government by filing a complaint at the WTO. In upholding the right of France to set a standard of ***zero risk*** for potential health effects related to the use of asbestos, here is what the Appellate Body had to say:

> (W)e note that it is undisputed that WTO members have the right to determine the level of protection of health that they consider appropriate in a given situation (para 168).

The original dispute settlement panel and the Appellate Body came to two other conclusions relevant to our discussion of precaution and uncertainty. First, the panel found that an absolute level of certainty cannot be required for a Member to take action

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with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects. (Article 10, paragraph 6)

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 intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects. (Article 11, paragraph 8)

under the GATT exceptions Article XX, second, the Appellate Body concluded that governments do not need to base decisions on majority scientific opinion. Here are the relevant paragraphs from their decisions:

> To make the adoption of health measures concerning a definite risk depend on establishing with certainty a risk … would have the effect of preventing any possibility of legislating in the field of public health. (WTO 2000, para 8.221)

> In addition, in the context of the *SPS Agreement*, we have said previously, in *European Communities – Hormones*, that "responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources." In justifying a measure under Article XX(b) of the GATT 1994, a Member may also rely, in good faith, on scientific sources which, at that time, may represent a divergent, but qualified and respected opinion. A member is not obliged, in setting health policy, automatically to follow what, at a given time, may constitute a majority scientific opinion. (WTO 2001, para 178)

Article XX is the exceptions article of the GATT and includes provisions for exceptions for measures taken to protect human, animal or plant life or health, and exhaustible natural resources; based on these decisions, we can expect measures taken to protect maize diversity will be accorded the same deference, as decisions by sovereign states on levels of protection they consider appropriate. In fact, a zero risk standard for Mexican maize contamination, and measures such as bans on the import of transgenic maize to accomplish that standard, would likely be judged WTO-legal.

2. Risks of GMOs

We can make the critique of risk assessment real and the discussion of precaution concrete by considering the ecological risks of GMOs. While the CEC report is intended to examine all potential impacts of GM maize – impacts on genetic diversity, on agriculture, human health, and natural ecosystems – we will concern ourselves here with impacts on natural ecosystems. Natural ecosystems are at the same time very complex and yet a simple topic compared to the complexities involved in peasant agricultural systems. We use them as an example, noting that this is just one of the dimensions of uncertainty surrounding the introduction of transgenes into Mexican maize.

If you investigate what we know about potential impacts of transgenes on natural ecosystems, you read a litany of statements about what we really don't know. As noted by the Ecological Society of America (2004), many of the ecological questions they raise have yet to be examined empirically. There is no need to re-state all these here, but for sake of example, let us take the case of impacts on non-target organisms as elaborated by

the authors of chapter 4. The potential impacts are extensive, and little to no research has yet been carried out to assess impacts that introduced transgenes might have on on non-target organisms in Mexican ecosystems.

Some of the general and specific impacts on non-target organisms discussed in chapter 4 include (these are all direct quotes from the chapter):

General impacts

- At an individual level, impacts of significance could include lethal and sublethal effects (e.g., effects on development time, reproductive characteristics, morphological characteristics)
- Impact on populations will depend on the consequence of effects on individuals and the variation of those effects. Sublethal effects on individuals may have impacts on the population growth rate, leading to small or inviable population sizes and to local extinction. Loss of genetic variation increases population or species risk of extinction.
- The presence or absence of populations or species within a community or ecosystem may have significant impacts on biodiversity, if the species provides a critical role in ecosystem dynamics. … (T)he removal or addition of a species or population may affect the function of an ecosystem, including nutrient dynamics and energy flow. Lastly, if a susceptible species is rare or has small populations, any mortality or sublethal impacts on its populations may exacerbate and existing high risk of extinction.

