Report 5

Are GM crops and foods well regulated?

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Canadian Biotechnology Action Network

GMO Inquiry 2015

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Collaborative Campaigning for Food Sovereignty and Environmental Justice

The GMO Inquiry 2015 is a project of the Canadian Biotechnology Action Network (CBAN). CBAN is a campaign coalition of 17 organizations that researches, monitors and raises awareness about issues relating to genetic engineering in food and farming. CBAN members include farmer associations, environmental and social justice organizations, and regional coalitions of grassroots groups. CBAN is a project on the shared platform of Tides Canada.

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SUMMARY

Government regulation determines what genetically modified (GM, also called genetically engineered) foods are on the shelves, and what GM crops and animals can be planted and raised. **For twenty years, the Canadian government has been approving genetically modified organisms (GMOs) in a process that is not transparent, and does not include public participation or consultation**. The regulatory system has been widely criticized but has not significantly changed in two decades.

In 1999, government departments asked The Royal Society of Canada to form *the Expert Panel* on the Future of Food Biotechnology to assess the ability of Canadian regulation to deal with GMOs. In 2001, the Expert Panel released a report that criticized the existing system, and made 53 recommendations for significant regulatory reform. Today, only two recommendations have been fully implemented.

The Canadian regulatory system for GMOs is designed around two competing goals: to support industry and protect public safety.

No new laws and regulations were created when GMOs were first introduced. Instead, the responsibilities were divided between existing regulations and government departments. GMOs are regulated under the broader categories of "Novel Foods" and "Plants with Novel Traits" that include products of other technologies such as conventional plant breeding.

The Canadian government does not do any of its own safety testing. Instead, Health Canada and the Canadian Food Inspection Agency rely on information and data submitted by the company requesting product approval. This information is not disclosed to the public or independent scientists because it is considered "Confidential Business Information." In fact, government departments do not disclose what GMOs they are reviewing unless companies have already released this information to the public.

Precisely how regulators assess the safety of GM crops and foods, and what data is evaluated, is unknown. The process to assess the risks of new GM foods, crops and animals happens behind closed doors. The only non-governmental party that has access to the regulatory process is the biotechnology industry itself. The only public document provided by the government in the process of GMO risk assessment is a short summary of each product approval decision, which is posted online after the decision has been made. These summaries are brief and only vaguely describe how and why a product has been approved.

GM foods and crops are regulated based on a very narrow set of considerations. The government limits risk assessment to (some) safety questions and does not consider "non-scientific" concerns such as economic impacts. GM regulation in Canada does not evaluate long-term impacts or include any formal mechanisms to track and re-evaluate impacts over time.

There is an almost total lack of transparency in the regulation of GMOs in Canada. The process takes place without public participation, based on data submitted by companies that is not disclosed to the public or independent scientists. There are no consultations with farmers or consumers. The government posts lists of approved "Novel Foods" and "Plants with Novel Traits" but the GMOs on these lists are not clearly identified and many are not actually being grown or sold. There is no mandatory labelling of GM foods in Canada.

There is an almost total lack of transparency in the regulation of GMOs in Canada

GMO INQUIRY 2015

Twenty years ago, in 1995, the Canadian government approved the first genetically modified (GM, also called genetically engineered or GE) canola varieties, as well as the first GM soy, GM tomatoes (not currently on the market) and GM potatoes (not currently on the market). With these decisions, the government introduced genetically modified crops into our environment and food system for the first time.

After 20 years, we still have major unanswered questions and hear conflicting messages about the impacts and risks of GM crops and foods. Even while our questions persist, the Canadian government has just approved the first-ever GM apple (this will be the first GM fruit grown in Canada) and could soon approve the first GM food animal (a GM salmon).

Canadian farmers and eaters want to know the impacts of GM crops – on our environment, our food and farming systems, our economy, and on our health. We want to know about the food we're growing, eating and buying. And we want to know who truly benefits from GM crops and foods, and who pays their costs and bears the burden of their risks.

The Canadian government has not monitored or shared detailed information to answer these questions. However, research in Canada and from around the world, as well as the experiences of farmers in Canada and other countries, helps shed light on the problems with GM over the past two decades. It's time to bring our research together and assess the evidence, so that we can decide whether GM crops have a place in the future of our food system.

This is the fourth of a series of reports that are part of **GMO Inquiry 2015**. All reports are posted at **www.gmoinquiry.ca**.

- Where in the world are GM crops and foods? www.gmoinquiry.ca/where
- Are GM crops better for the environment? www.gmoinquiry.ca/environment
- Are GM foods better for consumers? www.gmoinquiry.ca/consumers
- Are GM crops better for farmers? www.gmoinquiry.ca/farmers
- Are GM crops and foods well regulated? www.gmoinquiry.ca/regulation
- Do we need GM crops to feed the world? www.gmoinquiry.ca/feedingtheworld

Read and print the summary pamphlet for this report at GMOinquiry.ca/regulation

INTRODUCTION

> When transformative technologies are introduced into society, there is usually a time lag between their introduction and the proper control and regulation of their application to support the benefits and minimize their harmful effects.
>
> — Jeremy Gruber, Council for Responsible Genetics, 2014[1]

In 2000, the Government of Canada spent $2.5-million to send the pamphlet *Food Safety and You* to every household in the country.[2] This pamphlet told Canadians that new foods, including genetically modified foods, "go through a rigorous and thorough review process before they can be introduced into the marketplace."[3] But just one year later, in 2001, The Royal Society of Canada's *Expert Panel on the Future of Food Biotechnology* made 53 recommendations for fundamental change in Canada's regulation of GMOs. By this time, Canadian regulators had already approved some of the GM products that now dominate the market. Almost fifteen years after the wide-ranging critique of the Expert Panel, Canada's regulatory system has not changed in any significant way.

In Canada, the question of the social worth of individual GMOs is not determined through regulation but is left for the market to decide. The federal government has already decided that the new technology and the growth of the biotechnology sector serve the public good. In the framework of this approach, the government assesses the safety of individual products, but does not assess the benefits or social and economic risks.

The outcome of Canada's regulatory system was early commercialization of many GM crops and foods. Canada and the US were the first countries to approve GM crops and foods. In fact, Canada was the first country in the world to approve the production of GM animals (a pig and a fish, not yet approved for consumption) and the first to approve 2,4-D- and dicamba-tolerant crops (2012), ahead of the US. The only genetically engineered agricultural product denied approval by the government is Monsanto's Bovine Growth Hormone — a decision taken after Health Canada regulators publicly challenged the process.

Canadians are concerned about how the government regulates GMOs. An Ipsos Reid poll conducted for CBAN in 2015 shows that 57% of Canadians are not confident in the government's safety and regulatory systems for genetically modified foods.[4] Additionally, of the 88% of Canadians who want GM foods labeled, 47% are concerned about government transparency in regulation and 58% are concerned that not enough research has been done on the long-term health and environmental impacts. 48% of Canadians support a ban on genetically modified foods. Clearly, the regulation of GMOs is controversial in Canada.

What does it mean to say that GMOs are well-regulated? What do Canadians want from regulation? What do they expect? In the case of GMO regulation, the priorities of industry and the public are often in conflict.

