

# Mixed Messages

**Canada's domestic regulatory system for GEOs  
contradicts basic principles underlying the  
Cartegena Protocol on Biosafety**



**Canadian Institute for Environmental Law and Policy**  
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## Canada's domestic regulatory system for GEOs contradicts basic principles underlying the Cartagena Protocol on Biosafety

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**CANADA IS A SIGNATORY** (April 19,2001) to the Cartagena Protocol on Biosafety (or Biosafety Protocol or BP) and participates in the working groups designed to further its implementation<sup>1</sup>. Although the Biosafety Protocol is intended to govern transboundary movement of Living Modified Organisms (LMOs), domestic GE regulatory systems are intertwined with the provisions of the Protocol. It will be difficult, given global trade in food, for any nation to fully implement its commitments under the protocol, or avoid export losses, if the principles underlying its domestic regulatory system are fundamentally at odds with the principles of the Protocol. But this is the situation currently facing Canada. Several concepts that underlie the BP are at odds with the central tenets of Canada's system for regulating GEOs. These contradictions revolve around the precautionary approach, the role of sound science in risk assessment, and identification of LMOs to be used directly for food, feed or processing. Contradictions of the first two principles, we believe, will have significant consequences for export and for Canada's reputation as a participant in international agreements. Contradiction within the third issue area will have domestic political consequences. Canada anticipates making some legislative changes as part of the ratification process. We believe these changes should address the fundamental contradictions identified here so that these consequences are avoided.

### **Precautionary approach in the Biosafety Protocol text**

In the preamble and objectives, the BP reaffirms the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development. The language of Article 10(6) is consistent with that used to describe a precautionary approach:

“Lack of scientific certainty due to insufficient relevant scientific information and acknowledge 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.”

Similarly, Article 11(8) states,

“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.”

The precautionary approach also has relevance, in the Protocol, to domestic regulatory systems. Under Article 11(4),

“A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol. “

Since the precautionary approach is a key objective of this protocol, it is our contention, elaborated below, that Canada's domestic regulatory framework is not consistent with the central objective of the Protocol.

### **Risk Assessment**

In Annex III, under Article 15, the general principles of risk assessment are presented. It is our contention, that Canada's domestic regulatory framework violates at least two of the general principles elucidated:

## How Canada's domestic regulatory system contradicts these principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.
4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

We believe, elaborated below, that Canada's domestic regulatory system is not based on sound science and does assume absence of risk in the face of a lack of scientific knowledge or scientific consensus.

### Identification of LMOs intended for direct use as food or feed, or for processing

Article 18(2)(a) states,

2. Each Party shall take measures to require that at a minimum documentation accompanying;
  - (a) Living modified organism that are intended for direct use as food or feed, or for processing, clearly identifies them as "may contain" living modified organisms and as not intended for intentional introduction into the environment, as well as a contact point for further information. 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 entry into force of this Protocol.

It is our contention, elaborated below, that the current system in Canada of identifying LMOs for direct use as food, feed or processing is inconsistent with this approach.

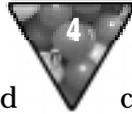
#### *1. Canada's legislative framework for GEOs does not have the precautionary approach as a specified objective*

Canada has no specific comprehensive legislation governing the regulation of GE products. Instead, pieces of legislation adopted before the development of genetic engineering are used, governing plants, foods, animals and drugs<sup>2</sup>. None of these acts have the precautionary approach as an objective. Only the Canadian Environmental Protection Act (CEPA) mentions the precautionary approach in its preamble. This mention does not, however, have weight in CEPA provisions. As well, only CEPA has any references to environmental and health aspects of biotechnology<sup>3</sup>, but this legislation has only a limited impact on the current regulatory process (except for microbes), since other legislation is deemed to take precedence over CEPA<sup>4</sup>. For example, CEPA provisions do not normally apply to the domestic regulation of LMOs used directly for food, feed or processing<sup>5</sup>.

The Acts used to regulate GEOs merely allow for regulations to be enacted concerning product quality and packaging. Evaluation of environmental or human health risks is not part of these Acts, hence, there is no clear legislative authority for the evaluation of GE crops or foods from an environmental or human health perspective<sup>6</sup>. As discussed below, this deficient legislative framework explains in part why much of the data submitted to regulators is primarily agronomic in nature, and not helpful for assessing environmental and health risks.