Specific impacts from a Bt gene

- Lethal and sublethal effects to non-pest species in these orders (Lepidoptera and Coleoptera) could produce changes in biodiversity within these orders, depending on the susceptibility of other species within these orders to Bt toxin and their exposure to the toxin. Indirect effects on community and ecosystem diversity could occur if other more distantly related species or taxon groups were connected witht these species through ecological relationships. For example, the abundance and diversity of the Lepidoptera could affect plant populations and species that depend upon butterflies and moths for pollination or could affect populations and species of predators that prey upon butterflies and moths. Predatory species could be impacted in two ways by impacts on Lepidopteran species. Alterations in abundance or availability of prey could alter abundance or diversity of predators, or Bt toxin in prey species could affect individuals, populations and species of predators susceptible to Bt toxin.
- Non-target effects could have implications for nutrient cycling and decomposition as well as plant pollination and abundance and diversity of prey and predator species depending upon Coleopterans.

The question then that must be asked is “so what?” Are any of these impacts likely to have serious or long-term irreversible consequences for maize producers in Oaxaca, for natural ecosystems, for species of special concern, and so on? We do not know.

What then do we know about engineered organisms? They are alive. They produce seeds. Farmers share those seeds. They can germinate on their own and live as weeds around agricultural fields. All this is to say that if there were a transgene that was a problem, there exist numerous mechanisms whereby that gene could persist in the environment, both in natural and farmer-managed ecosystems.

When ought we exercise concern? According to its recent position paper on genetically engineered organisms, the Ecological Society of America counsels:

> Long-term ecological impacts of new types of GEOs[3] may be difficult to predict or study prior to commercialization, and we strongly recommend a cautious approach to releasing such GEOs into the environment. Engineered organisms that may pose some risk to the environment include cases where:
>
> - there is little prior experience with the trait and host combination;
> - the GEO may proliferate and persist without human intervention;
> - genetic exchange is possible between a transformed organism and non-domesticated organisms; or
> - the trait confers an advantage to the GEO over native species in a given environment.

Clearly, maize with herbicide-tolerant and pesticidal transgenes, found in Mexico, fit most of these categories. Maize that contains pharmaceutical transgenes would also clearly fit these criteria. Additionally, the ESA recommends that "large-scale or commercial release of GEOs be prevented ***if scientific knowledge about possible risks is inadequate*** or if existing knowledge suggests the potential for serious unwanted environmental (or human health) effects." (ESA 2004) (emphasis added)

Significantly, the ESA makes comments similar to our regarding the limits of traditional risk assessment techniques to predict what the consequences of GMOs might be for natural ecosystems. For example, in the discussion on non-target effects, and risks assessment carried out to date on these effects, they conclude:

> Single-species studies of non-target effects represent a narrow approach to assessing the positive and negative ecological impacts of non-target effects. Understanding the ecological consequences of non-target effects also depends on accurately identifying what physical and biological processes a transgenic organism may alter, and understanding what impacts these alterations have on ecosystems. Much of the focus of non-target studies has relied on measuring changes in survival and reproduction of a limited number of focal species in laboratory and small-scale field studies, without addressing the potential for community and

[3] The Ecological Society of America uses the term genetically engineered organisms (GEOs) rather than genetically modified organisms (GMOs). The Cartagena Protocol on Biosafety uses the term living modified organisms (LMOs).

> ecosystem level effects after large-scale introductions. Negative non-target effects on one species or a group of species may cause a cascade of ecological changes that result in the disruption of biotic communities or in the loss of species diversity or genetic diversity within species …, or they may have no repercussions, especially in communities with high redundancy of ecological function.

Later in the document, the authors note that:

> Risk assessment that is carried out prior to commercialization has several inherent weaknesses. In general, small-scale, pre-commercial field experiments are not sufficiently sensitive enough to detect small or moderate effects of a GEO. Small-scale field studies will readily detect order-of-magnitude differences in an ecological effect, but less dramatic effects will be difficult to document due to variability among replicates. Adding more replicates can address this problem, but pre-commercial field studies are not likely to include the large amount of replication needed to identify small but important effects.
>
> Small-scale studies … may be insufficient and misleading, depending on the questions being asked and the statistical power of the data analysis.