> These foods go through a rigorous and thorough review process before they can be introduced into the marketplace.
>
> — Government of Canada, *Food Safety and You*, 2000[5]

The Royal Society of Canada's Expert Panel on the Future of Food Biotechnology

In December 1999, the Ministers of Health, Agriculture and Agri-Food Canada, and the Environment jointly asked The Royal Society of Canada to put together an Expert Panel to study the ability of Canada's regulatory system to address future applications of GM technology.[6]

The Royal Society of Canada (now called RSC: The Academies of Arts, Humanities and Sciences of Canada) is Canada's association of preeminent scientists. The RSC's members (fellows) are elected and number around 2000. One function of the Royal Society is to strike temporary expert panels to address important issues.

The terms of reference for The Royal Society of Canada's *Expert Panel on the Future of Food Biotechnology* were negotiated by the government and the Expert Panel. The Panel was made up of fifteen scientists and regulatory experts who conducted research including through interviews with government officials. The panel's report, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, was released in February 2001, and included 53 recommendations for change.

The government responded with an "Action Plan" and issued over 8 progress reports between 2002 and 2005.[7] However, a 2004 analysis found that only two of the Expert Panel's recommendations had been fully implemented.[8] A subsequent analysis in 2006 concluded that that "meaningful progress is extremely limited" in the areas of food safety, environmental assessment, peer review, transparency, and monitoring and surveillance.[9]

At the time, the *Toronto Star* called the Expert Panel's report a "polite but scathing indictment – of the industry, the academic research community and, particularly, of the federal government itself."[10]

WHAT IS REGULATION FOR?

Who is regulation for? What policy goals does regulation serve? In broad strokes, regulatory systems can be designed to support industry, protect public safety, and/or assess the benefits and risks of technologies or individual products for our economy and society.

Canadian regulation of GMOs was designed to support the emergence of new technologies and the new biotechnology industry, and is mandated to keep Canadians and our environment safe from harm. As Agriculture and Agri-Food Canada said in 1995, "The role of the regulator is to balance public concerns for safety with those of industries that wish to use technology to create national prosperity."[11] These two goals can be complementary or competing. In the case of GMOs, they compete.

Canadian regulation does not evaluate the economic and social impacts of GM crops and foods. The Canadian Food Inspection Agency (CFIA) says that, "The Government of Canada neither advocates for, nor opposes, specific products. Regulatory decisions are evidence-based and impartial."[12] However the regulatory system is designed around certain priorities and conclusions, and has its own its impacts on Canadian society and our economy.

GOAL 1: TO SUPPORT INDUSTRY

> "The licensing and approval process is absolutely critical to the future development and growth of the industry.
>
> — KPMG, 1994[13]

> "The federal government has made significant efforts and investments to support the development of biotechnology.
>
> — Health Canada, 2015[14]

The federal government's priority to support the growth of the new biotechnology industry as an "economic driver" was central to designing the regulatory system, and has continued to define how Canada regulates GMOs.[15] The government's announcement of the 1993 Federal Regulatory Framework for Biotechnology stated that "the goal of the regulatory framework is to minimize environmental risks while fostering competitiveness through timely introduction of biotechnology products to the marketplace."[16]

> "The goal of the regulatory framework is to minimize environmental risks while fostering competitiveness through timely introduction of biotechnology products to the marketplace.
>
> — Government of Canada, 1993[16]

The 1993 Federal Regulatory Framework for Biotechnology outlined the following principles for regulation:

1. *Maintain Canada's high standards for the protection of human health and the environment;*
2. *Use existing legislation and regulatory institutions to clarify responsibilities and avoid duplication;*
3. *Continue to develop clear guidelines for evaluating products which are in harmony with national priorities and international standards;*
4. *Provide for a sound scientific database on which to assess risk and evaluate products;*
5. *Contribute to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation and adoption of sustainable Canadian biotechnology products and processes.*[17]

Just one year later, the government-wide 1994 Federal Regulatory Plan asked all departments "**to reduce the regulatory burden on Canadian business and individuals**."[18] This was one of the principles used to design the regulatory system for genetic modification. Biotechnology was chosen as one of six target areas in this regulatory plan because, "**The [biotechnology] industry has pinpointed regulatory uncertainty and lengthy approval processes as the key impediments to investment and jobs.**"[19] *For a detailed history see "The Real Board of Directors: The construction of biotechnology policy in Canada 1980-2002" by Devlin Kuyek.*[20]

The speedy commercialization of new products is important to manufacturers because it means that they can sell their products sooner and quickly get returns to company shareholders. It also means that companies spend less money on regulation (conducting studies, preparing information, and answering questions from regulators, for example). **Approving products for sale in a timely manner is one of the main ways that our government encourages and protects investments in GMO research and development**. Peter Phillips, a policy professor at the University of Saskatchewan argues, "Regulatory systems are an integral part of the system that delivers new technologies to the market. Risings costs, lengthening review periods and pervasive uncertainty about which technologies will be acceptable in different markets have dampened revenues and investments and lowered the potential for plant biotechnology to contribute to global food security. Increased regulatory costs and an expanding approval process stifle innovation — the innovation that is needed to secure an adequate supply and, appropriate quality of food at affordable prices."[21]

Genetically modified products take a long time and a lot of money to develop, and the stakes in getting products to market quickly are therefore extremely high. For example, the genetically engineered veterinary drug recombinant Bovine Growth Hormone (BGH) cost companies an estimated $500-million to develop, and had a possible annual global market of $500-million to $1-billion.[22] Companies lost projected revenue every year that BGH was denied approval in Canada. In 1995, Monsanto threatened to pull its investments out of Canada if our government legislated a moratorium on approving BGH.[23] (Though approved in the US in 1994, Canada denied approval in 1999 – the only time, to our knowledge, that a GM agricultural product has been refused approval by Canadian regulators.)

> "The biotech race can be won – and I'm confident it will be – because it must be… Biotechnology is the background upon which all future technology battles will be fought… This time we must succeed. We must not let our lead slip away because of bad public policy.
>
> — Richard Mahoney, Monsanto CEO, 1993[24]

GOAL 2: TO PROTECT PUBLIC HEALTH AND THE ENVIRONMENT

Regulation also serves to protect the public and environment from harm. This purpose comes with the associated goal of reassuring Canadians that new products are safe to use. As Monsanto's CEO said in 1993, "Regulation is very appropriate, in our view, and it's needed not only to make prudent regulatory judgments but at least as important to assure the public that the products of this new technology are indeed safe."[25] The Canadian government has also connected regulation to the goal of establishing and maintaining public trust in the new biotechnology industry and its products. As early as 1993, Health Canada's Science and Policy Liaison said, "**As regulators we must do something to bridge the gap, to ensure the confidence in the industry, and to instill confidence within the population, that these types of products are safe**."[26]

The industry promotes its products as safe by referring back to government regulation. For example, the industry association CropLife Canada says: "Here in Canada, GM crops are subject to strict regulatory standards, ensuring that Canadians have access to one of the safest food supplies in the world. Extensive safety reviews are completed by the Canadian Food Inspection Agency (CFIA) and Health Canada before any of these crops are planted."[27]

> "Future availability [of food biotechnology] will require two things, regulatory approval and public acceptance.
>
> — Bob Ingratta, Monsanto Canada, 1993[28]

REGULATING WHAT?

