

Biosafety Protocol Issues Paper

*Prepared by the Canada Grains Council's Biosafety Grain Trade Committee
Approved by Canada's grain industry February 12, 2001*

Introduction

The Cartagena Protocol on Biosafety may have significant impact upon the international grain trade. This paper outlines the major issues, discusses the background and provides detailed recommendations.

The Protocol was adopted by the Conference of the Parties to the Convention on Biological Diversity in Montreal on 29 January 2000. It was opened for signature in Nairobi on 24 May 2000 and will remain open for signature in New York until 4 June 2001. To date about 80 countries have signed. The Protocol will come into effect 90 days after ratification by the 50th country, expected sometime in 2002.

The Protocol is designed to provide an adequate level of protection for the safe transfer, handling and use of living modified organisms (LMOs) produced through modern biotechnology to ensure the conservation and sustainable use of the world's biological diversity. It is not designed as an instrument to protect food safety. However, as an environmental instrument, it is designed to protect human health from adverse effects caused by changes in biodiversity brought on by the introduction of LMOs into the country. The Protocol defines the procedures to be followed in the trans boundary movement of LMOs. The procedures vary depending upon whether the LMO is to have a contained use, or is to be intentionally released into the environment or is to be used for feed, food or processing (FFPs). Pharmaceutical products are exempt.

In many instances the Protocol is vague, with further details to be determined later. For example, Article 18 on Handling, Transport, Packaging and Identification states that each Party shall take measures to require that documentation accompanying "living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment and a contact point for further information." It adds that the Parties to the Protocol "shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol." Thus in this instance one may argue that the 'may contain' requirement comes into effect immediately upon the Protocol's ratification but the detailed requirements specifying the LMO's identity will be determined later.

An Intergovernmental Committee on the Cartagena Protocol (ICCP) has been formed to prepare for the Protocol's implementation. The first meeting of the Committee (ICCP-1) was held in Montpellier, France during December 2000. The second meeting (ICCP-2) will be held in Montreal 1-5 October 2001.

Because of the Protocol's vagueness, the key to its impact upon the international grain trade will depend upon how it is implemented. Therefore the work being done by ICCP is critical. All Members of the United Nations are members of ICCP. Hence the United States, which could not participate directly in the negotiations leading up to the Protocol because it had not signed the Convention on Biological Diversity, can participate in ICCP meetings focusing on the Protocol's implementation. Once the Protocol is ratified, ICCP will terminate, leaving the responsibility for implementation to the Meeting of the Parties of the Protocol, made up of those countries ratifying the Protocol. It is important therefore to resolve outstanding implementation issues wherever possible before the Protocol is ratified.

The Canada Grains Council has formed a Biosafety Grain Trade Committee to advise the Government of Canada on how best to implement the Protocol to meet the needs of Canada's grain industry in international trade. At an industry meeting in Ottawa on 5 December 2000, the Committee was asked to prepare a "Biosafety Protocol Issues Paper" outlining each of the major issues and providing recommendations on how each issue should be resolved.

The following issues have been discussed:

- Harmonization of LMO Definitions
- Posting to the Biosafety Clearing House
- LMO Testing Methods
- Tolerance Levels and Adventitious Materials
- Documentation Requirements
- Liability and Costs:
- Precautionary Principle
- Capacity Building

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The papers were reviewed and revised at a Canadian Grain Industry Biosafety Protocol Workshop in Winnipeg, Manitoba on 12 February 2001.

Issue: Harmonization of LMO Definitions

Background:

The UN Protocol on Bio-Safety uses the term living modified organism (LMO). It is defined in Article 3 of the Protocol as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology”. A living organism is further defined as “any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.” Modern biotechnology is defined as “the application of in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family.”

The Protocol identifies five categories of LMO:

1. LMOs for Pharmaceuticals for humans (which are excluded from the Protocol);
2. LMOs in transit (which are not subject to the core provisions on import);
3. LMOs for contained use (which are not subject to the core provisions but are subject to documentation requirements)
4. LMOs for intentional introduction to the environment (which are subject to provisions in the Protocol specific to this use); and
5. LMOs for direct use as food, feed, or for processing (which are subject to provisions on import and documentation specific to this use).

The Protocol also provides for the establishment of a Bio-Safety Clearing House (BCH) to facilitate the exchange of scientific, technical, environmental and legal information on and experience with LMOs. All decisions made under the Protocol, or under domestic legislation implementing the Protocol are to be posted on the BCH. It is through the BCH that countries will be made aware of the LMOs in production in an exporting country. It is also through the BCH that importing countries will post the LMO approvals for import. It will become the core source of information for exporters and importers to determine whether, or not, a LMO has been cleared for its first trans-boundary movement into the country of import.