#### *2. GEO regulations, directives and guidelines are based on concepts and assumptions that are inconsistent with the precautionary approach*

Since the legislative framework for GEOs is not unified and provides little specific instructions to applicants or regulators, new regulations, directives and guidelines have been constructed within the context of specific pieces of legislation.



In Canada, these regulations, directives and guidelines for crops, foods and feed are designed around the concepts of familiarity and substantial equivalence. Both these concepts have been adapted to GEO environmental regulation, familiarity from the chemical industry and substantial equivalence from food safety regulation. They are used deliberately to limit the scope of environmental assessment; in fact, although regulatory theory suggests otherwise, they are used in Canada as substitutes for environmental risk assessment<sup>7</sup>.

If there is “knowledge of the characteristics of a plant species and experience with the use of that plant species in Canada”<sup>8</sup>, and their characteristics do not differ from the parent, then the GEO is deemed “familiar”. Regulators are confident that there will be no adverse effects specific to the GEO. If the characteristics are familiar, then existing legislative and regulatory frameworks can be used to assess them. Existing legislation helps determine familiarity, and the desire to assess familiarity makes existing legislation more useful than creating a new regulatory framework. For example, familiarity with the introduced trait, the environment, the crop plant and the interactions between them can all be used to justify a decision to permit widespread release of a GE crop<sup>9</sup>.

This approach, however, denies the possibility that the process of inserting genes can change the behaviour of the GEO relative to its familiar conventional analog. Insertion techniques are sufficiently imprecise that the placement of the transgenes is haphazard, unpredictable, and frequently unrepeatable. Consequently, the precision claim is highly contested since reliable targeting techniques are not yet available in rDNA technology<sup>10</sup>. This imprecision leads to unstable genetic constructs that companies try to weed out. They are not always successful, leading to unpredictable alterations and potential risks from problematic plant behaviour<sup>11</sup>. But Canada’s system effectively does not require examination of such possibilities and it is only in the post-release period, as independent scientists examine GEOs, that such effects are being identified.

If the molecular, compositional and nutritional characteristics of both GEOs and their conventional counterparts are comparable, then the GEO will be considered “substantially equivalent”<sup>12</sup>. If deemed substantially equivalent by regulators, a GEO does not have to undergo safety and environmental testing beyond that used to determine whether substantial equivalence applies. Using information on conventional crops or foods establishes the baseline for comparison.

However, the relationship between genetics, chemical composition, and toxicological and ecological risks is largely unknown. As well, the biochemical or toxicological effects of a GE food can not be predicted from its chemical composition. Seemingly minor changes in foods can have significant nutritional implications. For example, a stereo-isomeric alteration to a molecule (non-GE) has been shown to have significant impacts on infant nutrition<sup>13</sup>, something that would not be revealed by a chemical composition analysis. If relationships are largely unknown, how can similarity in composition be a predictor of equivalent ecological or toxicological behaviour as regulators presume?<sup>14</sup>.

Working together, these regulatory concepts assume that single-gene changes resulting from genetic engineering necessarily result in well-characterized plant responses. In fact, single genes can affect many traits and produced unexpected phenotypic expressions<sup>15</sup>. Millstone et al.<sup>16</sup> provide 2 examples of how single gene changes produce unpredictable outcomes: experimental genetic manipulation of oilseed crops, including rape, has led to the unexpected discovery of changes to lipid metabolism; glyphosate tolerance in Roundup Ready soybeans appears to occur at the expense of diminished heat tolerance due to changes to the plant’s lignin content<sup>17</sup>.

If the responses are often unpredictable, then substantial equivalence has no merit as a trigger for environmental assessments. The Expert Panel of the Royal Society of Canada is particularly critical of the use of substantial equivalence as a decision



threshold - the determination of whether a full risk assessment is required - and proposes that it be abandoned as a determination approach<sup>18</sup>.

A regulatory system that operates in this way is not about precaution. Rather, it is about limiting the scope of environmental and human health assessment in order to facilitate commercialization of GEOs<sup>19</sup>.