Definitions are important in regulation. So what are we regulating?

No new regulations or regulatory departments were established to regulate GMOs when they were first being introduced in Canada. Because of this, there is no distinct system to regulate GMOs. Instead, the responsibility for regulation was divided between existing government departments and legislation, with guidelines developed for the new regulatory categories called "Novel Foods" and "Plants with Novel Traits".

Canada regulates the products of genetic modification under these two broad categories of "novel" products that also include products of other technologies, such as conventional plant breeding and mutagenesis (exposing seeds to chemicals or radiation in order to generate mutants).

Novel Foods are:

- "Foods resulting from a process not previously used for food.
- Products that do not have a history of safe use as a food.
- Foods that have been modified by genetic manipulation, also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology-derived foods."[29]

A **plant with a novel trait (PNT)** is "a plant that contains a trait which is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to the environment and human health. These traits can be introduced using biotechnology, mutagenesis, or conventional breeding techniques."[30]

These regulatory categories have led to two decades of confusion over terms and definitions in Canada. While Canadian departments officially use the term "genetic engineering" to refer to recombinant DNA technology, the public and food industry in North America have begun to widely use the term "genetic modification."[31]

Health Canada defines **genetically modified organisms (GMOs)** as those organisms "altered through any method, including conventional breeding" and an organism as **genetically engineered** "if it was genetically modified using techniques that permit the direct transfer or removal of genes in that organism. Such techniques are also called recombinant DNA or rDNA techniques."[32] (However, these terms are used inconsistently by government departments.[33]) The 2001 Royal Society of Canada's *Expert Panel on the Future of Food Biotechnology*, which assessed Canada's regulation, decided to use the terms genetic modification, genetic engineering and biotechnology synonymously.[34] In this report, we use the terms genetic modification and genetic engineering interchangeably, and commonly refer to GMOs.

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These categories of "Novel Foods" and "Plants with Novel Traits" reflect the Canadian government's approach that assesses products of genetic modification, and not the process.[35] An organism is regulated in Canada if it has "novel traits", and not because it is genetically modified. The process of changing the organism is seen as incidental in Canadian regulation because Health Canada argues that, "genetic modification does not introduce unique risks."[36] However, this conclusion is highly contested and has direct implications for risk assessment. The process of genetic engineering can create unintended and unpredictable changes in organisms that may have important implications for health and safety.

An analysis of the risks inherent to the process of genetic engineering and the implications for safety is presented in the GMO Inquiry report "Are GM Foods Better for Consumers?".

The categories of "Novel Foods" and "Plants with Novel Traits" were created in Canada (and are unique to Canada) in order to regulate products of the new technology while simultaneously accommodating the political decision not to create any new laws for GMOs.[37] **Regulating GMOs without naming them was a way to deal with the new technology without developing special regulations**. As Canadian researcher Elizabeth Abergel argues, "It also served to keep GE technique invisible in the legislative and regulatory system."[38]

What is genetic modification?

Genetic modification (GM) is the introduction of new traits to an organism by making changes directly to its genetic makeup, e.g. DNA, through intervention at the molecular level. It's also called genetic engineering or GE. With genetic engineering, scientists can change the traits of plants and animals by inserting DNA pieces, whole genes, or long stretches of DNA segments from many different organisms. These sequences can also be taken from the same species or be newly made up. Scientists can also delete or swap DNA sequences in organisms or introduce genetic material to silence genes.

Unlike conventional breeding and hybridization, genetic engineering is a laboratory technology that enables the direct transfer of genes between organisms in different species or kingdoms that would not breed in nature, and the introduction of new sequences that do not even exist in nature.

WHO REGULATES IN CANADA?

> One of the principles of the framework was that existing legislation and regulatory bodies would be used to regulate biotechnology products, and that they would build on existing laws and expertise, rather than developing entirely new laws and agencies. This means that agricultural products of biotechnology are regulated under the same broad legislation and structures, with the addition of some new regulations and administrative procedures, as agricultural products produced in more traditional ways.
>
> — CFIA[39]

In 1996, a House of Commons Standing Committee on Environment and Sustainable Development recommended that the government study the potential creation of a "gene law" or "transgenics agency" but no new regulations or regulatory departments were established for GMOs in Canada.[40] Instead, the regulation was divided between existing departments and existing regulatory responsibilities, with guidelines for the new categories of "Novel Foods" and "Plants with Novel Traits."

CFIA (CANADIAN FOOD INSPECTION AGENCY):
Environmental risk assessment of GM plants for growing; safety assessment of GM foods for animal feed; safety of GM field trials.

HEALTH CANADA:
Safety assessment of GM foods for human consumption.

ENVIRONMENT CANADA:
Environmental risk assessment for GM animals including fish.

CANADIAN FOOD INSPECTION AGENCY

The Canadian Food Inspection Agency (CFIA) is the lead agency responsible for regulating genetically modified plants or "Plants with Novel Traits" (PNTs) for environmental safety under the Seeds Act. It grants approval for field trials ("confined release") and for commercial growing ("unconfined release"). The CFIA also approves crops for use as animal feed under the Feeds Act and Regulations. The CFIA enforces food safety standards through inspection and monitoring activities.

The CFIA was established in 1997 to consolidate all federal food inspection services as well as plant protection and animal health programs – services that were previously provided by four departments: Agriculture and Agri-Food Canada, Fisheries and Oceans Canada, Health Canada, and Environment Canada. The CFIA took over Health Canada's responsibility for food safety inspections and Agriculture Canada's enforcement duties.

The CFIA reported to the Minister of Agriculture until 2013 when the federal government moved the CFIA's mandate to Health Canada. This move addressed a long-standing critique that Agriculture and Agri-Food Canada had a conflict of interest because it was responsible for regulating genetically modified plants at the same time that it was taking a lead role promoting the technology.[41] Until it was moved, Agriculture and Agri-food Canada was acting as a regulator through the CFIA, a promoter through its role in trade and public communications, and a product developer through its research branch.[42] For example, in the early 2000s, the CFIA was assessing the safety of Monsanto's GM glyphosate-tolerant wheat, but the wheat was developed in collaboration with Agriculture and Agri-food Canada's Cereal Research Centre, with a government investment of $4-million.[43] This meant that the department would have received royalties if the CFIA, which it oversaw at the time, approved the GM wheat (Monsanto withdrew its requests for approval in both Canada and the US in 2004 due to widespread farmers and consumer protest).[44]

Now that the CFIA has been moved to Health Canada, the Minister of Health is responsible for all food labelling. (Health Canada was traditionally responsible for nutrition labelling and health warnings, and the CFIA was responsible food labelling for non-health reasons such as country of origin and irradiated foods.[a]) This means that the mandatory labelling of GM foods to provide consumer choice would rest with the CFIA and the Minister of Health.