A final conclusion from the ESA document: "***The scientific rationale for a precautionary approach to regulation should not be ignored amidst this controversy.*** (on precaution)… ***Simply put, precautionary actions have been justified even in the absence of clear scientific evidence that a hazard is likely to occur… these actions involve "scientific evidentiary standards that err on the side of preventing serious and irreversible health and environmental effects."*** (NRC 2002)**"**

3. Maize, GMOs and precaution

Maize in Mexico is an exceptional case to consider as we evaluate the potential impacts of GMOs. Mexico is the center of origin and diversity of maize; maize is one of the world's most important food crops. It would be difficult to overestimate the value to humankind of the crop and the genetic diversity of Mexico's maize landraces.

Maize also plays a central role in the culture of people's throughout Mexico. As proclaimed in the manifesto delivered to the CEC on behalf of many organizations and communities in Oaxaca: "We are people of maize. The grain is our brother, foundation of our culture, reality of our present. It is in the center of our daily life. … We eat it, but it is not only food. It is a cause for celebration, for exchange, for coexistence, for mutual help. It is our life. Maize is in the center of our culture, in that which has a sacred character. We don't want it to be otherwise."

Maize plays an important economic role in agricultural production, and indeed the life, of the peasant farmer. The farmer is dependent on production whether or not the crop is sold to the market. In fact, the subsistence farmer is perhaps even more dependent on the crop than those farmers with more links to the marketplace. He or she is likely producing on marginal lands, characterized by uneven terrain, high slopes, irregular rainfall, and/or low soil fertility. Poor farmers are more vulnerable to the vagaries of the weather and the market. Crop failures and negative impacts on agro-ecosystems will have more serious effects on those already living on the margins of existence. This point is also made in chapter 2 of the CEC report:

> Farmers who depend solely on their primary production for subsistence face much more immediate food security risks. Smallholder farmers in Mexico are dependent on their own production for food on the table and crop failures are a significant risk. … Long-term stability concerns the ability of the farming operation to continue over a period of years. Here, damage to agro-ecosystem function in the form of fertility losses can have economic as well as environmental consequences.

Mexico is one of the mega-diverse countries of the world, with an astounding diversity of plants, insects, other animals, ecosystems, fungi and bacteria. Ecological impacts on an ecosystem scale in Mexico may have consequences more far-reaching than those that might occur in the industrial corn-belt of the United States.

It is within this scenario that we must consider the possible impacts of GMOs, in particular, transgenic maize. Clearly there is much of value to protect, there is much of value to lose. And we know that with the open genetic system of *campesino* farmers in Mexico, there is little damage that we could prevent once transgenes are introduced into Mexican maize agriculture. Consider the scenario put forward by the authors of chapter 8; imagine that one or more of the transgenes mentioned codes for a drug or an industrial chemical:

> First, an uncontrolled diffusion of transgenes to non-transgenic populations may take place. Second, if varieties with different transgenes become available and are planted, it is possible that, due to gene flow and recombination, maize populations may end up harboring multiple transgenes. These combinations may include transgenes that were never tested together and could even include transgenes that should not enter the human food chain. Third, if transgenic varieties that have been designed and produced with several transgenes, which may or may not be linked, enter the system, the same process of recombination and migration may cause the multiple transgenes to diffuse… Fourth, the introgressed transgene(s) will be introduced into different genetic backgrounds – those of local maize populations – and since the expression of a gene depends on the genetic background in which it exists, the expression (or lack) of the transgene may be very different from the expression in the original phenotype.

Given all that we do not know about the potential impacts of transgenes in Mexican maize – impacts on culture, on genetic diversity, on natural ecosystems, on agricultural production in marginal environments, why would we take the step to introduce engineered maize into Mexico? Given that only a few small steps along this path will likely lead us down a road of no-return, why take the risk?

Bt cotton and precaution in the United States

The US Environmental Protection Agency (EPA) has had to address the question of gene flow into wild and feral species of cotton. Without admitting to it, they have implemented the Precautionary Principle – they have taken action to prevent gene flow even in the absence of scientific information that there is some harm that will result. In fact, one might conclude from their actions that they view gene flow to wild and feral species of *Gossypium* (cotton) as something to avoid – a pollutant, if you will. In their determination, the risks posed by gene flow to these cotton relatives are unacceptable.