### *3. The Canadian regulatory system has very limited capacity to assess whether GEOs have any societal benefit*

A second important feature of the precautionary approach is weighing the benefits of a technology in the face of scientific uncertainty about risks. A higher level of uncertainty about risks might be tolerated if the technology provides very significant societal benefits. But, as elaborated in the Canadian Regulatory Framework for Biotechnology, only the direct environmental and health risks of GEOs need be investigated; assessments of the broader long-term social, economic, and ethical implications of these products are not required. The regulatory system determines whether a product is efficacious, but it does not evaluate benefits in any broader sense. For example, the system evaluates whether a variety expresses Bt toxin as claimed, but not whether broad social benefits result from the use of Bt crops. The government view is captured in this quote:

No socio-economic assessments [are conducted] .... whatever assessments are conducted are strictly science-based. In terms of potential management issues arising from the environmental release of GMOs, the Market place does its own cost/benefit analysis. Policy makers at AAFC deal with rural issues, not with cost/benefit analysis issues.<sup>20</sup>

This is a major deficiency that must be addressed if Canada's regulatory system is to be consistent with the precautionary approach.

### *4. The science employed by applicants and accepted by regulators is not sound*

The most widely accepted measure of scientific soundness is review by peers. Industry applications to regulators are not reviewed publicly and it is only through Access to Information requests that some of the applications have become public. As they become available, a disturbing pattern is emerging. The data submitted by applicants are of such poor quality that they would not likely pass a peer review. And regulators accept these data as sound and as demonstrating there are no environmental risks.

One industry application that has been thoroughly analyzed is a Roundup Ready Canola (GT73) developed by Monsanto<sup>21</sup>. The regulators determined substantial equivalence based on the company's submitted data, so no full safety assessment was required.

However, there are major deficiencies in the application, so much so that the analysts<sup>22</sup> doubt their usefulness for determining risk. Oddly, the statistical treatment of the data by Monsanto appears not to meet the standard imposed by CFIA in its 1996 revisions to field trial guidelines — that the designs be sufficiently statistically valid to be acceptable for inclusion in peer reviewed journals.

Some examples of the problems:

- many of the tests were poorly performed, with a lack of duplicate measurements, small sample sizes, uneven comparative scales, inappropriate data pooling, comparison of the parent with varieties other than that subject to the application, a lack of statistical consistency, indiscriminate use of data from trials to support the applicant's claim of substantial equivalence, and conclusions that are not supported by the actual data.
- limited temporal scales (some studies contained only 1 year of data).
- methodologically unsound field studies were performed, especially that most of them are agronomic studies not ecological ones.

- insufficient scope in the studies to adequately assess environmental safety - many of the studies assume that certain tests can be proxies for a full range of environmental phenomena; for example, allelopathy tests were used to draw conclusions about a whole host of soil / crop interactions, a completely illegitimate proxy. This is a critical flaw because independent scientists have already demonstrated that GE crops can have negative effects on soil biota<sup>23</sup>.
- studies of such limited surface area that they have no hope of predicting how the GE crop will behave once planted on millions of acres.
- failure to adequately explain variability in the results when in fact the variability could result from the insertion of the gene expressing the herbicide tolerant trait; strong tendency to treat variability as natural and to ascribe unusual results to “outlier effects”

Similar problems with the quality of environmental data submitted by industry to United States (US) and European Union (EU) regulators, and the conclusions drawn from them, have been identified by Hilbeck et al. (2000), the National Academy of Sciences (2000), Benbrook (2000), Purrington and Bergelson (1995), and Wrubel et al. (1992)<sup>24</sup>.

Similar problems appear to exist with the quality of data submitted by industry for food safety assessments<sup>25</sup>:

- Industry requirements to provide data on toxicity are limited. Of the 27 food safety assessment decisions available on Health Canada’s web site (as of 2000), 17 submissions did not present any evidence of laboratory or feeding trial measurements of toxicity<sup>26</sup>. The Royal Society of Canada concluded that regulatory requirements for toxicological assessment appear to be ad hoc, and that there did not appear to be any validated study protocols available to assess GE foods in their entirety<sup>27</sup>. This problem is endemic within GE food assessment as very few peer-reviewed feeding trials have been published<sup>28</sup>.