AGRICULTURE AND AGRI-FOOD CANADA

Since the CFIA has been moved from Agriculture and Agri-Food Canada to Health Canada, the department has no regulatory mandate relating to GMOs, meaning that it is no longer responsible for GM crop approvals. The department does however promote trade in agricultural products from Canada including GMOs. See www.cban.ca/llp

a In Canada, irradiation is only permitted on potatoes, onions, some flour and spices.

HEALTH CANADA

> "Health Canada's mandate is to ensure that all novel foods, including GE salmon, are safe and nutritious prior to entering the Canadian food supply.
>
> — Director General, Food Directorate, Health Canada, 2013 [46]

Health Canada is responsible for assessing the health risks of genetically modified foods including meat from genetically modified animals, as well as the safety of veterinary drugs, pharmaceuticals, pesticides and cosmetics. Health Canada regulates under the Food and Drugs Act and Regulations, using the "Novel Food Regulations" and "Guidelines for the Safety Assessment of Novel Foods".

The Minister of Health is now also responsible for the CFIA which regulates "Plants with Novel Traits" and was previously under Agriculture and Agri-Food Canada. Health Canada also regulates pesticides under the Pest Management Regulatory Agency.

ENVIRONMENT CANADA

Environment Canada plays a surprisingly small role in regulating genetically modified organisms. The Canadian Environmental Protection Act (CEPA) is used as a "catch-all" to regulate GM products that fall outside the responsibilities of other departments.[46] This means that CEPA covers the environmental assessment of genetically modified animals.[47]

Environment Canada could have been chosen to regulate crops for environmental safety but the responsibility was given to Agriculture and Agri-Food Canada (AAFC), through the CFIA. In 1997, the Ontario Corn Growers described this decision as "the implementation of a national agricultural policy

which ensured that regulation of agricultural biotechnology would occur within AAFC, rather than within the anti-biotech confines of Environment Canada."[48]

The first GM animal ever approved (and presumably the first one ever assessed) by Environment Canada was the GM "Enviropig." In February 2010, Environment Canada granted approval to the University of Guelph to produce Enviropig.

(Health Canada was presumably also assessing the Enviropig for approval but a food safety decision was not made before the University of Guelph canceled the project under public protest. *See www.cban.ca/enviropig*)

Environment Canada was then tasked with assessing the environmental risks of GM fish eggs production, in partnership with the Department of Fisheries and Oceans (DFO), because DFO repeatedly failed to develop its own regulations (see below).

DEPARTMENT OF FISHERIES AND OCEANS

The Department of Fisheries and Oceans attempted to develop regulations under the Fisheries Act to govern the introduction of genetically engineered fish but gave up after 16 years.

Failure to develop regulations for GM fish

- Beginning in 1992, the Department of Fisheries and Oceans Canada (DFO) made commitments to develop regulations for "transgenic aquatic organisms" including genetically engineered (GE) fish.
- In 1997, DFO drafted a *Policy on Research with, and Rearing of, Transgenic Aquatic Organisms*.
- In response to a 2001 Environmental Petition to the Commissioner of the Environment and Sustainable Development filed by Greenpeace, asking for information on the regulation of GE fish, DFO committed to developing regulations for "new biotechnology-derived aquatic organisms" under the Fisheries Act.[49]
- A 2004 audit from the Commissioner found that DFO had made little progress and repeatedly missed deadlines to create new regulations. DFO agreed to develop a new regulatory strategy and new policy by 2005.[50]
- A follow-up audit in 2008 found that DFO had failed to develop a regulatory strategy despite the fact that "it had recognized the need for regulations dealing with aquatic biotechnology". The audit pointed to weaknesses in Canada's regulations including the "need to strengthen oversight of research and develop mandatory reporting requirements for GE fish and for accidental releases of genetically engineered organisms into the environment."[51]
- Ultimately, DFO concluded that GE fish would continue to be regulated under the Canadian Environmental Protection Act, which it said "functions as a safety net for new substances proposed for import or manufacture, including research and development activities on genetically engineered organisms that are not covered by other legislation," through a Memorandum of Understanding with Environment Canada and Health Canada.[52]

Regulating the world's first GM fish

Canada was the first country to grant any approval to the company AquaBounty for their genetically modified Atlantic salmon. Canada's Minister of the Environment approved the commercial production of the GM salmon in November 2013 (the GM fish was approved for human consumption in the US in November 2015, but not in Canada as of December 2015). **This decision is under court challenge**.

Unlike GM crops that are assessed for environmental risk by the Canadian Food Inspection Agency (under guidelines for "Plants with Novel Traits"), the environmental risks of GM animals are regulated by Environment Canada and Health Canada, under the Canadian Environmental Protection Act (CEPA). For GM fish, this regulation includes a Memorandum of Understanding with the Department of Fisheries and Oceans (DFO) which conducts risk assessments.[53] This means that the regulatory process for GM animals has some different components to the process for GM crops. (The safety assessment for human consumption of GM animals is the same as other "novel foods" assessed by Health Canada.)

Under CEPA, a new GM animal is either approved, not approved, or its use can be limited through declaration by the Minister of Environment. Any unapproved uses of the GM animal will be a "Significant New Activity" (SNAc) if, in the opinion of the Minister, those new uses might result in the GM animal becoming "toxic or capable of becoming toxic" in the environment (as per the definition of toxic under CEPA). According to CEPA, this assessment must conclude in 120 days, unlike other GM product reviews that have no specific timeline.

To approve the GM salmon, the Minister of the Environment published a Significant New Activity Notice in the Canada Gazette (the Government of Canada's newspaper where new laws and regulations are published for public notice and comment).[54] This notice is how Canadians learned that the GM fish was approved (until that point the public did not know it was under assessment, see pages 17-18).

DFO conducted a risk assessment of GM fish eggs production. This assessment was then peer-reviewed through a meeting that included three scientists from outside government, and a summary was posted online.[55] The assessment concluded that the risk of environmental exposure via escape and survival of the GM salmon eggs was negligible but that if escape happened, the environmental hazard would be high, including the risk to wild Atlantic salmon populations.

DFO scientists evaluated the company's proposed scenario for producing GM fish eggs in PEI, for shipment to Panama for grow-out and processing. This included an understanding that "no more than 100,000 eggs will be exported to Panama in any given year."[56] **However, the Minister's approval went far beyond the request from the company and the scenario assessed by DFO**. The approval from the Minister allows for the production of GM fish eggs or fish, anywhere in Canada, as long as the production is in on-land containment. This decision is contrary to the advice from DFO which clearly stated that uses differing from the proposal would require new risk assessments.

