Submission to the Canadian Biotechnology Advisory Committee (CBAC)
by the Canadian Institute for Environmental Law and Policy (CIELAP)
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Comments on the Interim Report "Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada"
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Our comments on this CBAC interim report are based on nearly 20 years of research on biotechnology. The Canadian Institute for Environmental Law and Policy (CIELAP) first began investigating biotechnology regulation in 1984, when we organized the first conference in Canada on environmental issues regarding biotechnology. At that time we identified the need for a comprehensive policy framework for the regulation of products of biotechnology. Since then we have participated in numerous conferences, workshops, and almost every government consultation concerning biotechnology. We have also published a number of documents dealing with biotechnology including *Enabling Biotechnology*; *A Review of Biotechnology Regulation in Canada;* a paper on the biosafety protocol; and the 1995 *Citizen's Guide to Biotechnology* (now being updated for March 2002 release).

We believe that this CBAC interim report advances the possibility of an improved food biotechnology regulatory system in Canada. Many of the recommendations are worthy of implementation if some underlying obstacles to policy and regulatory change are addressed at the same time. It is on these underlying obstacles that this commentary focuses. Some of these obstacles have been addressed in part by CBAC, others have not. Some are overarching policy themes, others deal with the details of scientific study design and how regulators interpret scientific data. It is our believe that addressing these obstacles is so fundamental to successful implementation of the recommendations in the CBAC interim report that they must be integrated into the final report.

<u>Obstacle 1: the absence of a national food policy</u>

CBAC rightly highlights (p. 51) that the absence of a national food policy is seen by some to be a roadblock to further work on food biotechnology regulation. However, the discussion in the report does not reflect the profound way in which the absence of a national food policy that advances health, food security and environmental sustainability impedes implementation of

CBAC recommendations.

In the current policy vacuum, government officials continue to be guided primarily by the traditional agricultural policy pillars of production efficiency, reasonable returns to producers, and low and stable food prices for consumers. A careful reading of AAFC policy documents shows that sustainable development concepts are visible, but rather than being central to decision making, continue to stand largely on the fringes. Consequently, the food biotechnology regulatory apparatus continues to be framed by these traditional agricultural policy pillars. Farming systems and technologies that are more consistent with sustainable development approaches than the current food biotechnology applications are relatively penalized.

Several recommendations and considerations of CBAC are adversely affected by this reality, including:

- The Acceptability Spectrum (p. 49). There is no authority, guidance or set of tools that can currently be used by AAFC and Health Canada to make this a reality.
- All recommendations on improving environmental assessment. Given the current policy apparatus, environmental considerations are always deemed secondary to the "apparent benefits" associated with productivity and efficiency.

We recommend that CBAC move to a more prominent place in the report the discussion about the need for a national food policy and elaborate on its importance for guiding food biotechnology assessment. CBAC should recommend that such a food policy be publicly debated and implemented in order to provide guidance to GE food regulation.

Obstacle 2: the absence of full parliamentary debate on both GE regulation and patenting

Related to obstacle 1, we also believe that CBAC's efforts to recommend actions that build public confidence in GE regulation will not be successful in the absence of full parliamentary debate about GE regulation and patenting. Recommendation 3.1 is too vague.

Many citizens believe that the acceptability of GE applications goes beyond strictly utilitarian or technical questions. In our political system, discussions related to values and social and economic impacts should normally take place at a parliamentary level, instead of a bureacratic and strictly regulatory one, from where the current system has been constructed. The widespread erosion of public confidence in public institutions is partly related to a feeling that democratic processes have been usurped by both prime ministerial and cabinet authority, and bureaucratic rule making. Consequently, the construction of the GE regulatory system confirms this erosion of public confidence and can only be countered by a highly visible parliamentary debate. Parliamentary debate and referral to committee provides more formal possibilities for policy development participation than the current consultation format employed by the civil service.

We recommend that CBAC advise parliament to have such debate, and should the need for changes be identified, to draft legislation to address the outcomes of the debate, and refer that

legislation to committee for public review.

Obstacle 3: the absence of systems for comparative technology assessment

The absence of a coherent food policy means that there is no impetus to examine how different systems and technologies help advance sustainable food policy objectives. Instead, officials are concerned primarily with ensuring a suite of technologies are in place that drive the narrower objective of production efficiency.

Instead, regulators should be carrying out comparative technology assessments to identify which approaches to solving problems in agriculture are most likely to produce optimal societal benefits with minimal risks. Currently, the regulatory system has no capacity to do this. Such assessments have been carried out by independent researchers, so methodologies have been established.