Outline of the Issue:

Canada established guidelines for the food, feed and environmental assessment of novel traits in 1994. A plant with a novel trait (PNT) was defined within those guidelines as any “plant possessing a characteristic not normally present in a distinct, stable population of a cultivated species in Canada, which has been intentionally selected, created, or introduced in a population of that species”. The process used by the developer to introduce the novel characteristic is immaterial in Canada’s guidelines. Hence, any form of traditional plant breeding techniques, biotechnology techniques, or modern biotechnology techniques would qualify as a PNT in Canada when a novel characteristic is the result of the breeding procedure.

Canada’s guidelines are “product based” but the UN Protocol is “process based”. The product based guidelines in Canada has resulted, and will continue to result, in PNTs that would fall outside the Protocol’s definition of a LMO. Nevertheless, Canada has a number of web sites providing information on PNTs approved in Canada which is available, across the Internet, to the rest of the world.

The expectation for the operation of the BCH is to have an electronic database that is made possible by electronic linkages to individual country databases. Some suggestion is included within UN Protocol documents that many industrialized countries already have databases that the BCH could link into. However, if any of the existing Canadian databases for PNTs were linked to the BCH, it would provide

erroneous information because it would be providing product based PNT information rather than the required process based LMO information.

The broader scope of the Canadian guidelines would, if the BCH was linked to existing CFIA databases, result in misleading and false information to importing countries accessing the BCH. It could result in delays and information requests in regard to PNTs developed through technologies outside the definition of a LMO.

Recommendations:

1. It is essential Canada (and all countries) develop a database specific to the requirements of the UN Protocol on Bio-Safety. A database that deals only with the PNTs approved in Canada fitting the Protocol's definition of an LMO is required and must be clearly titled accordingly. Once established, it is the only database that would be linked to the BCH. It should also serve as the only database serving the needs of other international agreements such as Codex Alimentarius, the OECD Seed Scheme, and labeling regimes of other countries.
2. It is also essential Canada places a very clear disclaimer on all other Canadian databases dealing with PNTs (in CFIA) and novel foods (in Health Canada). This will help to ensure readers of the existing databases are made aware Canada's system is product based and is broader than the international definitions within the Protocol, Codex Alimentarius, OECD, etc.
3. The databases developed specifically for the purposes of the Protocol must state clearly that those databases relate only to the Bio-safety Protocol and its provisions. These Protocol databases need to meet the requirements of the Protocol but might not represent the total requirements of the importing country in regard to their food, feed and environmental safety guidelines. In regard to other existing databases that may relate to GMOs, PNTs, etc., it must be stated clearly on those databases that they do not relate to the Protocol and should not be referenced for purposes of the UN Protocol.

Issue: Posting to the Bio-Safety Clearing House

Background:

The Protocol provides for the establishment of a Bio-Safety Clearing House (BCH) to facilitate the exchange of scientific, technical, environmental and legal information on and experience with LMOs. All decisions made under the Protocol, or under domestic legislation implementing the Protocol are to be posted on the BCH. It is through the BCH that countries will be made aware of the LMOs in production in an exporting country. It is also through the BCH that importing countries will post the LMO approvals for import. It will become the core source of information for exporters and importers to determine whether, or not, a LMO has been cleared for its first trans-boundary movement into the country of import.

Canada must develop an electronic link to the BCH to post information on LMOs that have been approved in Canada.

Outline of the Issue:

The Canadian guidelines for plants with novel traits (PNTs) results in environmental reviews conducted under confined conditions well before the PNT actually enters unconfined release in Canada and certainly well before the PNT reaches commercial production. This would also be true of environmental review guidelines in several other countries.

Although a PNT may enter another country under confined release prior to having met the environmental assessment requirements in Canada, this would not be the case for LMOs for feed, food, or processing. Only once the PNT has obtained food, feed and environmental approval in Canada and has been developed into a plant variety suitable for commercialization would the potential for the PNT/LMO exist to enter international trade.

There have been examples in Canada, and they undoubtedly exist in other countries as well, where a PNT/LMO has received environmental approval for unconfined release at least two years prior to any commercial plant variety being developed for production. One such example is bromoxynil tolerant canola. That PNT obtained environmental clearance in February of 1997. However, it was not until February 2000 that a canola variety of the PNT was registered for commercial production in Canada. It would not have been until harvest of the 2000 crop that any production would have entered the commercial grain handling and exporting system. Clearly, this PNT was given environmental clearance in Canada 3 full years prior to its commercialization. When, however, would Canada have posted that PNT to the BCH? Any posting prior to commercialization in Canada would have sent misleading information to the BCH on the status of commercialization in Canada and the potential to have that LMO in shipments for food, feed, or processing.