In order to prevent hybridization of Bt cotton with Hawaiian cotton and feral populations of cotton in the Florida keys and on the Virgin Islands and Puerto Rico, the US EPA has instituted restrictions on the planting of Bt cotton in those areas. There is **no** planting of Bt cotton allowed in south Florida nor in the Virgin Islands. Only experimental uses (no commercial planting) of Bt cotton are allowed in Hawaii and Puerto Rico, with significant containment requirements. (USEPA 2001)

If such measures are taken to prevent gene flow to feral cotton in south Florida, surely the maize center of diversity is worth at least as much precautionary action.

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Comments to the NAFTA Commission for Environmental Cooperation Article 13 report

Maize and Biodiversity: The effects of transgenic maize in Mexico Comments on chapters 2 and 8

Submitted by Greenpeace, 12 April 2004

We provide here comments on chapter 8 of the CEC draft report on transgenic maize. We also address briefly chapter 2.

In a separate document we provide detailed comments on three topics that are not adequately addressed in this chapter: the precautionary principle, specific risks of GMOs relevant to risk assessment, and the specific case of GMOs and maize.

Comments on chapter 8

a. The chapter would benefit from a careful review and standardization of terminology. There is a huge amount of conflation to terms in the chapter that must be clarified in order for any of the discussion to make sense. For example, the word assessment is used in various ways – to describe the process of determining risks, but also in a more general way meaning judging risks and benefits. The first paragraph of the abstract also reflects this terminological chaos.

Risk optimization and prior informed consent are characterized at various times as philosophies, principles, orientations, methods or approaches to assessing risk. They are probably none of these. Rather risk optimization, prior informed consent, and the precautionary principle may be considered ***frameworks*** for decision-making. The author of chapter 2 calls them "strategies in risk management" or "philosophical approaches" to risk management. The decision frameworks differ in terms of a number of variables: who makes decisions and whose opinion matters, different mechanisms for involvement of affected parties; what kind of information is relevant to the decision process; what kinds of information is balanced during decision-making (cost-benefit, ability to opt out of risk). ***These frameworks/strategies all rely on techniques of risk assessment to provide information for that decision-making; precautionary approaches to decision-making are also dependent on risk assessment for information.***

Whether or not a society is "democratic" is by and large irrelevant to the discussion in section 8.2, and the section should be given a more appropriate title.

b. The tone of the chapter is at times very condescending – expert opinion is clearly the most important information for the decision-making process in the eyes of the authors. There is no reflection of some of the most basic conclusions of chapter 2 in the chapter.

For example in chapter 2, the author notes that whether a transgene "in the wrong place" is already a harmful event or whether it needs to have demonstrable adverse impact before it can be considered harmful, "***is not the sort of question that the biological sciences are equipped to answer***." The authors of chapter 8 then indicate on page 21 that indeed, biological scientists are equipped to answer that question and assert dismissively that "***this view of hazards*** (transgenes as contaminants) ***has been rejected by a number of scientific committees convened to review the risks of transgenic crops***."

The authors go on to state that farmers can have their own opinions, but only if "based on accurate information and sound reasoning." (p. 22) It appears that farmers can't think for themselves, but that peasant view of contamination "may be more related to the perceptions from other groups in society and to whether a stigma is associated with transgenes." (p. 22) Such condescending perspectives are hardly likely to engender trust in the scientific community.

Chapter 2 goes on to explain what some consequences for this type of behavior might be. On page 14, Thompson states:

> It is also worth noting that when people feel that their values and concerns have been subverted in a systematic way, there is the potential for fairly widespread damage to public confidence in public and private institutions… When scientific studies are used to legitimate such actions, the upshot may be a decline in public support for science-based activities , or for the use of science to inform public decision-making.

