Comments on Low Level Presence

Low Level Presence Sacrifices Food Safety for Trade Policy: LLP is indefensible from a public health and safety standpoint

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1. Summary

The Canadian Biotechnology Action Network (CBAN) objects, in the strongest terms, to the establishment of so-called "Low Level Presence" or LLP in Canada. CBAN objects to LLP on the basis of our concern for health and safety as well as our concern for the future of public health policy and regulation relating to genetically modified (GM, also called genetically engineered) products.[i]

LLP is indefensible from a health and safety standpoint and would fatally undermine federal food safety regulation (already heavily criticized as inadequate, particularly in relation to GM foods) as well as public confidence in our food system (already undermined by the prevalence of GM foods and various related factors).

LLP clearly subordinates food safety to trade policy. While consultation documents state that "food safety is a high priority for the Government of Canada" (AAFC AGRIDOC #2671654 page 7), CBAN insists that food safety should be the Government's highest priority.

2. Introduction

Canada is proposing "approaches to manage unintended, low levels of unauthorized genetically modified (GM) materials found in imported grain, seed, food or feed products, these materials being authorized for commercial use or sale in one or more countries, but not in the country of import" i.e. low level presence or LLP (AAFC AGRIDOC #2812902 page 2). Currently, "the presence of a genetically modified product unapproved in Canada, including low-level presence, in agri-food commodities in the Canadian marketplace constitutes a regulatory non-compliance." (AAFC AGRIDOC #2812902 page 3) LLP would change the status quo of non-compliance to establish a process or processes whereby GM foods that are not approved in Canada would be permitted onto grocery store shelves.

The rationale for LLP is stated as follows: "In the industry's view, Canada could serve as a model to influence countries with trade-restrictive LLP policies by adopting alternative domestic LLP policy approaches." (Agriculture Canada Power Point on LLP). The trade problem is described as follows: "If trace amounts of such unapproved genetically modified product are found in import shipments [from Canada], in a country where the genetically modified crop is not approved, often times these imports will be rejected…The unpredictability of rejection of such imports is a growing concern, given the potential economic impacts low-level presence will have on global trade." (AAFC AGRIDOC #2821497 page 5) This rationale for LLP is clearly based on trade policy and has no scientific basis or basis in health and safety policy.

Most of Canada's trading partners have not approved the GM crops that are grown in Canada and Canadian exports contaminated by GM products consequently face market rejection. Canada likewise maintains a "zero-tolerance" policy for contamination from unapproved GM foods. Zero-tolerance for contamination of foods from other countries that have not yet been assessed as safe by domestic regulatory agencies is sound public health and food safety policy. LLP proposes to "redefine zero", a suggestion that exposes how unjustifiable LLP is.

Low Level Presence would effectively dismiss or side-step Canada's existing regulation of GM foods for health and safety in certain cases. Though the federal regulatory system for GMOs has been strongly criticized as inadequate[ii], it remains a fact that, however problematic, Health Canada currently evaluates data to determine safety before allowing GM foods onto Canadian grocery store shelves. LLP would avoid that system, on a case-by-case basis, and make Health Canada's evaluation effectively irrelevant in these cases, with possible broader, long-term implications for the application of regulation for health protection.

Consultation documents state that, "Canada currently has a strong, well-functioning regulatory process that has the flexibility to deal with unapproved GM crops and protect the health and safety of Canadians." If Canada's regulatory process is strong and well-functioning, then the federal government should rely on this process to protect the health and safety of Canadians rather than deciding that we have the "flexibility" to ignore it in certain cases.

3. LLP is indefensible from a public health and safety standpoint

The review of the LLP proposals state the consideration of eight factors including the safety of food, feed and the environment and the scientific basis of the approach. LLP dramatically fails on both counts. LLP is trade policy that directly undermines public health protection policy. There is no scientific basis for LLP and there is no justification for LLP that can be accepted if food safety is a priority.

A stated justification for LLP is that, "With the increasing number of GM products being developed globally for commercial production, low-level presence is unavoidable." Firstly, this not the case and, secondly, this is not an adequate justification for establishing LLP. Firstly, contamination is not unavoidable and the federal government should take every possible measure to stop contamination of our food system with unapproved GM foods from other countries. Furthermore, since the first GM crop was approved in 1995, few experiments to develop GM foods have actually reached the market and there is no reason to assume that current research will translate into commercialized products.[iii] Secondly, the possibility of contamination from unapproved GM foods is no justification for legally sanctioning it.