- Allergenicity testing is undertaken mostly by homology to known allergens. While this approach may be reasonable for known allergens, it is thought by many to be wholly inadequate for assessing products with no current history of allergenicity<sup>29</sup>.
- The data sets of industry applications are very inconsistent. Doses, durations and other aspects of experimental design appear to be at the discretion of the applicant, not determined by the regulatory protocols. This raises questions again about whether the data are of peer-review quality<sup>30</sup>.

Given these problems with the data, the ability of regulators to carry out good risk assessments is in serious question.

*5. The Canadian regulatory system effectively assumes that the absence of evidence of risk should be interpreted as the absence of risk or that risks are manageable*

The Canadian regulatory framework is designed to minimize the likelihood that regulators conclude there is an effect when one doesn’t exist, resulting in unnecessary regulation (known in statistics as minimizing the possibility of a type I error). However this approach to regulation increases the likelihood of creating a different kind of error — believing there is no effect when one actually exists (or a type II error)<sup>31</sup>. The dominant scientific tradition reinforces this approach because much of scientific inquiry is predicated on the assumption that if a phenomenon has yet to be observed, then it does not exist. In this view, there is no room for the possibility that the effect has yet to be observed because we do not know how to “see” it<sup>32</sup>. Stated another way, in Canada’s regulatory approach, “it would be more scientifically “sound” to claim that GEOs are safe when they are actually hazardous”<sup>33</sup> than the other way around. The emerging evidence of ecological problems with GE crops reported in the peer reviewed literature appears to support the view that scientists are not seeing environmental and health risks associated with GEOs because the developers and regulators do not know where to look for the potential problems<sup>34</sup>.

Rather than acknowledge uncertainty, the Canadian system effectively determines that GEOs do not present risks or that the risks are manageable. Precaution, however, is not even exercised at this late stage — risk management — of the risk assessment process. “Article one of the Cartagena Protocol specifies that the entire objective of the document is to protect biodiversity according to the precautionary approach. Therefore, precaution is the first consideration when decisions are made on biosafety, rather than a risk-management measure that is triggered late in the process by an adverse event.”<sup>35</sup> But the Canadian approach, in the limited cases where potential problems are actually identified, uses risk management to address them despite the absence of any empirical evidence that the risks can, in fact, be properly managed. One example is CFIA’s conclusions regarding volunteer Roundup Ready canola and volunteer Roundup Ready wheat. They have concluded that both are manageable by farmers using other herbicides and weed management approaches<sup>36</sup>. This is purely conjecture, since, by the conditions of confined field trials, there can be no farm-scale, multi-year data that show whether volunteer GE crops could be adequately managed without generating additional environmental risks.

The farmers who have to deal with the potential problems are very concerned about how to manage these volunteer GE crops<sup>37</sup>. Volunteer canola plants resistant to one, two or three herbicide tolerant traits at the same time have already been found<sup>38</sup>. Dealing with RR canola volunteers requires, relative to conventional canola volunteers, that glyphosate spray tanks be spiked with additional products. Adopting this practice was already underway because of weeds glyphosate did not control well, but RR canola volunteers have made it a requirement.

Volunteer wheat is very competitive in canola, even more so than wild oats on a per plant basis, can sprout up to 6 years after planting, and may cause serious yield losses<sup>39</sup>. Volunteer RR wheat will not be controllable in canola with Roundup, an herbicide that is very effective against conventional

volunteer wheat. Other, generally more expensive, herbicides will be required in the tank mix, the same ones that are already causing weed resistance problems<sup>40</sup>. All together, this will make weed management more complicated and may result in increased herbicide spraying, a result that would contradict the expressed purpose for developing the technology. Dr. Hartley Furtan, professor of Agricultural Economics at the University of Saskatchewan, is completing a report on the farm economics of herbicide tolerant wheat. His work so far suggests that any possible weed control benefits of RR canola could be lost when followed by RR wheat. He has stated, “Then you’re going to have to use a more complex herbicide cocktail .... There will be increased costs in the second crop, which reduces the total benefits.”<sup>41</sup>

Monsanto acknowledges that RR wheat should not go forward without effective management of volunteer RR wheat<sup>42</sup>. The CFIA, however, has deemed all these problems manageable and without additional environmental hazards.