The chapter 8 authors have apparently not even read some of their own words. On page 5 of chapter 8, the authors state that "it is thus almost always critical for people with a rich and locally informed understanding of the values, institutions and practices at risk in a given setting to be intimately involved in the process of ***identifying and conceptualizing risk***." That is, people – not just scientists – should be involved in identifying what exactly a hazard may be in any particular situation. In the case of maize contamination, a transgene in the wrong place may indeed be what people determine as the hazard itself. This is certainly the message that came from the Oaxacan community members during the public forum. That ***community members have an essential role to play in identifying and conceptualizing what is at risk*** is an important message from chapter 2.

Chapter 2 ends with a final comment on this point.

> Failure to note a category of risk that is extremely important to one group of affected parties can either bias the results unfairly, or can undermine the credibility and legitimacy of the entire effort to base decisions on a scientific assessment of risks. Such sources of significant … bias may arise when technical experts more accustomed to analyzing risk as a form of decision support are enlisted to prepare documents that have a more ambiguous and less easily controlled function. …

> This report itself … may reflect existing practices utilized in risk analyses designed for much narrower advisory purposes more than it reflects a complete or balanced compendium of the benefits and risks relevant to open-ended political decision making and debate.

The authors should really re-read chapter 2 and revise the chapter accordingly.

c. Sections 8.3 through 8.6 have some technical problems, some of which result from the improper use of terminology. The paragraph in the abstract that describes these sections is the most problematic:

> Methodologies based on risk optimization have traditionally been used to assess transgenic technologies around the world. Elements of the informed consent approach have also been employed. The precautionary principle has gained prominence, particularly with the ratification of the Cartagena Protocol on Biosafety by many countries, including Mexico. Risk optimization methodologies rely to a great extent on the scientific method and on scientific evidence, but also involve assumptions, value judgments, and uncertainty.

There are two serious inaccuracies in this paragraph:

- Methods to assess transgenic technologies are not based on risk optimization. As noted above and in chapter 2, risk optimization is a management framework. So neither have "elements of informed consent" also been employed in risk assessment. The description of risk assessment in section 8.3 is more or less accurate and appropriately doesn't mention anything about risk optimization or informed consent.
- All management methods rely on the scientific method and on scientific evidence. The precautionary principle and informed consent also rely on the scientific method and on scientific evidence. It doesn't make any sense to single out risk optimization methods of decision making as relying on science.

8.3 the risk assessment approach: overview of distinct methodologies for RA and approaches/models for RM.

The title here is not correct. This is not actually an overview of distinct methodologies for risk assessment, nor does it discuss approaches/models for risk management. It lays out in a general way the common steps used in traditional risk assessment approaches. It addresses some critiques and shortcomings of risk assessment but not in any sort of systematic way and with little to no reference to existing literature. The risk management section provides little information. We provide some further discussion of risk assessment in a separate document on the precautionary principle.

Value judgements in the discussion, such as "whether this popular conception should be adopted by policy-makers is, however, not all certain" (p. 8) are inappropriate.

Some discussion of why other dimensions of risk (p. 9) are not taken into consideration during the risk assessment phase would be appropriate.

8.4 assumptions behind methodologies for risk assessment and approaches/models for risk management

This is a completely inaccurate title. These are some assumptions made by some scientists and some regulators in some agencies in some countries. They are not assumptions behind risk assessment methodologies, nor are they assumptions underpinning models of risk management. They are not general assumptions at all, but specific assumptions by a specific set of individuals, about how they think about transgenes "out of place."

In particular, the treatment of assumption 1 disregards a whole realm of the scientific literature, as well as some of the chapters in this report. It ignores the conclusions of the Ecological Society of America (ESA) in its recent position paper on genetically engineered organisms. (Ecological Society of America 2004) To be at all accurate, this assumption must be highly qualified in its presentation. Moreover, use of a single citation (Crawley 2001) to conclude that "current evidence supports the familiarity model" is a rather bold overstatement of what those data actually show.

assumption 2 – This assumption is qualified in the recent ESA position paper. "We reaffirm that risk evaluations of GEOs should focus on the phenotype or product rather the (sic) process of genetic engineering…, but we also recognize that some GEOs possess novel characteristics that require greater scrutiny than organisms produced by traditional techniques of plant and animal breeding." (Ecological Society of America 2004)

assumption 3 – It's not clear why there is so much text devoted to this assumption. It is almost a truism that there is no way to demonstrate absolute safety. All technologies may carry some risk; it is a political decision for a society to determine whether it wants to accept that risk, in part or at all.