In a comparative assessment, the GE application is examined to determine whether, compared to other practices or systems:
1. it presents significantly less risk to human health, wildlife or the environment;
2. it is relatively effective, also taking into account the risk of acquired resistance;
3. it has relative economic or practical benefits for the user;

There are four main outcomes from a comparative analysis:
1. The application is found to be superior, and is approved.
2. The application is found to be at least as good as other options and is approved with no impacts on other options.
3. The application is found to be useful in certain circumstances, requiring some limitations on its use.
4. The application is found to be unacceptable because it does not add anything to the existing tool box of options.

Comparative assessment is a recognized component of applying the precautionary principle[1]. This kind of assessment is already part of the US and European pesticide regulatory systems. In Europe, some of this thinking has been incorporated into GE regulatory decision making. Broader societal assessments of the benefit of recombinant Bovine Growth Hormone, kept it off the market on the grounds that the restructuring that would occur in the European dairy sector would have adverse affects on farmers. The recently negotiated Biosafety Protocol permits countries to use as part of their process for reviewing trade in living GMOs, "socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."

We ask that CBAC adopt a recommendation requesting that comparative assessment of GE food and crop applications become an integral part of the review of GE applications, and that detailed regulatory directives and guidelines be developed to help industry and regulators prepare and review such assessments.

Obstacle 4: the lack of ecological literacy in the regulatory system

CBAC rightly makes a number of recommendations regarding the need to strengthen ecological assessment within the regulatory system. However, the problem is even more profound than the CBAC report acknowledges. For example, having an expert panel recommend ecological testing protocols (recommendation 5.3), a useful recommendation, will not have full effect if the industry scientists carrying out the studies do not have the knowledge base to properly implement the studies, and if both they and the regulators cannot properly interpret the results. And we believe this is the current situation. Since industry applications to regulators are not reviewed publicly, 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[2]. 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[3] doubt the usefulness of the data 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.
- some studies contained only 1 year of data, which is far too limited.
- 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 taken as examples of a full range of environmental phenomena. This is a critical flaw because independent scientists have already demonstrated that GE crops can have negative effects on soil organisms[4].
- 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 several studies, including Hilbeck et al. (2000), the National Academy of Sciences (2000), Benbrook (2000), Purrington and Bergelson (1995), and Wrubel et al. (1992)[5]. Hilbeck et al (2000) found the ecological knowledge base of industry scientists was so poor that they could not ensure that the test organisms were actually consuming the test diets. The knowledge of regulators was so limited that they did not recognize the problem with the studies.

We ask that CBAC amend recommendation 5.3 to read: " ..... Independent panels with a strong ecosystem perspective should oversee *major revisions to the regulatory directives, guidelines and protocols that are part of the environmental assessment process. The panels should also advise industry and regulators on human resource policies to attract the appropriate expertise in ecology and evolutionary biology to implement the revised guidance, with particular emphasis on the skills to examine environmental persistence of GM organisms, effects on biogeochemical cycles, reproductive biology such as pollen flows, harmful effects of horizontal gene transfer, effects on non-target organisms, diminution of biodiversity, insect resistance to GM insecticidal products and cumulative effects. As part of this process, any use of substantial equivalence as a trigger for environmental assessment should be eliminated from all regulatory directives, guidelines and protocols.*"

See also our discussion under obstacle 5.

<u>Obstacle 5: Inappropriate testing protocols and statistical treatment of data are being employed if precaution is to be exercised</u>

Several CBAC recommendations make direct or indirect reference to the need to apply precaution in the regulatory system. For precaution to have effect, it must begin, not at the risk management stage of the risk assessment cycle but at the very beginning of the cycle, with the very design and statistical treatment of scientific studies.

Even if industry data were of high quality, the study designs and statistical treatments of the data would not ensure precaution was being followed. The dominant standard in regulatory science is a chance of error less than 1 in 20, designed to avoid false positives, the possibility of concluding there is an effect when in fact there isn't. But the focus on avoiding false positives means that false negatives are missed. A false negative is a conclusion that there is no effect when in fact there is and it has been missed by the inquiry. Ecological and epidemiological phenomena, including the behaviour of GE crops and foods, are very subject to false negatives because of the complexity of ecological systems.

There are statistic approaches that do a better job of balancing the likelihood of experiments making type I and II errors. The CFIA needs to explicitly recognize this in its regulatory directives so that industry can change the kinds of experimental protocols they follow. The US EPA has done this in some of its directives on pesticides. Here are some examples of the kinds of approaches that can be discussed in a directive:

1. increase the number of replicates;

2. for assessing impacts on wildlife, the EPA recommends more sophisticated experimental designs such as paired plot designs[6];
3. as part of a weight of evidence approach, statistical analyses do not adhere to a strict 5% confidence interval; when confidence falls between 5 and 40%, scientists look for confirming or refuting evidence; for example, a 10% percent significant level (0.10) is specifically used because of the importance of avoiding Type II error rates in Everglades management and restoration[7];
4. statistical power calculations[8] to determine the probabilities of false positives and false negatives; however, given the current amount of available data, successful use of these calculations is probably dependent on generating more data.