#### *6. Canada’s system for regulating GEOs effectively has no mandatory provisions identifying LMOs for food, feed or processing*

In the Canadian system, under the Seeds Act and Regulations there are quality control, traceability, and identification requirements for registered seed<sup>43</sup>, whether GE or non-GE. But there are no regulated requirements at any level — farm, warehouse, broker (domestic or export), wholesale, processor (food or feed), retail — to identify LMOs destined directly for food, feed or processing, except consumer labeling when the LMO has not been deemed substantially equivalent, and a health risk.

Until 1995, all imported genetically modified plants required an import permit. The import permit effectively acted as an identification at the importer level. Now, however, those that have been approved for unconfined release in Canada are exempted from this requirement. As well, those “considered substantially equivalent [to genetically modified plants] .... are also exempted provided

that the intended use is similar, the plants do not display any additional novel traits, do not contain novel genetic elements and have not been subject to interspecific breeding.”<sup>44</sup>

Regarding the retail level, under the Guidelines for the Safety Assessment of Novel Foods<sup>45</sup>, labels identifying GE foods are only required when the food has characteristics that generate a safety hazard or nutritional or compositional change relative to its conventional analog. But since all applications to date for unconfined release have been deemed substantially equivalent, there are no GE foods on the market that require consumer labeling. Voluntary positive or negative labeling is permitted as long as the claim is not misleading or deceptive and is factual. Very few companies have voluntarily used a positive label (i.e., identifying the food as coming from a GE crop or having ingredients derived from GE).

Regarding GE feeds<sup>46</sup>, although there are extensive rules on labeling of feeds, there is no requirement that GE crops or microbes used in feeds be identified as derived from genetic engineering, for either domestic or imported feeds. All feeds on the market have been deemed substantially equivalent to their conventional analog. A few feed manufacturers have voluntarily identified GE feed ingredients, usually microbes. The CFIA awaits the outcome of the Codex Alimentarius discussions on GE food labeling to determine whether labeling of GE feed ingredients will be required<sup>47</sup>.

Clearly, Canada’s domestic system is at odds with the intent of Article 18(2)(a), which states that LMOs used directly for food, feed or processing have a “may contain” identification. The article also states that the details of this identification are to be worked out and since formal negotiations on it have not yet commenced, Canada’s position is not clear. It is conceivable, given that the BP does not require consumer-level identification, but only identification for transboundary movement, that the federal government might only implement identification provisions at levels in the food and feed chain below the consumer level. Their contention has always been that consumers have

no reason to be informed about LMOs in their diet unless there is something different about their safety or composition. However, to comply with the BP, industry will have to do the work of establishing segregation and traceability systems. They will put in place the basic systems they currently claim, when explaining their opposition to consumer-level information, are impossible to implement or overly costly. Refusing to then go the next step and provide consumer-level information would likely be a significant public relations problem, and leave Canada open to criticisms that it has more concern for trade than the information needs of its own citizens.

## Conclusion

To have legitimacy as a signatory and ratifier of the Biosafety Protocol, Canada will have to completely overhaul its domestic system for GEO regulation. If it does not, Canada’s exports of LMOs, whether for unconfined release (e.g., seed) or for direct use as food, feed or in processing, may be jeopardized. Since, under BP provisions, countries of import can make decisions based on their domestic regulatory framework, it is very likely that nations whose systems are based on the central principles of the Biosafety Protocol — particularly, precaution and sound science — will reject imports of Canadian LMOs (or require additional risk assessments before agreeing to import) because they lack confidence in the assessment process. The deficiencies of Canada’s system also leave LMO exports vulnerable to reviews of decisions (Article 12). Given the poor quality of risk assessments, it is highly likely that new information will emerge post release challenging the environmental or human health safety of Canadian LMOs. In all these scenarios, Canada demonstrates the weakness of its domestic system for regulating GEOs.