8.5 uncertainty and irreversibility in decision-making

Scientific uncertainty should be dealt with first in the section on risk assessment. There are many ways that traditional techniques of risk assessment can generate uncertainty and these should be included in any discussion of risk assessment. The types of uncertainty described here are some types of uncertainty that are described in the literature, but this is certainly not an exhaustive list and does not reflect an academically rigorous approach (nor does this section include a single citation).

It is not clear from the chapter exactly how uncertainties are integrated into decision-making. Uncertainties that result from the risk assessment process are certainly important to the decision-making process, regardless of the framework chosen for making decisions, and this point should be clarified.

At least two claims in the section are incorrect:

- "Lack of evidence of adverse effects at the organismal and population levels in small-scale trials is a good indicator that no adverse effects are likely to occur at the community and ecosystem levels."
- "Experimental data from field trials of transgenic organisms have increased the level of confidence in the technology."

Neither of these claims are supported by either the discussion in chapter 4 of this report, nor by the Ecological Society of America (2004).

Straw men and hyperbole (current evidence does not point to potential global calamities – p. 14) are inappropriate to this discussion.

Regarding social uncertainty – if this topic is to be addressed, there should be some academic foundation to the discussion and some reference to published literature. As it is written now, it seems to be used as a mechanism to cast as inferior those parts of society that don't really know what the risks of GMOs are and therefore irrationally judge GMOs as risky.

Irreversibility is never discussed in this section, so should be eliminated from the title.

8.6 the special case of Mexico and implications for risk assessment and management

At least one more sub-section should be added here. There is little assessment of the potential risks of transgene contamination outside of the agricultural context, in particular touching on issues raised in chapter 4 and chapter 7, in light of the specific conclusions found at the bottom of p. 18. This is a huge lacuna in the chapter. The specific case of introgression of pharmaceutical transgenes in a center of diversity needs to be addressed.

8.6.6 assessing benefits

Two comments regarding baselines. First, the discussion of the first baseline on p. 24 is completely inappropriate with respect to Bt genes in Oaxaca. There is no target insect and hence no current pesticide use to control the target insect. How any of this information could be useful in an evaluation of the broad range of impacts of a contaminating transgene in Oaxaca is not explained.

In addition, the human health and natural ecosystem baselines need to be included in section 8.6.6 on page 24.

Finally, it seems that the authors are treating irreversibility as a problem in itself, and cavalierly dismissing the issue with the statement that "humans constantly make decisions that lead to … irreversible consequences." Actually, what is relevant to this discussion is what it is actually that is irreversible, that is, the severity of the threat, the value of the resource that is damaged, and so on. Planting a garden in your backyard is irreversible, as is paving your driveway. These are not the kinds of effects we are worried about here. Irreversible contamination of maize landraces with a pharmaceutical transgene is. We don't imagine the authors mean to so cavalierly dismiss this potential

threat; the chapter should discuss the problem of a pharmaceutical transgene as a contaminant of landraces and the center of diversity in the context of its discussion of irreversibility.

8.6.7 balancing benefits and risks.
None of the risk management strategies introduced in chapter 2 have been discussed; we had thought this was to be one of the central pieces of the chapter. It is merely asserted, without discussion, that a precautionary approach should be considered together with a risk optimization approach. Then the precautionary approach is dismissed in the next sentence. We attempt to add significantly to this analysis with our accompanying contribution on the precautionary principle.

8.9 Conclusions

We do not agree that available methodologies for risk assessment are adequate for the case of transgenic maize in Mexico. We elaborate on this point in our document on the precautionary principle.

Comments on chapter 2

Two additional references should be included in the discussion. Charles Benbrook reviewed US pesticide use data from 1996-2004 and found results different from those cited in the CAST report. Also, in February, the Ecological Society of America published a new position paper on genetically engineered organisms and the environment that has some bearing on the issues considered in this report. Both citations are below.