Two Canadian environmental groups, Ecology Action Centre (NS) and Living Oceans Society (BC), represented by EcoJustice, are challenging the approval as unlawful because it failed to assess whether the GM salmon could become invasive, potentially putting ecosystems and species such as wild salmon at risk.[57] Instead of assessing the impact of escape, the Minister approved GM fish production based on an assessment of containment measures. In making this decision, the Minister also allowed the department to waive a requirement for some ecological risk data from the company (and the public notice of this decision was not published until after approval was granted).[58] Furthermore, the Minister's approval went above and beyond the company's request to product GM salmon eggs in PEI, and approved the production of the GM salmon eggs and fish anywhere in Canada.

www.cban.ca/fish

LACK OF TRANSPARENCY IN CANADIAN REGULATION OF GMOS

THE PROBLEM OF TRANSPARENCY

> The Government of Canada supports consumer choice, and strives to provide consumers with access to meaningful, credible, and truthful information as it relates to biotechnology and food. — CFIA[59]

> The [Royal Society's Expert] Panel was also critical of the level of secrecy surrounding testing of new GM products.
>
> — Royal Society of Canada, 2001[60]

This report focuses on the obvious and fundamental problem of a lack of transparency in Canada's regulation of GMOs. This lack of transparency is almost total in all of the steps of the approval process (outlined in the next section) and has a number of important impacts including, in the words of The Royal Society of Canada's *Expert Panel on the Future of Food Biotechnology*, an "inability to evaluate the scientific rigor of the assessment process."[61] It is symptomatic of the fundamental problem that Canada's regulation of GMOs was designed to lock out public participation. However, **while transparency is necessary and valuable, transparency is only a first step to creating processes of democratic decision-making**.

Transparency in regulation would serve a number of important goals, but it is not equivalent to participation. As researcher Devlin Kuyek writes, "It is assumed that transparency will satisfy the demands of representative democracy. But transparency only means that the public should be able to see how and on what grounds a decision is made. The public remains on the outside looking in…The view for the observer through the peek hole of transparency is not part of the decision making process. **There is no inherent democracy in transparency**."[62] While transparency can, in the words of the federal government, "ensure that Canadians and Parliament are better able to hold the Government and public sector officials to account,"[63] this is less effective if transparency is not accompanied by mechanisms for public participation. Transparency is one core tool to serve the goal of public participation, but without processes for public engagement and consultation, it will likely only partially serve this goal.

In respect to GMOs, transparency is most often discussed as a tool to enhance public trust in biotechnology, rather than a tool for democratic debate or to enhance government accountability. For example, in 2014, Health Canada said, "As a regulator, Health Canada plays an important role in protecting the health and safety of Canadians and is committed to greater transparency and openness **to further strengthen trust in our regulatory decisions**" (Emphasis added).[64]

In place of regulatory transparency, the federal government has provided information for public education on biotechnology and regulation.[65] In the words of The Royal Society of Canada's Expert Panel: "CFIA has engaged in active media campaigns promoting agricultural biotechnology, and seeking to allay public fears about risks associated with GM foods."[66] For example, the federal government spent at least $13-million on public communications between 1997 and 2002[67] because, as the

then-Minister of Agriculture said, "The government believes that it is important to respond to the public's desire to understand biotechnology and the safety of its products."[68] To support this education, the government funded the (now defunct) Food Biotechnology Communications Network (FBCN), whose paying members included Monsanto and other major biotech companies.[69] The CFIA helped fund the "installation and promotion" of the FBCN's toll-free phone line for the public and supported the development of their website and materials.[70] This is one example that explains why, in 2002, researcher Devlin Kuyek argued, "The information [the government] does make available is most often merely public relations propaganda produced by PR firms in collaboration with its industry 'clients.'"[71]

For details on these past government communications see the GMO Inquiry report "Are GM Foods Better for Consumers?" For samples of government publications see www.cban.ca/PRarchives

> "It was necessary for the biotech industry to proceed with the implementation of its plans without public interference. — Devlin Kuyek, 2002[72]

Missing Transparency in Canadian Regulation of GMOs

NOTICE OF APPROVAL REQUESTS/SAFETY ASSESSMENTS	X	Health Canada, the CFIA and Environment Canada will not disclose when they are assessing a GMO unless the company has already publicly released this information. Industry can voluntarily post a notice on the CFIA's website via the "Biotechnology Notices of Submission."
PUBLIC CONSULTATIONS	X	There are no consultations with consumers or farmers. The "Biotechnology Notices of Submission" invites public comment on notices that companies allow the CFIA to post (see pages 19-20 for details of the severe limitations of this process).
RELEASE OF PRODUCT DATA/SCIENCE USED IN ASSESSMENTS	X	The government protects company data submissions as "Confidential Business Information." The science behind government safety assessments is not accessible to the public or independent scientists.
NOTICE OF DECISIONS	~	Approved GM foods and crops are posted as part of the lists of "Novel Foods" and "Plants with Novel Traits" but are not clearly identified as GM for the public. Approvals of GM animals are posted in the Canada Gazette.
INFORMATION ABOUT DECISIONS	~	Departments post "Decision Documents" that summarize decisions in vague terms, at an unspecified time after product approval.
LIST OF APPROVED GMOS	~	Approved GM foods and crops are added to broader lists of approved "Novel Foods" and "Plants with Novel Traits" but are not clearly identified as GMOs for the public.
PRODUCT LABELLING	X	There is no mandatory labelling of GM foods in Canada.

MISSING TRANSPARENCY – STEP BY STEP

> The Panel concludes that the lack of transparency in the current approval process, leading as it does to an inability to evaluate the scientific rigor of the assessment process, seriously compromises the confidence that society can place in the current regulatory framework used to assess potential risks to human, animal and environmental safety posed by GMOs.[73]

In the regulation of individual GMOs, each of the following steps, with the exception of one experiment in partial transparency called the "Biotechnology Notices of Submission Project," is untransparent and has no mechanism for public engagement.

STEP 1.
NOTIFICATION OF ASSESSMENT

Health Canada does not notify the public when a company requests approval for a GM product. In fact, Health Canada does not tell Canadians what products it is assessing at any given time unless the companies requesting approval have publicly released that information. Companies are invited to voluntarily notify the public via the CFIA's website through what is called "Biotechnology Notices of Submission."[74] However, because this is a voluntary system, **GM foods, crops and animals can be under government safety assessment without the public being made aware**.

CASE 1:
GM POTATO — IS HEALTH CANADA ASSESSING A GM POTATO?

In July 2015, CBAN wrote to Health Canada to ask if a GM potato (from the company Simplot), that had been recently approved in the US, was under assessment by Canadian government regulators.

Regulators responded saying they could not disclose that information: *"Submissions for the purposes of obtaining an authorization for the environmental release of a plant with a novel trait (PNT) for use as livestock feed, or for use as a novel food are* ***considered confidential business information. As a result, we are unable to disclose whether a given product has been submitted for authorization****. Since 2004, proponents have been invited to submit a Notice of Submission at the time they submit their novel plant product for safety assessments for its use as a PNT, novel feed, and novel food. Note, however, that the Notice of Submission (NOS) process is voluntary."*[75] In October 2015, a notice was posted on the CFIA's "Biotechnology Notices of Submission" website indicating the company's request for approval.

CASE 2:
GM SALMON — WERE HEALTH CANADA AND ENVIRONMENT CANADA ASSESSING A GM FISH?