A second example exists in Canada whereby a PNT was given environmental clearance and the PNT was never commercialized. A herbicide tolerant flaxseed PNT was given clearance for unconfined environmental release in Canada in May 1996. At the same time, a variety was registered in Canada called CDC Triffid. Because the Canadian flaxseed industry relies on exports markets to the USA, Europe and Japan and this PNT was never approved for food, feed and environmental clearance in those countries, the variety was never commercialized beyond pedigreed seed multiplication. Would this PNT/LMO be posted on the BCH as a LMO in production in Canada? Again, because of the lack of commercialization, it would be misleading to post this LMO to the BCH and potentially disrupt trade for a LMO that does not exist in commercial production for food, feed, or processing.

The example with flaxseed also begs the question of when does a LMO get removed from the BCH if it is no longer in commercial production.

Recommendations:

1. The BCH has the potential to provide Parties to the Protocol with useful and truthful information about LMO production in countries of export. To be truthful and not misleading, the BCH must be established with a number of windows to the LMO database of information.

Window #1: This window could house information related to LMOs that are under confined release assessment in a country. In this way, other countries would be provided with an early warning system regarding the future potential for that LMO to enter their country. In response, the country of import could initiate with the LMO developer confined trials within their country. This Window would serve to facilitate environmental reviews in advance of commercialization for food, feed, or processing. By doing so, it would also facilitate uninterrupted trade on the LMO once commercialized.

Window #2: This window could house information on LMOs with environmental clearance in the country of export but which are not yet commercialized. The delay in commercialization may be due to delays in food or feed approvals or may be due to the time required to incorporate the trait in a commercially viable plant for food, feed, or processing. This window would also serve to provide countries the knowledge that this LMO is nearing commercial production and, if Window #1 did not serve as an early warning system, having the LMO move into Window #2 should serve as that warning.

Window #3: This window would house the LMOs in commercial production in a country and hence, those LMOs that would probably be found in commodity shipments for food, feed, or processing.

Window #4: This window would house those LMO traits that are no longer in commercial production. Although this window may be a short list of products at present, as the science develops and new LMOs replace currently existing LMOs, the list would develop.

Issue: Capacity Building

Background:

Capacity building has been an important priority among developing countries, in particular among the least developed and small island states. Article 22 of the Biosafety Protocol states that “the Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol.” It adds “cooperation in capacity building shall include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety.”

The Global Environment Facility (GEF), the financial mechanism for the Convention on Biological Diversity, is named in Article 28 as the financial mechanism for the Biosafety Protocol. The GEF announced at the Montpellier meetings of the Intergovernmental Committee for the Cartagena Protocol (ICCP) that it has allocated \$26 million to support 100 countries to develop their national Biosafety frameworks and to facilitate the exchange of experience and best practices among developing countries and countries with economies in transition (former communist countries). This amount is to be reviewed in 2001 to incorporate the outcomes of the ICCP Montpellier meeting.

Several countries including Australia and New Zealand, Canada, Germany and Cuba submitted papers at Montpellier calling for capacity building action. Australia and New Zealand recommended that biosafety capacity building efforts be built on other international capacity building initiatives, particularly those related to quarantine policy and managing sanitary and phytosanitary issues. Canada suggested the development of regional agencies among developing countries with similar biodiversity to facilitate rapid development of the necessary expertise. Germany outlined capacity building requirements needed to implement the Biosafety Protocol including policy advice to “base government decisions, regarding the import of LMOs and LMO-FFPs on the precautionary approach as laid down in the Protocol, if necessary” and “to include socio-economic considerations into risk assessment.” Cuba called for an international workshop to facilitate developing countries and countries with economies in transition in identifying their specific capacity building requirements and to bring greater co-ordination among different capacity building initiatives being undertaken.

Outline of the Issue:

Considerable capacity building initiatives will be undertaken over the next two years to help developing countries gain the capability to administer the terms of the Biosafety Protocol. Priority will be given to those countries signing the Protocol, thus providing a significant enticement for developing countries to sign early.

Each country is being asked to develop a “list of experts” who could be available as resource people. Some countries, such as Germany, are offering considerable financial support. Environmental groups are asking that their resource people be included in the list of experts.

There is considerable risk that people with no or little commercial understanding will dominate the list of experts and thus these views will be exported to developing countries, island states and countries with economies in transition. While these countries do not represent a large segment of the international grain trade, it is important to recognise that there are 100 countries currently targeted to receive capacity building assistance and they will represent the majority of countries who eventually form the Meeting of the Parties to administer the Biosafety Protocol.