LLP does not change the existing approval process, it ignores it. Consultation documents state that, "The proposed approaches will not reduce or change the rigor of the Canadian approval process for genetically modified products or change the rules for certification of organic products." (AAFC AGRIDOC #2812902 page 2) Instead, LLP will make the approval process for GM products, in certain cases, irrelevant. In certain cases, Health Canada's approval process will not be engaged before a GM food is allowed in our food system. **LLP establishes exceptions to Canadian food safety regulation of GM foods.**

Either Health Canada's evaluation for safety of GM foods matters or it is irrelevant.

- Establishing LLP communicates to the public that the federal government no longer values this scientific evaluation of GM food safety.
- More importantly, LLP materially allows for GM food products to enter Canada without this safety assessment.

4. LLP will increase public uncertainty

There is already a major problem of public distrust of Canadian regulation of GM foods. LLP will further undermine the legitimacy of federal regulation of GM foods, with possible wider impact on public perception of broader food safety regulation. Public confidence in Health Canada will be undermined and LLP will escalate the existing public controversy over GM foods in Canada.

- There are existing serious issues of transparency in regulation that will be compounded by LLP. For example: There is no mandatory labeling for GM foods; Health Canada's regulation of GM foods relies on corporate data that is classified as "Confidential Business Information" and is therefore not accessible to the public or independent scientists; and there is no public notification when GM products enter into the assessment process and the public is actually denied this information if requested. All of these same problems will be replicated with LLP and will be exposed in relation to GM products unapproved in Canada.

- Canadian consumers already bare the burden of researching to identify which GM foods are approved by Health Canada and on grocery store shelves, without the benefit of mandatory labelling or accessible information from regulatory agencies.[iv] LLP will permit unapproved, and unidentified, GM products to contaminate widely, at possibly changing thresholds. The public will be uncertain of all the food on grocery store shelves: Which foods on the shelves have been approved by Health Canada and which have not? How has LLP contamination been justified in each case? What level of LLP contamination is allowed in each case?

LLP introduces great uncertainty into the future as we cannot predict which unapproved GM foods from what countries may ultimately be accepted if Low Level Presence is established.

5. LLP and GM food of the future

Canada's largest trading partner currently approving GM foods is the United States. It is therefore required that we look to the U.S. example as the first possible origin of LLP. It is important to note that the U.S. and Canadian governments have previously made different regulatory decisions based on the same safety data. For example, the U.S. approved Monsanto's recombinant Bovine Growth Hormone while Health Canada did not. While the final regulatory decision in Canada was based on animal welfare concerns rather than human safety, it points to the possibility that Canadian and U.S. regulatory departments can make different safety conclusions on GM products, from the same data.

If Canada establishes LLP this may provide corporations with a way to begin circumventing Health Canada's approval process altogether. Rather than ask for approval in Canada, companies could ask for approval in the U.S. or another country first, knowing that Canada would then allow for LLP. This possibility and its implications need to be assessed relative to a consideration of how LLP will impact "the promotion of and incentive for compliance with Canada's regulatory system for genetically modified products." (AAFC AGRIDOC #2813902 page 2)

6. Stakeholder consensus on the goal of synchronized GM food approvals should not be assumed

Agriculture Canada has articulated the long-term goal of synchronizing GM food approvals among key trade partners. Consultation documents state that the "The long term objective for the management of low-level presence would be to work towards synchronized approvals among key trading partners…" (AAFC AGRIDOC #2821497 page 5). This means that in the future, Canada hopes to have the same or similar regulatory processes as other countries or will accept the decisions of certain countries such that Health Canada does not necessarily need to conduct its own evaluation of GM foods.

- The federal government should not assume that synchronizing approval is a goal shared by all stakeholders.
- Synchronizing regulation is a race to the bottom unless Canada fully reforms our current regulation of "novel foods" as per the recommendations of the Royal Society of Canada Expert Panel on the Future of Food Biotechnology (2001) and follows the example of other countries with stronger regulation, such as those of the European Union.

7. The dual mandate of trade and regulation for safety is not acceptable

The proposals for LLP show the federal government, once again, engaging in a dual and conflicting mandate of both trade promotion and regulation for safety, whereby safety is compromised. The dual mandate of supporting trade in GM foods and regulating for safety has already been criticized as a fundamental problem embedded in the Canadian Food Inspection Agency regulation of GMOs. Through LLP, Agriculture Canada is extending this dual mandate to Health Canada.