## Endnotes

- <sup>1</sup> As of time of writing, there were 101 signatories to the Biosafety Protocol. Only three, however, have ratified and 50 signatories must ratify the Protocol for it to come into effect. Canada has not yet ratified the Protocol and is not likely to do so in the short term since, according to a federal government official, there are significant matters to be resolved regarding liability, the body that will ensure compliance, how to document transboundary movement, and mechanisms to help developing countries (Personal communication, Desmond Mahon, Environment Canada, June, 2001).
- <sup>2</sup> These pieces of legislation include the Food and Drugs Act, the Feeds Act, the Fertilizers Act, the Seeds Act, the Plant Protection Act, and the Health of Animals Act.
- <sup>3</sup> CEPA provisions have been changed in the latest revisions to the Act, revisions that significantly reduce legislative capacity to examine risk. See, for elaboration, Bjorkquist, S. and Winfield, M. 1999. *The Regulation of Agricultural Biotechnology in Canada*. Canadian Institute for Environmental Law and Policy, Toronto. However, CEPA provisions are still sufficiently in force that a petition was filed May 9, 2000 by several environmental organizations with the Auditor General claiming that the federal government is violating CEPA (and other federal provisions) in the way in which it is regulating genetically engineered foods. The petition proposed a number of significant changes that must be made to the current system. Seven ministries responded without addressing any of the issues raised in a substantive way, and now the petitioners are examining ways to contest the adequacy of the responses. See [www.cielap.org](http://www.cielap.org) for details.
- <sup>4</sup> The federal government is currently going through the formal process of listing exempted legislation (e.g., the Feeds Act, the Fertilizers Act, the Health of Animals Act and the Seeds Act) under schedule 4 of CEPA 1999 (where exempted legislation must be listed to prevent an environmental assessment of GE crops under CEPA).
- <sup>5</sup> If GE microbes were feed additives or played a role in processing a food, then CEPA provisions might apply.
- <sup>6</sup> Bjorkquist, S. and Winfield, M. 1999. *The Regulation of Agricultural Biotechnology in Canada*. Canadian Institute for Environmental Law and Policy, Toronto.
- <sup>7</sup> Barrett, K. and Abergel, E. 2000. Breeding familiarity: environmental risk assessment for genetically engineered crops in Canada. *Science and Public Policy* 27:2-12.
- <sup>8</sup> Regulatory Directive Dir94-08: Assessment criteria for determining the environmental safety of plants with novel traits. December 16, 1994. <http://www.cfia-acia.agr.ca/english/plaveg/pbo/dir9408e.shtml#A4>
- <sup>9</sup> Barrett, K. and Abergel, E. 2000. Breeding familiarity: environmental risk assessment for genetically engineered crops in Canada. *Science and Public Policy* 27:2-12.
- <sup>10</sup> Visser, A.J.C. et al. 2000. *Crops of Uncertain Nature? Controversies and Knowledge Gaps Concerning Genetically Modified Crops: An Inventory*. Plant Research International B.V., Wageningen University, Wageningen, The Netherlands
- <sup>11</sup> Clark, E.A. 1999. The faulty assumptions of field crop genetic engineering. Presentation to "Is Your Food Safe?" sponsored by the Professional Institute of the Public Service of Canada. 7/8 May.
- <sup>12</sup> Substantial equivalence is "the equivalence of a novel trait within a particular plant species, in terms of its specific use and safety to the environment and human health, to those in that same species, that are in use and generally considered as safe in Canada, based on valid scientific rationale." Regulatory Directive Dir94-08: Assessment criteria for determining the environmental safety of plants with novel traits. December 16, 1994. <http://www.cfia-acia.agr.ca/english/plaveg/pbo/dir9408e.shtml#A4>
- <sup>13</sup> Medical Research Council (UK). 2000. Report of a MRC Expert Group on Genetically Modified (GM) Foods. June 2000.
- <sup>14</sup> Millstone, E. et al. 1999. Beyond substantial equivalence. *Nature* 401:525-526.
- <sup>15</sup> For a review, see Clark, E.A. and Lehman, H. 2001. Assessment of GM crops in commercial agriculture. *J. Agricultural and Environmental Ethics* 14:3-28.
- <sup>16</sup> Millstone, E. et al. 1999. Seeking clarity in the debate over the safety of gm foods. *Nature* 402, 575 (December 9 1999) (Reply to letters to the editor).
- <sup>17</sup> This is thought to occur because the insertion of the glyphosate-resistant EPSPS in these varieties alters product distribution in the shikimate pathway which leads to the creation of aromatic amino acids, lignin, some vitamins and other secondary metabolites. See Gertz, J.M. et al. 1999. Tolerance of transgenic soybean (*Glycine mar*) to heat stress. 1999 Brighton Crop Protection Conference: weeds. Proceedings of an international conference, Brighton, UK, 15-18, 3:835-840. November 1999.
- <sup>18</sup> An Expert Panel Report on the Future of Food Biotechnology Prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada. 2001. Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. January.
- <sup>19</sup> Barrett, K. and Abergel, E. 2000. Breeding familiarity: environmental risk assessment for genetically engineered crops in Canada. *Science and Public Policy* 27:2-12.
- <sup>20</sup> Industry Canada official, quoted in Abergel, E. 2000. *Growing Uncertainty: the environmental risk assessment of genetically engineered herbicide tolerant canola in Canada*. Ph.D. Dissertation. York University, Toronto.
- <sup>21</sup> Barrett, K. 1999. *Canadian Agricultural Biotechnology: risk assessment and the precautionary principle*. Ph.D. Dissertation, Department of Botany, University of British Columbia; Abergel, E. 2000. *Growing Uncertainty: the environmental risk assessment of genetically engineered herbicide tolerant canola in Canada*. Ph.D. Dissertation. York University, Toronto.
- <sup>22</sup> Barrett, K. 1999. *Canadian Agricultural Biotechnology: risk assessment and the precautionary principle*. Ph.D. Dissertation, Department of Botany, University of British Columbia