The international grain trade will benefit from a strong scientific capacity within developing countries to support risk management decisions.

Recommendations

1. Canada's grain industry should encourage Canada to take an active role in facilitating global capacity building efforts to prepare for the Protocol's implementation.
2. Canada should encourage global capacity building activities to be designed to ensure biosafety regulatory frameworks are compatible to international trade requirements.
3. Canada should encourage building on existing regional institutions as an efficient practical method to deliver capacity building initiatives to developing countries. This approach also recognizes that biodiversity challenges cross international boundaries.
4. Canada should encourage the adoption of the Australian and New Zealand recommendation to build biosafety capacity building upon existing international capacity building efforts, particularly related to quarantine policy and phytosanitary regulations. This approach builds on an existing commercial system.
5. Canada should provide leadership by focusing on the Protocol's objective to protect global biodiversity through targeting its capacity building support on those countries that are centers of origin to crops exported by Canada.
6. Canada should support the Cuban initiative to host an international workshop to identify, prioritize and co-ordinate capacity building activities and to use this occasion to articulate recommendations 2, 3, 4 and 5.
7. Canada's grain industry should prepare and submit to the Canadian Government a list of experts who would be able to assist developing countries in establishing biosafety frameworks and who would be knowledgeable about the commercial requirements of the international grain trade.
8. Canada's grain industry should encourage the international grain industry to provide their respective governments with a list of experts knowledgeable about biosafety and international trade.

Issue: Testing Methods

Background:

Article 18 2(a) of the Cartagena Protocol on Biosafety states that “ documentation accompanying Living modified organisms that are intended for direct use as food or feed, or for processing (i. e., bulk commodities), clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment”. Furthermore it is stated that,“ The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol.”

With reference to this article, as stated in an AAFC Discussion Document on the Protocol (July 17, 2000), “the federal government may use the period of negotiating detailed requirements as the time to discuss with other countries the establishment of tolerance levels, accepted testing methods, the scope of the documentation, and enforcement measures.”

In addition in Annex III- Risk Assessment- Methodology 9 (f) it is noted that “another point to consider is suggested detection and identification methods and their specificity, sensitivity and reliability”.

Outline of the Issue:

The “may contain” statement included in the protocol, with reference to movement of bulk grains, may lead to requests for more stringent documentation and identification requirements. This statement refers to movement of LMO bulk commodity and does not deal with the initial situation, which would be bulk shipments of conventional grain containing some LMO grain. In addition, there is an absence of defined thresholds for permitted amounts of admixtures of LMOs or foreign material containing LMO material. Undoubtedly, signatories to the protocol will eventually want to implement tolerance levels as a natural evolution of the protocol. Such tolerances will add an additional burden and cost to the grading system since highly sophisticated testing will be needed to verify that tolerances are being met.

Any agreement on tolerance levels must consider both the technical feasibility of testing for the agreed upon level (based on statistical sampling and the sensitivity of testing methods used) and the economic feasibility of testing (based on the cost of testing). There is major concern over the negotiation of tolerances because there are currently no internationally accepted methods capable of rapidly testing grain, for LMOs at low levels, in a working environment such as a grain terminal.

Consequently, standard international testing and sampling methods are critical to the Protocol's implementation. Testing will need to be performed at point of export and will only be effective if the method of sampling and testing are agreed upon. It is too expensive to correct problems if tests are conducted at point of unload.

Currently, there are no internationally acceptable and agreed upon testing procedures, which have been scientifically verified, available to test at loading for all potential LMO grains, dockage or foreign material that may be present in conventional shipments of bulk grain. Yet, the need for such tests is essential to the negotiation of any tolerance levels. Such tests are optimistically a minimum of one and up to three years away.

Will internationally acceptable, fast and economical methods be in place to test for LMOs at loading? If not then the grain industry may be in a position where they are required to meet tolerances that cannot be verified by scientifically accurate tests. Testing after the fact with slower methods is not acceptable. Note that it is very expensive to discharge loaded cargo and even more expensive to deal with out an of specification cargo which has sailed. Essentially, once the grain is on the vessel the die is cast.

Tests will need to be fast and inexpensive, and have a detection level that will allow for an effective application of whatever tolerance or specifications are established. As LMO varieties become

registered and commercially grown and as the need to segregate and meet customer tolerances increases, there will be an increasing need for verifiable quantitative LMO test methods. The need for LMO test methods will continue to increase with increasing attention given to the Protocol.