Until a GM salmon was approved for commercial production by the Minister of the Environment, Canadians were unaware that Environment Canada was reviewing the product (as of November 2015 it is not yet approved for human consumption):

- On November 14, 2013, CBAN wrote to the Ministers of Health and the Environment to ask if their departments were assessing the GM fish for approval.[76]

- On November 23, 2013, Environment Canada notified the public that the GM salmon was approved for commercial production (a New Substance Notification was published in the Canada Gazette as per the *Canadian Environmental Protection Act*).[77]
- On November 27, 2013, Health Canada responded to CBAN that they could not answer this question (see below).[78]

In the absence of government transparency, the Director General of the Food Directorate of Health Canada responded to CBAN by referring to information provided by the company requesting approval, AquaBounty, and the Canadian media. The following is his response to CBAN's question, "**Is Health Canada reviewing a GE fish for approval?**" (www.cban.ca/regulationletters):

> *"Health Canada continues to strive for openness and transparency as part of its overall decision making process, of substances it regulates. The Department must balance this objective with adhering to the regulations that govern the assessment of novel products and respecting confidential business information submitted by developers.* ***As you may know, the Department is not legally permitted to release information that companies submit and consider confidential****, as per 20 (1) of the Access to Information Act.* ***This includes even the mere fact that a submission to the Department has been made****. This is not unique to GE foods and is broadly applied to all products regulated by the Department.*
>
> *As you point out in your letter, if an authorization for the GE salmon was granted, it would be the first GE animal permitted for sale in Canada. This has raised a significant amount of media and public interest in Canada and globally.* ***Numerous news articles have been published and broadcast on this product in Canada. Furthermore, Aquabounty has been open about the status of this product in Canada and the United States, as well as about their plans for producing the fish. The amount of media coverage suggests that Canadians should be well aware of the existence of this product and its potential for introduction to the Canadian market at the conclusion of a safety assessment by Health Canada****.*
>
> *The level of media interest in this GE salmon is, however, an exception. Most GE products do not receive this level of interest and your larger point that Canadians should be made aware of the GE products being submitted for authorization is well understood by the Department. In the interest of transparency, Health Canada encourages companies to notify the public when GE products are submitted for assessment. To facilitate this for GE crops, a voluntary notification, known as a "Notices of Submission," is posted on the CFIA's website.* ***This mechanism is useful in permitting the Department to notify the public of products submitted for authorization****, while remaining compliant with the laws respecting the release of information. At this time this mechanism exists only for GE crops.* ***It is fortunate that the proponent for the GE fish has been so forthcoming regarding its submission****.*
>
> *The Department is continually looking at ways to improve the system for regulating novel foods in Canada and your comments regarding the transparency of the system will be considered in any future work in this area." (Emphasis added).*

In actual fact, however, AquaBounty was not forthcoming about regulatory status in Canada. For example, on September 9, 2013 (only two months before Environment Canada announced its approval), CBAN's Coordinator asked AquaBounty's President Ron Stotish twice in person if the company had submitted a request for approval and he twice responded that the company "does not comment on regulatory files."[79]

In April 2014, CBAN found out that AquaBounty had actually asked Health Canada for approval in February 2012. This information was disclosed by the company in their filing to the US Securities and Exchange Commission.[80]

STEP 2.
SAFETY ASSESSMENT

ASSESSMENT refers to the government risk assessment/evaluation of information submitted by the proponent (company or institute) that wants a product approved.

The Canadian government regulates each GM food, crop and animal separately, on a case-by-case basis. Government scientific evaluators are responsible for deciding if GM foods are safe to eat and if GM crops and animals are safe to be released into the environment. Evaluators assess a "submission package" of information sent in by the company or institute ("proponent") that wants their product approved. Government regulators do not conduct any safety testing.

We do not know what science government regulators use in GM product assessments. The information and data submitted by companies to government departments is classified as "Confidential Business Information" and is not accessible to the public, even under Canada's Access to Information law. Regulators may consider relevant public science if there is any but exactly what studies are considered remains undisclosed. While the government provides general questions for companies to answer, the exact questions can vary and there are no specified methodologies required to answer the questions, including no requirement for animal feeding trials. (see page 26)

Additionally, we do not know exactly how government regulators assess the information provided to them by companies. At some point after approvals are granted, the departments publish "Decision Documents" that summarize why and how a GM product was approved. However, these documents (generally 2-6 pages) do not include any reference material. The documents discuss product assessment in broad terms and are often so vague that it is hard to determine what, if any, particular studies or questions were assessed (see pages 26-27).

There is no public involvement or consultation in the safety assessment process. There is only one invitation for public comment through the voluntary "Biotechnology Notices of Submission" project but the integrity of this as a mechanism for public comment is severely compromised including because, in the words of the CFIA, it was "not designed to provide a mandatory public consultation process."[81] (see below).

Biotechnology "Notices of Submission"

> "This should not be mistaken for a consultation as there is no data or any significant information provided on which to comment.
>
> — Appeal from two Ontario farmers for an environmental assessment of GM alfalfa to Ontario's Environmental Commissioner, 2013[82]

"The CFIA, Health Canada (HC) and CropLife Canada have jointly developed a Notice of Submission pilot project designed to facilitate transparency in the Approval Submission process. When a new submission is received by CFIA and HC, a description of the product and the data submitted from CropLife member companies will be posted on the CFIA website. This is the first time in Canada that

continued…

Biotechnology "Notices of Submission" continued

the public will be notified of new biotechnology crop, feed and food product submissions under review by government. As well, it is the first time that the public will have access to a list of the scientific studies conducted on the products regarding safety."[83] — CropLife.

Not to be mistaken for a consultation, the "Biotechnology Notices of Submission" invites the Canadian public to comment on a company's submission for approval:

1. without providing the submission package itself,
2. with an invitation to comment on non-scientific concerns without any formal mechanisms to consider such concerns,
3. only if the company voluntarily participates.

FIRSTLY, THE COMPANY'S SUBMISSION TO THE GOVERNMENT IS NOT PROVIDED. A short (often two-page) product summary from the company is posted online and the CFIA **invites scientific comment, without actually presenting any scientific information**: the public is given 60 days to send in comments on a submission whose contents remain confidential. The CFIA says that the notices "describe the product and the data they receive from certain product developers who have requested safety assessments."[84] However, in relation to the GM apple, for instance, the posting was a table of contents that did not describe the data provided by the company or list specific scientific questions examined or studies done. The summary did not give enough details on the contents of the submission for the purposes of making scientific comment.[85]

SECONDLY, THERE IS NO MECHANISM TO CONSIDER NON-SCIENTIFIC CONCERNS. The CFIA says it accepts non-scientific comments in this project, despite having no mandate or formal mechanism to assess these comments. The public is invited to comment on non-scientific considerations (such as economic impacts) but regulators do not consider non-scientific concerns in their decision-making. The CFIA's Biotechnology Notices of Submission web page states, "**Scientific questions or information** will be forwarded to CFIA and Health Canada evaluators for consideration in the assessment. **Non-scientific input** will be evaluated and appropriate ways of addressing it will be explored."[86] However, the public may not be aware that there are no formal mechanisms to evaluate non-scientific input and there is no reporting to suggest that, as stated by the CFIA, the non-science input is considered. In fact, CFIA officials have clarified, in email correspondence with the National Farmers Union, that, "All comments received in response to the Notice of Submission are reviewed by the Government of Canada (GoC) although **only those comments providing science-based evidence are considered by the GoC as part of the assessment of the novel product**."[87] (Emphasis added).