One final comment, on page 11 the author felt the need to qualify risks with potential benefits. If this is done in the section on environmental risks, then a similar qualification on risks could be added to the benefits section. Either the sections should be balanced, with a paragraph in each (e.g., for completeness, it is important to reiterate that there is also the potential for offsetting environmental risks that correlate with each of these categories of environmental benefit) or each of the sections should be left solely to reflect what is in the title.

Benbrook, C. 2003. Impacts of genetically engineered crops on pesticide use in the United States: The first eight years. BioTech InfoNet, Technical Paper Number 6. Sandpoint, Idaho: Benbrook Consulting Services. www.biotech-info.net/highlights.html#technical_papers

Ecological Society of America. 2004. Genetically engineered organisms and the environment: Current status and recommendations. Ecological Society of America position paper on genetically engineered organisms. 26 February.

Comments to the NAFTA Commission for Environmental Cooperation Article 13 report

Maize and Biodiversity: The effects of transgenic maize in Mexico Comments on chapter 10

Submitted by Greenpeace, 12 April 2004

We would like to make three brief points regarding this chapter.

1. First, we underline the citation in chapter 10 of the Cartagena Protocol, Article 11.8, where the precautionary principle is articulated in the text of the agreement. This article in fact deals with imports of commodities. The provision in question clearly says that (excerpting): "lack of scientific certainty… shall not prevent that Party from taking a decision… with regard to the import of that LMO… in order to avoid… potential adverse effects."

This is a clear reference to the possibility of a country banning the import of an LMO – even in the situation of scientific uncertainty – that is, taking trade-related measures in a precautionary way to avoid potential impacts.

2. Second, we note that even the Mexican government has recently announced a ban on cultivation of certain types of maize (producing drugs and industrial chemicals) in Mexico – not just areas free of such transgenics. We call attention to the curious fact that the government has gone further than the chapter authors in what they suggest as necessary measures to take to prevent contamination of Mexican maize.

We quote here the English translation of the Mexican government announcement (Statement by México on transgenetic maize with properties that limit its consumption as food):

> Being a center of origin and diversification of maize, México
> - Paying due attention to the reproductive biology of maize as an open-pollenization (mainly subject to wind) crop;
> - Considering the dynamic character of the traditional farming systems regarding seed exchange and gene flow between local varieties and varieties originated in several geographical regions;
> - Reaffirming the importance of conservation and sustainable use of that resource and biodiversity, and
> - Understanding the strategic nature of the crop as food for the Mexican people;
>
> Manifests
>
> That has decided not to allow the release to the environment of genetically modified maize that has been modified in such way as to be no longer suitable as food. That is, México prohibits both experimentation and

> release to the environment of maize that has been modified to obtain pharmaceutical products, vaccines, industrial oils, plastics, or any modification that limits or affects its properties as food.

3. Given precedent in international and national law, it is difficult to understand how it a chapter that is supposed to be a comprehensive look at management options should leave out the potential for a ban or moratorium as possible options.

However, the chapter authors are well-known promoters of biotechnology. One of the authors is a well-known critic of México's moratorium on field trials of transgenic maize. One of the authors is a well-known advocate of US agricultural biotechnology, including transgenic maize, and was flown in to be a speaker at the official US government press conference announcing its WTO complaint against the EU.

Certainly all the chapter authors write from particular political positions. However, the lack of even a mention of bans or moratoria as management options at the very least displays a significant lack of academic rigor. The very grave problem here is that the CEC has a general obligation to member governments, petitioners, and civil society at large to present the entire range of management options in an unbiased way. The significant bias presented by the chapter authors does nothing to enhance the credibility of the CEC, the report, or the process and, in fact, does a great deal instead to damage their credibility.

The chapter authors have not taken a comprehensive look at all potential measures to manage risks; their ideological affiliations have clearly stood in the way of their ability to present an appropriate final chapter. The chapter does not belong in this report. The CEC should commission another chapter to take its place or risk challenging the legitimacy of the entire report and process.