The need to test for the absence of any LMO, i. e., negative testing, will also be a major challenge and issue. In such cases, rather than performing a single test to confirm the presence of a specific event or inserted trait, a battery of tests theoretically would have to be used to show that a sample did not have any potential approved or unapproved events or inserted traits. A single test could be used to detect a protein or DNA segment if common to a group of approved events. However, as new events are approved with different DNA fragments and expressed proteins then more tests will be needed. All such tests need to be evaluated to ensure that they do not give false positives.

In essence, it is not possible to show that a sample or grain shipment is “free from” or has a “0” content of LMO grain no matter what testing methods are developed.

Both grain buyer and sellers must tie validated testing and associated sampling methods in with a clear understanding and acceptance of detection limits. For example, sampling of grain, a biological material, have associated uncertainties that result in testing errors. These errors are inherent characteristics of sampling and testing for LMOs in grain and they must be understood as testing is introduced to meet protocol requirements. There must be a balance between statistically based sampling plans, appropriate testing methodologies, costs, and the focus of the protocol, which is to protect biodiversity. In recognition of these issues, some risk may have to be assumed to achieve such a workable balance.

Recommendations:

1. Internationally, agreed upon testing procedures and statistically-based sampling plans, which have been scientifically verified, must be available before tolerance levels of LMOs in conventional grain shipments are negotiated. The most prudent approach may to have internationally accepted testing and sampling protocols in place before the protocol is ratified.
2. As part of the variety registration process, CFIA should be approached to explore the desirability of requiring developers of GM varieties to provide access to sequence information, antibodies or other information needed for the development of testing procedures.
3. Because of its relationship to testing needs, the “may contain” statement in the protocol that refers to “movement of LMO bulk commodity” must be clarified with respect to the prevalent present situation, which is bulk shipments of conventional grain containing some LM grain. It should be recognised, however, that for some grains (canola, soy, corn) there already is a much higher volume of traded LM commodity grain along with conventional grain.
4. Canada must play an essential role, both in the development of such methods, to ensure that they meet the needs of the Canadian grain industry, and in the international standardization of both the testing methods and sampling plans. It is recommended that the most effective means of meeting this goal is to enroll participation of key international associations including the American Association of Cereal Chemists (AACC), The International Association of Cereal Science and Technology (ICC), AOAC International and the International Seed Testing Association (ISTA). Canada has representatives who play key roles in these organizations and so would have direct input into the development of methods and sampling protocols. At the same time, the international aspect of these societies would hopefully facilitate acceptance of standardized protocols.
5. In the Canadian context, tests are needed, in 3-5 years, for implementation at the primary and at the terminal elevator levels. Development of testing capabilities in such a short time frame will necessitate research and development funding. The burden of these costs will fall to the farmer

and grain industry but they are not in a position to afford these costs. Consequently, the Canadian government should provide additional funding for the testing initiative to provide for staffing (research scientist, technical staff, education, secretarial/management support), equipment, operations/maintenance/licenses/legal, laboratory space and education/training. Part of this funding would be used to support collaborative testing through the above mentioned international organizations to verify testing and sampling methods and encourage their international acceptance to meet the needs of the protocol.

Issue: Precautionary Principle

Background:

Although the Cartagena Protocol on Biosafety is part of an international agreement dealing with the environment (the Convention on Biological Diversity), the Protocol contains provisions which intrude into matters covered by other existing international agreements, specifically trade issues. The Protocol focuses on the transboundary movement of LMOs resulting from modern biotechnology “that may have adverse effect on the conservation and sustainable use of biological diversity ...”. However, transboundary movement is also the concern of World Trade Organization agreements. Protocol articles, and their possible implications, introduce new questions concerning compliance with, enforcement of, or exemption from, existing WTO obligations in regard to risk assessment, sanitary and phytosanitary measures, among others. How do these Protocol provisions dealing with trade interact with national rights and obligations under the WTO agreements? The underlying cause for these questions is the recognition and status granted the “precautionary principle” by the Protocol to trade in LMOs.

A precautionary approach to decision making was approved at the 1992 UN Conference on Environment and Development. Principle 15 of this Rio Declaration says that “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.”

Precaution is also recognized within the Codex Alimentarius in which Principle 5 of the Working Principles for Risk Analysis simply states that “precaution is an essential element of risk analysis in the formulation of national and international standards in food safety laws.”

Because the Biosafety Protocol intrudes into international trade, in effect the Protocol introduces the precautionary principle (taken from environmental risk assessments and food safety regulations) into international trade, something existing WTO trade agreements based on scientific assessments do not recognize.