- Dual mandates in regulatory departments should be eliminated and safety must established as the priority over trade in every instance.

8. LLP fails to achieve stated trade policy goals

LLP does not even achieve the trade goal articulated as the rationale for this policy. There is no guarantee, or indeed any reason to believe, that by setting the global example of removing zero-tolerance via establishing Low Level Presence, our trading partners will follow. On the contrary, LLP may simply serve to further undermine domestic and international confidence in Canadian regulation and GM products, without ever moving Canada closer to the desired trade outcome. The federal government should carefully consider the negative domestic and international consequences of being the first country in the world to establish LLP.

9. Action Required

The trade problem that LLP aims but fails to address could be solved if Canada reevaluates its policy approach to GM products and institutes a stronger regulatory regime that includes economic considerations. To eliminate the risk of market shutdowns, rather than establishing LLP in Canada as "a model to influence countries", the federal government should ensure that any GM crops approved for growing in Canada are first approved by our major trading partners.[v]

Additionally, Canadian regulation of genetically modified products needs immediate and systemic reform as per, at least, the 58 recommendations of the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology.[vi] The terms of reference for the panel, commissioned by regulatory agencies, were to look ahead to forecast the types of food products expected to be developed and examine the ability of regulatory procedures to assure the safety of foods now and in the long-term. In light of the presumption of an "increasing number of GM products being developed globally for commercial production" it is incumbent on the federal government to address these recommendations.

Rather than establish LLP, Canada's policy approach to genetically modified crops and foods needs to be reevaluated in light of our 17 years of experience with GM products, as well as in light of the continuing public controversy.

<u>Recommendations:</u>

1. Low Level Presence sacrifices food safety for elusive trade goals and should be rejected outright in favour of maintaining our zero-tolerance policy for unapproved GM foods.
2. The federal government should immediately place a moratorium on approving any new genetically engineered foods, crops or animals until a process of full regulatory reform and public consultation on the future of genetic engineering

is completed.

3. Instead of considering LLP, Canada should also take every available step to ensure that contamination itself is not an issue. The federal government and all agencies and research institutions need to take the risk of contamination seriously and institute stronger segregation (biosafety measures) of GM commodities in order to avoid contamination.
4. The federal government needs to audit regulatory departments, the Canadian Food Inspection Agency and Health Canada in particular, to remove all dual mandates whereby trade considerations threaten to compromise human safety.
5. Canada needs to stop approving GM crops for growing in Canada that are not also approved in our major export markets.

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[i] CBAN notes with interest that the proposals for LLP relate specifically to genetically modified foods as distinguished from other foods and crops that fall under the existing "Novel Food" and "Plants with Novel Traits" regulations: "For the purposes of this document, "genetically modified" refers to new plants that have been modified using recombinant DNA technology. A genetically modified crop refers to a crop plant with a specific trait or traits that have been introduced via recombinant DNA technology". (Footnote to AAFC AGRIDOC #2812902 page 2) LLP consultation documents recognize the unique trade issue raised by GM products and seemingly propose an exemption for GM foods from the application of Novel Food regulations.

[ii] Most notably via the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada." 2001.

[iii] After 17 years, there are only 8 GM food crops on the market globally: corn, canola, soy, cotton, papaya, squash and alfalfa.

[iv] Health Canada and the CFIA maintain lists of approved "Novel Foods" and "Plants with Novel Traits" on their respective websites but these lists include products of conventional plant breeding as well as rDNA technology and, additionally, do not reflect the reality of what is currently on the market.

[v] In 2010, this was proposed via Bill C-474, tabled by NDP Agriculture Critic Alex Atamanenko. The Bill would have required that "an analysis of potential harm to export markets be conducted before the sale of any new genetically engineered seed is permitted" and received strong endorsement particularly from associations of alfalfa growers in Canada who see the introduction of GM alfalfa as a threat to their markets.

[vi] See "Genetically Modified Organisms and Precaution: Is the Canadian Government Implementing the Royal Society of Canada's Recommendations?" by Peter Andrée and Lucy Sharratt, October 2004 for a full analysis of how the federal "Action Plan" failed to address these recommendations.