THIRDLY, THE PROJECT RELIES ON VOLUNTARY SUBMISSIONS FROM COMPANIES. The notices of submission are posted on the government website at the discretion of companies. The CFIA says, "It is important to note that in Canada there is no legal requirement for developers to participate in the Notice of Submission process nor any ability for the CFIA to require developers to participate," and, "The Notice of Submission project was not designed to provide a mandatory public consultation process for individual novel product submissions."[88] Because the project is voluntary and was set up by government departments through an agreement with the industry association CropLife Canada, any companies that fall outside CropLife membership (as is the case with GM animals, for example) are presumably even less likely to participate. **This means that there is no way for the public to know if the posted notices of submissions are representative of all the GMOs submitted for approval at any given time.**

STEP 3.
NOTIFICATION OF DECISIONS

The government posts lists of approved "Novel Foods" and "Plants with Novel Traits" that *include* GMOs but **the government does not provide a clear list of approved GMOs for the public**.

On the list of approved "Novel Foods" and "Plants with Novel Traits":

- Many of the products listed are not GMOs;
- GMOs on the list are not clearly identified as GM; and
- Not all approved GMOs listed are on the market.

Rather than providing clear and accessible information, these lists are commonly misinterpreted by the general public and Canadian media.[89] *See the GMO Inquiry report "Where in the World are GM Crops and Foods?" for CBAN's table that contrasts the government's list of approved "Plants with Novel Traits" with the GM crops that are approved and on the market*.

As mentioned, departments will also publish "Decision Documents" that summarize why and how a GM product was approved.

Additionally, Canada has **no mandatory labelling of GM foods**. This means that consumers in Canada can only guess where GM foods are on grocery store shelves.

> "Information published in the Decision Documents is insufficient, too general, and too late to allow detailed public scrutiny, much less effective intervention prior to the commercialisation of GE crops.
>
> — Katherine Barrett and Elisabeth Abergel, 2000 [90]

CONFIDENTIAL FIELD TRIAL LOCATIONS

The CFIA also regulates the experimental field trials of all "Plants with Novel Traits" including genetically modified crop plants and trees, conducted by product developers. Once a year the CFIA posts a list of all plant species and their GM traits that were tested in each province,[91] but the locations of the field trials are not disclosed to the public, neighbouring farmers or other levels of government. When, in 2001, Prince Edward Island's Agriculture Minister asked the CFIA where GM wheat field trials were located in the province, he was referred to the company Novartis, which refused to provide this information.[92] When asked about this federal government policy, then-CFIA official Stephen Yarrow (now with the industry association CropLife Canada) stated, "We are on the side of the protection of proprietary information. That's how it looks because that's how it is."[93]

HOW DOES CANADA REGULATE?

> After reviewing the relevant documents and holding discussions with Health Canada personnel, it appears to the Panel that no formal criteria or decision-making framework exists for food safety approvals of GM products by Health Canada. Decisions are largely made on a case-by-case, ad hoc basis. — Royal Society of Canada's Expert Panel, 2001[94]

GMOS AS "SUBSTANTIALLY EQUIVALENT"

> The concept of substantial equivalence is used as a guide in the safety assessment of genetically modified foods by comparing the novel food to its unmodified counterpart which has a history of safe use.
>
> — Health Canada[95]

The lack of transparency in Canadian regulation means that exactly how Canada assesses the safety of GM foods, crops and animals is unclear. This lack of clarity begins with the use of two central regulatory concepts called "familiarity" and "substantial equivalence." Fifteen years after their use was strongly critiqued by The Royal Society of Canada's *Expert Panel on the Future of Food Biotechnology*, the role of these concepts in Canadian regulation remains unclear, partly also because they are designed to provide flexibility in safety assessments.[96]

The concept of substantial equivalence has been critiqued, in Canada and internationally, as a vague concept that has no legal or scientific definition.[97] The flexibility that substantial equivalence provides to regulators, combined with a lack of transparency, also means that the application of the concept remains unknown outside of government and industry. According to The Royal Society of Canada's Expert Panel, "**Symptomatic of the lack of clarity in the current process is the ambiguous application of the principle of "substantial equivalence**"."[98]

The Canadian government regulates GM foods and crops by comparing them to other products that are already on the market and have a "history of safe use." The concepts of "familiarity" and "substantial equivalence" were developed internationally to facilitate this comparative approach to regulating GMOs. The Organisation for Economic Co-operation and Development (OECD), a key institution in this development process, stated, "The concept of **substantial equivalence** embodies the idea that existing organisms used as food, or as a source of food, can be used as the basis for comparison, when assessing the safety of human consumption of a food or food component that has been modified or is new."[99]

Familiarity is defined by the government as "our knowledge of the characteristics of a plant species and experience with the use of that species in Canada." A crop or food is first judged to be "familiar", and then judged "substantially equivalent" or not. For example, the CFIA implements this comparative approach for the environmental release of GM crop plants and says, "Substantial equivalence is used in the comparative assessment of a PNT [Plant with Novel Trait] relative to its counterpart to assess its relative and acceptable risk."[100]

The major critique of substantial equivalence is that it can be used to preclude a detailed risk assessment. This was one of the principles behind its development. The OECD said, "If the new or modified food or food component is determined to be substantially equivalent to an existing food, **then further safety or nutritional concerns are expected to be insignificant**" (Emphasis added).[101] In 2000, Canadian researchers Katherine Barrett and Elisabeth Abergel argued that, as implemented in Canada, substantial equivalence "can indeed **substitute for risk assessment**."[102] The possibility, as stated by The Royal Society of Canada's Expert Panel, that substantial equivalence could "pre-empt any requirement in Canada to assess further the new variety for unanticipated characteristics" led the Panel to say that "conceptual and practical implementation of 'substantial equivalence' is thus the most critical element in the current approval process."[103]

E. Ann Clark of the University of Guelph described the application of substantial equivalence in these terms: "This means – literally – that if a GM submission looks like a potato, grows like a potato, and was not intended to be anything other than a potato, then it doesn't need any special testing."[104] The Royal Society of Canada's Expert Panel said that if substantial equivalence is used this way, it "does not function as a scientific basis for the application of a safety standard, but rather as a decision procedure for facilitating the passage of new products."[105]

> "This means – literally – that if a GM submission looks like a potato, grows like a potato, and was not intended to be anything other than a potato, then it doesn't need any special testing.
>
> — E. Ann Clark, 2004[104]