Outline of the Issue:

The Protocol is not clear concerning the relationship which is to exist between potentially conflicting environmental risks and trade obligations. The Preamble to the Protocol states that trade and environmental agreements should be “mutually supportive”, that the Protocol does not imply a change under existing international trade agreement obligations, but that the Protocol is not subordinate to other international agreements. Therefore, which takes precedence, the Protocol or WTO, should a dispute arise over an importer’s right to reject based on the precautionary principle contained within the Protocol, or an exporter’s right to insist on fair access based on no scientific evidence of harmful risk? A major concern is that references within the Protocol to the mutually supportive, non subordinate, and equal relationship between trade and environmental agreements is contained in the Preamble; whereas discussion about the introduction of the precautionary principle is contained within Article 1. Experience in international trade disputes suggests elements within the body of an agreement (ie. within the Articles) take precedence over elements mentioned only elsewhere (ie. within the Preamble).

Article 2 states that Parties are not precluded from taking “action that is more protective” than is called for in the Protocol.

Articles 10.6 (LMOs for deliberate release) and 11.8 (LMOs for direct use as food or feed) state, in effect, that Parties are not precluded from making a decision to reject importation of LMOs by the “lack of scientific certainty” that they pose an adverse effect.

“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 ...”

Article 26 introduces a new factor into risk assessments, “socio-economic” impacts on indigenous and local communities. Such impacts are nowhere defined and would appear to have little if anything to do with the environment.

Taken together, the precautionary principle introduced into trade relations by the Protocol (as described in Articles 1, 2, 10.6, 11.8, and 26) permits a Party to reject the importation of LMOs in ways not allowed in existing trade agreements:

- risk assessment using such non-science based factors as undefined socio-economic impacts;
- a lack of scientific evidence to support claims of potential adverse effects, whether environmental, health, or socio-economic, is no longer an impediment to rejection;
- “action that is more protective” is not precluded;
- and by this combination to avoid compliance with existing WTO scientific-based trade obligations.

Recommendations:

1. Since the Biosafety Protocol regulates trade in genetically modified seeds and crops, but employs elements from biological and environmental science, food and health safety; therefore all regulations proposed within the Protocol must be founded on sound scientific principles.
2. The relationship between the rights of Parties under national laws, WTO agreements, and the Biosafety Protocol must be clarified to avoid continuous, lengthy, costly, and confusing litigation. The potential for countries to use the precautionary principle within the Protocol to take trade decisions at odds with Sanitary, Phytosanitary (SPS) requirements must be clarified.
3. Assessment of “risk” to human health from “hazards” in food are to be distinctly identified and separated from “risk” to biological diversity arising from “hazards” engendered to the environment by LMOs. However, all assessments should require relevant scientific evidence, not vague “suggested” adverse effects which “may” occur. Science must “indicate” a risk exists.

Issue: Liability and Cost

Background:

Article 25 of the Cartagena Protocol on Biosafety pertains to the illegal transboundary movement of LMOs. It reads as follows:

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.
2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.
3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article 27 of the Protocol describes work to be done on liability and redress as follows:

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Outline of the Issue:

Issues of liability and cost, which are insufficiently addressed under the Protocol, are a major concern to the Canadian grain industry.

Under Article 25, if a transboundary movement of an LMO is deemed to be illegal, the Party of origin would have to dispose of the LMO at its own expense through repatriation or destruction. Therefore, without established tolerance levels, as well as standardised testing and sampling methods, exporters could face substantial costs in the event of adventitious co-mingling of non-approved LMO's in a shipment. Those costs could include sales contract penalties, a drop in value of the cargo as the exporter looks for an alternate market, additional freight costs, damaged customer relations, or the cost of possible repatriation or destruction.

Exporters are also at risk in the event that the illegal movement was the result of another's actions given the uncertainty around the definition of "Party of Origin". Article 25 requires a great deal of clarification with respect to determining who is the Party of origin. Questions arise as to whether a "Party" or government will accept liability for the actions of exporters, or does their liability concern only the posting of accurate information on the clearing house. As well, in the international grain trade there are many third party sales. It must be determined, for the purpose of the Protocol, who the Party of origin is in the case of a transshipment or resale, and at what point the liability passes from one party to another.

It is the position of the grain industry that liability passes upon transfer of ownership, and when this occurs a party is no longer responsible as long as they have met the testing requirements. It should also be noted that the more times ownership and liability is transferred in a transaction, the greater the need for testing and, as a result, the greater the costs.

The liability issues are particularly worrisome given that, according to Article 27, a process to deal with dispute settlement, liability or redress may not be finalised until four years after the first meeting of the Parties. It will be important that when the work on liability and redress is underway, that any proposed solutions do not contravene existing laws by which exporters and importers conduct themselves and to that end, there must be a thorough understanding of current laws. The Canadian grain industry must

establish a position on how, and under what agreement (the Protocol, existing agreements, or otherwise), they feel the issue is best addressed.