We ask that CBAC recommend that 2 independent panels, one with expertise in ecology (the panel recommended in 5.3) and one with expertise in human and animal epidemiology, toxicology, and nutrition, be empowered to revise CFIA regulatory directives, guidelines and protocols to ensure that study designs and statistical treatments reflect up to date practice in scientific precaution.

<u>Obstacle 6: Post-release monitoring programs are currently impossible because there are no mandatory requirements for segregation, and no regulatory powers that encourage industry post - release monitoring.</u>

CBAC makes several recommendations related to improved post-release monitoring expertise, for both health and environmental impacts. However, none will be effective in the absence of mandatory segregation (and associated traceability and labelling) and mandatory industry participation in post-release monitoring work. As well, there must be thresholds of harm developed[9], that once crossed, result in use restrictions or an application being pulled from the market.

HT canola is a telling case study of the failures of current approaches to post-release monitoring. According to those in the canola trade, contamination of canola seed supply is so widespread that few, if any, pedigree seed producers will guarantee seed free of GE varieties or of GE traits acquired through gene flow. GE canola volunteers have now become a serious management problem for many farmers[10]. The organic canola industry has now effectively been destroyed as a result of GE contamination. These problems were predicted by critics before the first GE canola application was commercially released. Monsanto's own data provided clues to what would happen, but CFIA regulators deemed the problems manageable, without providing any analysis or data to justify this conclusion[11] If rigorous segregation systems had been applied, if thesholds of harm existed, and had penalties been in place to encourage more vigorous post release monitoring on the part of GE crop developers, this situation might have been avoidable.

Some companies have already realized, apparently before the federal government, that mandatory segregation and reporting is inevitable. To comply with provisions of the Biosafety Protocol, companies will have to develop mandatory segregation, traceability and reporting systems in order to trade internationally[12]. These same systems are the basis for a more effective post release monitoring program and for mandatory consumer labelling. Unless the federal

government acts, we could have a situation where companies comply with the provisions of the Biosafety Protocol, but are not using that information to advance post - release monitoring programs in Canada.

We ask that CBAC adopt recommendations asking the federal government to enact mandatory segregation, traceability and labelling provisions to both improve post-release monitoring capacity and also to help Canada be compliant with its obligations under the Biosafety Protocol. Such a recommendation also requires significant changes to several recommendations in the interim report, including 2.2, 2.3, 2.4, 4.2, 4.3 and 5.1.

With these changes, CIELAP believes that the current set of recommendations in the CBAC interim report will have a chance of effectively improving GE food and crop regulation in Canada.

Endnotes:

1. Barrett, K and Raffensperger, C. (forthcoming). From Principle to Action: applying the precautionary principle to agricultural biotechnology. International J. Biotechnology.

2. 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.

3. Barrett, K. 1999. Canadian Agricultural Biotechnology: risk assessment and the precautionary principle. Ph.D. Dissertation, Department of Botany, University of British Columbia

4. 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.

5. 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); 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 modifed 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 trangenic plants. BioScience 42:280-289.

6. From EPA's Ecological Effects Test Guidelines - Field Testing for Terrestrial Wildlife http://www.epa.gov/docs/OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/Drafts/850-2500.pdf

7. http://serc.fiu.edu/fiuwww/flumeprj/integr~1.pdf

8. Statistical power describes in mathematical terms the probability of an experiment or monitoring program actually detecting an effect where one exists.

9. For more on thresholds of harm, see Barrett, K and Raffensperger, C. (forthcoming). From Principle to Action: applying the precautionary principle to agricultural biotechnology. International J. Biotechnology.

10. For more on how HT canola complicates farm management, see our paper, Mixed Messages: Canada's domestic regulatory system for GEOs contradicts basic principles underlying the Cartegena Protocol on Biosafety. http://www.cielap.org.

11. Abergel, E. 2000. Growing Uncertainty: the environmental risk assessment of genetically engineered herbicide tolerant canola in Canada. Ph.D. Dissertation. York University, Toronto.

12. See our paper, Mixed Messages: Canada's domestic regulatory system for GEOs contradicts basic principles underlying the Cartegena Protocol on Biosafety. http://www.cielap.org.