- <sup>23</sup> Hilbeck, A. et al. 2001. Bt Proteins in Soil: is enough known to assess the impacts of Bt plants on soil ecosystems? Report to Greenpeace International. EcoStrat, Zurich, Switzerland.
- <sup>24</sup> Hilbeck, A. et al. 2000. Review of Non-target Organisms and Bt Plants. Report to Greenpeace International, Amsterdam. EcoStrat GmbH (Available at [www.greenpeaceusa.org](http://www.greenpeaceusa.org)); National Research Council. 2000. Genetically Modified Pest-Protected Plants: science and regulation. National Academy Press, Washington, DC; Benbrook, C. 2000. Comments submitted to Docket Number OPP-30487a: registration application for Cry3Bb transgenic corn modified to control the corn rootworm. Submitted to the Environmental Protection Agency March 20, 2000; Purrington, C.B. and Bergelson, J. 1995. Assessing weediness of transgenic crops: industry plays plant ecologist. *Trends in Ecology and Evolution* 10(8):340-342; Wrubel, R.P. et al. 1992. Field testing transgenic plants. *BioScience* 42:280-289.
- <sup>25</sup> Not as much of the data used for food safety assessments is currently publicly available, so criticisms are based more on international literature and decision documents posted on Health Canada's web site.
- <sup>26</sup> Clark, E.A. 2000. Food Safety of GM Crops in Canada: toxicity and allergenicity. *Genetic Engineering Alert Canada*. Available at: [www.canadians.org](http://www.canadians.org). See also, Clark, E.A. and Lehman, H. 2001. Assessment of GM crops in commercial agriculture. *J. Agricultural and Environmental Ethics* 14:3-28.
- <sup>27</sup> An Expert Panel Report on the Future of Food Biotechnology Prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada. 2001. Elements of Precaution: recommendations for the regulation of food biotechnology in Canada. January 2001.
- <sup>28</sup> Domingo, J.L. 2000. Health risks of GM foods: many opinions but few data. *Science* 288(June):1748-1749.
- <sup>29</sup> An Expert Panel Report on the Future of Food Biotechnology Prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada. 2001. Elements of Precaution: recommendations for the regulation of food biotechnology in Canada. January 2001.
- <sup>30</sup> Clark, E.A. 2000. Food Safety of GM Crops in Canada: toxicity and allergenicity. *Genetic Engineering Alert Canada*. Available at: [www.canadians.org](http://www.canadians.org).
- <sup>31</sup> Barrett, K. and Raffensperger, C. 1999. Precautionary science. In: C. Raffensperger and J. Tickner (eds.). *Protecting Public Health and the Environment: implementing the precautionary principle*. Island Press, Washington. Pp. 106-122.
- <sup>32</sup> MacRae, R.J. et al. 1989. Agricultural science and sustainable agriculture: a review of the main scientific barriers to sustainable food production and potential solutions. *Biological Agriculture and Horticulture* 6:173-219.
- <sup>33</sup> Barrett, K. and Raffensperger, C. 1999. Precautionary science. In: C. Raffensperger and J. Tickner (eds.).
- Protecting Public Health and the Environment: implementing the precautionary principle*. Island Press, Washington. Pp. 106-122.
- <sup>34</sup> Barrett, K. 1999. Canadian Agricultural Biotechnology: Risk Assessment and the Precautionary Principle. Ph.D. Dissertation, Department of Botany, University of British Columbia.