In addition to the potential costs of co-mingling outlined above, other issues of cost remain outstanding, particularly the cost of monitoring shipments for unapproved LMOs. When increased monitoring of a shipment is required by the market, usually a market premium is available to cover the additional costs. However, in the case of the Protocol where increased monitoring is the result of regulation, the cost will likely have to be covered by the exporter and will be pushed back to Canadian farmers.

There must be a clear understanding of the potential increase in costs to the Canadian grain industry and farmers from segregation and monitoring, including sample collection and retention. It is difficult to estimate costs until documentation requirements, tolerance levels and standardised testing methods are established. However, it is known that as tolerance levels decrease, the cost of segregation and monitoring increases exponentially.

An example of the potential cost of testing for the presence of GMO's in a non-GMO shipment, in a case where individual events are not approved for import in the EU is as follows¹:

Carrier	Tonnage (tonne)	Unit cost (US\$)	Total (\$ per tonne)
Truck (2 strip tests)	10	7	0.690
Barge (postage costs to send sample to lab)	1,396	15	0.011
Barge (quantitative PCR test)	1,396	370	0.265
Barge (additional qualitative test for 12 events non-approved for import in the EU)	1,396	900	0.645
Ocean vessel hold (quantitative PCR test at export location)	1,200	370	0.308
Ocean vessel hold (quantitative PCR test at import location)	1,200	370	0.308
Total			2.226

As the authors note, “If such testing is not done, the exporter takes the risk that his shipment may be refused at the importer’s facility if a test there shows that they are contaminated, even in small proportions, by unapproved varieties.”

Recommendations:

1. Work with the Government of Canada to seek clarification on the definition of the Party of origin under different grain sales and movement scenarios.
2. Develop a strategy on liability and redress, i.e., how, and under what agreement (the Protocol, existing agreements, or otherwise), the issue is best addressed.
3. Identify, and present to the Government of Canada, the potential costs associated with the requirements under the protocol, and identify options for cost-sharing.

Issue: Documentation

Background:

¹ Bullock, D.S., et al. “The Economics of Non-GMO Segregation and Identity Preservation.” Department of Agricultural and Consumer Economics, University of Illinois. October 21, 2000.

The Cartagena Protocol on Biosafety describes documentation requirements for three categories of LMOs as follows:

1. Food, feed, or processing (Article 18.2(a)): Documentation must identify (1) that they "may contain" LMOs, (2) that they are not intended for intentional introduction into the environment, and (3) a contact point. The detailed requirements are to be worked out no later than two years after the Protocol comes into force.
2. Contained use (Article 18.2 (b)): Documentation must identify (1) that they are LMO's, (2) handling, storage, transport and use requirements, and (3) a contact point.
3. Intentional introduction into the environment (Article 18.2 (c)). Documentation must (1) identify them as LMO's; (2) specify the identity and relevant traits and/or characteristics, (3) outline handling, storage, transport and use requirements, (4) include a contact point, as well as the importer and exporter; and (5) include a declaration that the movement conforms to the Protocol.

At the ICCP-1 in Montpellier, the decision was made for France and Canada to co-host an Expert Committee that will consider the types of measures required by Parties to meet their obligations under Articles 18.2(b) and (c). They are to report at the ICCP-2 (October 1-5, 2001 in Montreal). Discussion around Article 18.2(a) was kept out of the terms of reference for the Expert Committee despite the efforts by numerous countries to include it. The Expert Committee is expected to meet in Paris in mid-June.

It was also decided at the ICCP-1 that governments and international organizations would be invited to submit to the Executive Secretary information on current practices, rules and standards with respect to Articles 18.2(a), 18.2(b) and 18.2(c) prior to the meeting of the expert committee. The submissions are due by the end of March and will be summarised, along with "other relevant information" by the Secretariat and distributed back to governments.

Outline of the Issue:

Documentation requirements under Article 18.2(a) are a major concern for the Canadian grain industry. There is a potential that meeting Protocol requirements will be onerous for exporters and importers if additional documentation is required to accompany each shipment outside of standard business practices. It is unclear whether documentation related to Protocol requirements must accompany the actual shipment, or if it could be made available through the clearing house.

Other issues to be worked out with respect to documentation include the application of the Protocol to non-LMO shipments, thresholds for unapproved GMO foreign material unintentionally co-mingled in bulk commodity shipments, and the lack of information in the "may contain" statement.

Article 18.2(a) was a major point of contention in the negotiation of the Protocol and the breathing space for working out the detailed requirements that was incorporated into the provision was central to its acceptance. Omitting 18.2(a) from the Export Committee's terms of reference ensures that the discussion will not be accelerated beyond that intended in the Protocol, and allows more time to develop a Canadian position paper. However, the Expert Committee's work on Articles 18.2(b) and 18.2(c) may set a precedent for documentation requirements that may impact 18.2(a).

It is important that the grain industry experts be able to feed information into the Expert Committee's work through the Canadian expert and by being on the ground, because that work may significantly impact the Canadian seed industry and because it may set a precedent for commodity documentation requirements. The federal government will be asking the industry, along with environmental groups and others, for advice on Articles 18.2(b) and 18.2(c). This material will be included in a briefing book for the Canadian expert, yet to be named.

Although the details around Article 18.2(a) are not to be discussed yet, the invitation to submit information on current practices, rules and standards includes those related to 18.2(a). Therefore, the interpretation by the Executive Secretary and the presentation of the material at the ICCP-2 may bias discussion around 18.2(a). It will be necessary, therefore, to monitor and be able to respond to the information being submitted.

Recommendations:

1. Work with the Government of Canada to influence the Protocol Secretariat and the Government of France on how the Expert Committee Process on Articles 18.2(b) and (c) is organised and conducted.
2. Work with the Government of Canada to determine Canadian representation on the Expert Committee.
3. Work with other international trade organisations to co-ordinate a meeting of the international grain trade to facilitate the development of a common position before the ICCP-2.
4. Facilitate the development of appropriate background papers for the Expert Committee and develop a strategy for information sharing on the ground at the Expert Committee meeting in Paris.
5. Work with the Government of Canada on the submission of information on current practices, rules and standards with respect to Articles 18.2(a), 18.2(b) and 18.2(c).
6. Establish a strategy to ensure that information gathered under the Expert Committee process or the request for submissions do not prematurely accelerate discussions around Article 18.2(a).
7. Develop a strategy to address Article 18.2(a) documentation requirements.

Issue: Adventitious Material / Tolerance Levels

Background:

Article 18 2(a) of the Cartagena Protocol on Biosafety requires that provisions be implemented for the "Handling, Transport, Packaging and Identification" of certain living modified organisms that are intended for direct use as food or feed, or for processing.

With reference to this article, as stated in an AAFC Discussion Document on the Protocol (July 17, 2000), "the federal government may use the period of negotiating detailed requirements as the time to discuss with other countries the establishment of tolerance levels, accepted testing methods, the scope of the documentation, and enforcement measures."

Tolerance levels generally refer to the level of material that might be expected within a cargo of the same species. Adventitious is the term used to describe trace quantities of genetically modified material that is unintentionally present in the shipment.

Outline of the Issue:

As the acreage of unconfined commercial production of genetically modified (GM) varieties continues to increase, the amount of adventitious materials from all sources is directly related to the percent acreage planted to GM crops. A zero tolerance for events that are in crops that are widely grown in unconfined commercial production is not achievable.

Tolerance levels must take into account that there will always be trace amounts or background levels of adventitious material despite rigorous procedures for production and segregation. This consideration is included in the assessment for unconfined release.

Under the Biosafety protocol, the tolerance level applies only to living GM event and may be different from tolerance levels established for other purposes.

Generally the GM event is approved in the country where the crop species and varieties are adapted for production. The grains industry routinely transports the production to many countries where the crop is not grown. This will lead to adventitious levels being transported to countries where the event may not be approved.

The tolerance level will have a direct impact on the choice and cost of testing method.

The tolerance level will determine the method and extent of sampling. The "exporter", prior to shipment, using an agreed test method and tolerance level, must conduct the official test. All subsequent testing must be done using the same method and tolerance level. The grain trade refers to this as a "certificate final."

If the tolerance level is very close to the actual level found in a shipment, the tolerance level for subsequent testing must be higher in order to avoid random rejection of shipments due to sampling variation.

Recommendations:

1. The initial approval for unconfined release of an event must include assessment of the event moving at adventitious levels throughout the handling system.
2. Countries must undertake a harmonized approach to approving events that are widely grown in unconfined commercial production. Otherwise a zero tolerance for adventitious unapproved events may apply which is unachievable in commodity shipments.
3. Tolerances must be internationally harmonized with the sampling and testing methodology.
4. Tolerances must be set at a level that is within the means of the production and handling system to achieve, given reasonable isolation and segregation procedures.

- If the tolerance level is very close to the actual level found in a shipment, the tolerance level for subsequent testing must be higher in order to avoid random rejection of shipments due to sampling variation.