- <sup>35</sup> Myers, N. 2000. The U.S. and the Precautionary Principle: An NGO Response in the Context of the Cartagena Protocol. Presented at a SEHN workshop on the precautionary principle at the International Committee on the Cartagena Protocol in Montpellier, France, December 2000.
- <sup>36</sup> For canola, since in CFIA's view Monsanto's Roundup Ready canola showed the same volunteer characteristics as was found in its conventional analog, it deemed it manageable. See CFIA Plant Biosafety Office. 1995. Decision Document DD95-02: Determination of Environmental Safety of Monsanto Canada Inc.'s Roundup® Herbicide-Tolerant *Brassica napus* Canola Line GT73. <http://www.cfia-acia.agr.ca/english/plaveg/pbo/dd9502e.shtml#A8>.
- For wheat, the CFIA implies that volunteer GE wheat should not be a problem, although their discussion is very cursory and focuses primarily on it as an invasive weed, rather than as a weed management problem for farmers. See CFIA Plant Biosafety Office. 1999. Regulatory Directive Dir1999-01: The Biology of *Triticum aestivum* L. (Wheat): A companion document to the Assessment Criteria for Determining Environmental Safety of Plant with Novel Traits. <http://www.cfia-acia.agr.ca/english/plaveg/pbo/dir9901e.shtml>.
- <sup>37</sup> See stories on this topic in numerous 2001 issues of the Manitoba Cooperator and Western Producer.
- <sup>38</sup> See MacArthur, M. 2000. Triple-resistant canola weeds found in Alta. *Western Producer*. February 10, 2000.
- <sup>39</sup> From The Growers Manual, Canola Council web site. <http://www.canola-council.org/>
- <sup>40</sup> Scott Day, Manitoba Agriculture, personal communication, April 2001.
- <sup>41</sup> Ewins, A. 2001. Study will help farmers with economics of GM production. *The Western Producer* January 18. P. 10.
- <sup>42</sup> Rance, L. 2001. Farmers want protection from Roundup Ready wheat. *Manitoba Cooperator* March 1, 2001. P. 17.
- <sup>43</sup> Seed that is not registered can still be sold, but sales for some crops may be quite restricted.
- <sup>44</sup> CFIA. 1998. Import Permit Requirements For Plants With Novel Traits (Including Transgenic Plants), And Their Products. D-96-13. <http://www.cfia-acia.agr.ca/english/plaveg/protect/dir/d-96-13e.shtml>.
- <sup>45</sup> The Guidelines are available on Health Canada's web site, [http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel\\_foods\\_and\\_ingredient/novel\\_foods\\_and\\_ingredient.html](http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/novel_foods_and_ingredient.html). Novel foods are defined, by an October 1999 amendment to the Food and Drug Regulations (Schedule 948) that formalized health safety assessments of GE foods, as:

“(a) a substance, including a microorganism, that does not have a history of safe use as a food;

(b) a food that has been manufactured, prepared, preserved or packaged by a process that

(i) has not been previously applied to that food, and

(ii) causes the food to undergo a major change; and

(c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that

(i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,

(ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or

(iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.”

The amendment can be accessed at the same URL.

<sup>46</sup> For a general overview of Canada’s approach to GE feeds, see <http://www.cfia-acia.agr.ca/english/anima/feebet/bfeebete.shtml>

<sup>47</sup> Catherine Italiano, CFIA, personal communication, June 5, 2001.







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