The Expert Panel was highly critical of the use of substantial equivalence to replace testing and declare safety: "**The Panel finds the use of 'substantial equivalence' as a decision threshold tool to exempt GM agricultural products from rigorous scientific assessment to be scientifically unjustifiable and inconsistent with the precautionary regulation of the technology**."[106] In interviews, regulators told Panel members that they used substantial equivalence as more of a guiding principle rather than a substitute for risk assessment[107] and in a letter to the Panel after their report was published, the Deputy Minister of Health objected to what he called the Expert Panel's "fundamental misunderstanding" about the department's application of substantial equivalence.[108] However, the Expert Panel retained their critique and responded to the Deputy Minister, "In our direct discussions, Health Canada personnel did not provide sufficient information to allow us to assess the extent or rigour of the protocols used. Our request at the time for detailed data pertinent to those protocols produced no subsequent response. The Expert Panel was therefore unable to verify the overall consistency or appropriateness of the assessment process…"[109]

There is a core assumption about the risks of genetic modification that is embedded in the use of substantial equivalence. The international consultations that developed the concept concluded that the "use of these techniques does not result in food which is inherently less safe than that produced by conventional ones."[110] This conclusion is the

foundation of Canada's regulation of GMOs. As Health Canada says, "Given that the use of genetic modification does not introduce unique risks, the potential for long term effects on GM foods is **no different from conventional foods with a long history of use in Canada**."[111] This is a highly contested conclusion. *See the GMO Inquiry report "Are GM Foods Better for Consumers?"*

The Expert Panel was concerned that **approvals may be based upon "unsubstantiated assumptions about the equivalence of the organisms, by analogy with conventional breeding**."[112] Barrett and Abergel argued that "familiarity" and "substantial equivalence" imply regulatory certainty, in contrast to what they argue is the actual persistent uncertainty surrounding genetic engineering.[113] The Panel similarly said that, "the goal should be to move away from an assumption of 'precise' genetic engineering."[114]

Further, Barrett and Abergel argued that, over time, the concepts of familiarity and substantial equivalence have the ability to "re-define baselines of 'acceptable risk'" and establish precedents against which future releases of GMOs are assessed,[115] meaning that as each "novel food" is approved, it has the potential to become a possible comparator of safety for future GM foods. In other words, under this concept of substantial equivalence, GM foods could become foods with a "history of safe use" for use in future comparative assessments.

"SCIENCE-BASED" REGULATION — WITHOUT SCIENCE?

> The claim that the assessment of biotechnology risks is 'science-based' is only as valid as the independence, objectivity and quality of the science employed.
>
> — Royal Society of Canada's *Expert Panel on the Future of Food Biotechnology*, 2001[116]

> The Panel's recommends that the Canadian regulatory agencies implement a system of regular peer review of the risk assessments upon which the approvals of genetically engineered products are based. This peer review should be conducted by an external (non-governmental) and independent panel of experts. The data and the rationales upon which the risk assessment and the regulatory decision are based should be available to public review.
>
> — Royal Society of Canada's *Expert Panel on the Future of Food Biotechnology*, 2001[117]

Canada calls its regulation of GMOs "science-based," however the science behind government decisions to approve GM crops and foods is kept confidential. Health Canada does not conduct its own safety tests on GM foods but relies on data submitted by the proponent (company or institution) that wants to sell the GM product. This data is classified by the government as "Confidential Business Information" and is not accessible to the public or independent scientists (even through Access to Information requests). If a product is approved, the government posts a summary description (the equivalent of 1-6 pages) of why this decision was made. **These "Decision Documents" are the only public record from the government on each GM food, crop or animal that is approved**.

As The Royal Society of Canada's Expert Panel said, "the science behind the regulatory decision remains largely obscure."[118]

Health Canada does not conduct any safety testing. Health Canada approves GM foods as safe for human consumption based on an assessment of industry-submitted information. This information is often entirely industry-generated and rarely peer-reviewed. This means that the science behind Canada's GM food approvals is largely not part of the published, peer-reviewed scientific literature.

Without peer review, the quality of the information assessed by government regulators cannot be verified. The Royal Society of Canada's Expert Panel concluded that without access to the science behind GM food approvals, "there is no objective way for the public or independent scientists to evaluate fully the scientific rigor of these assessments."[119] The Expert Panel was clear that, "Peer review and independent corroboration of research findings are axioms of the scientific method, and part of the very meaning of the objectivity and neutrality of science."[120] Without peer review, the data behind Canada's GM food approvals cannot be assumed to be good science, or indeed "science" at all.

> "In the judgment of the Expert Panel, the more regulatory agencies limit free access to the data upon which their decisions are based, the more compromised becomes the claim that the regulatory process is "science based". This is due to a simple but well-understood requirement of the scientific method itself — that it be an open, completely transparent enterprise in which any and all aspects of scientific research are open to full review by scientific peers.[121]

The CFIA states that, "The quality of information in the data package should be equivalent to that provided for peer reviewed publications."[122] However, this equivalency can only be determined through the peer review process itself. The Royal Society of Canada's Expert Panel concluded that, "CFIA directives indicate that statistically valid experimental designs are required for testing plants with novel traits, and that all such work is to be of the standard required for peer-reviewed research publications. **In the absence of independent peer review, however, the Decision Document is in no sense equivalent to a peer-reviewed scientific paper**."[123]

> "In the Panel's view, the decision-making process in general lacks transparency, and thus credibility.[124]

The assessments carried out by government regulators are based on a set of broadly defined questions that companies need to answer but do not include any specific required tests or test methodologies. As the Expert Panel summarized, "although the proponents are required to provide new data in some areas, there is no means for independent evaluation of either the quality of the data or the statistical validity of the experimental design used to collect those data. Furthermore, it appears that a significant part of the decision-making process can be based on literature reviews alone."[125] The Expert Panel concluded that, "there is no means of determining the extent to which these information requirements are actually met during the approval process, or of assessing the degree to which the approvals are founded on scientifically rigorous information. The Panel attributes this uncertainty to a lack of transparency in the process by which GMOs are approved within the present regulatory framework."[126] Certainly, "neither the design of the experiments on which the assessment was based, nor their results, are included in the public Decision Document."[127]

Health Canada can request additional information and clarification from companies (send "deficiency

Health Canada does not conduct any safety testing

letters") if regulators are unsatisfied with submitted data packages. However, we know that in at least two cases, Monsanto pushed back on such requests. Internal Health Canada memos released through Access to Information requests show that in 1999, in relation to a GM potato review, "Monsanto objected to these requests; believing that their data adequately supports their conclusions that these products present 'no significant environmental, feed or food safety risk.'"[128] Negotiations, including two meetings with Monsanto that included the president of the CFIA, resulted in an agreement that if Monsanto provided the data, Health Canada would decide on product approval within 30 days of receiving it. Internal memos also show that John Dossetor, the Senior Policy Advisor to the Minister of Health, was kept up to date about these negotiations, which suggests a high-level political interest in this approval. (Less than two years later, Dossetor was hired by Monsanto to be their top lobbyist in Ottawa "responsible for the development and implementation of Monsanto's government affairs strategies in Canada," in a move that was then subject to an ethics complaint,[129] see page 33). In a similar case, internal documents revealed that, in 1990, Monsanto was also reluctant to provide more data on BGH (see page 32).[130]

These examples in Canada are, seemingly, not unique: In 2009, the European Food Safety Authority asked Monsanto to repeat an animal feeding trial on the GM corn LY038, but the company withdrew their application instead, citing reduced commercial interest in the product.[131] (LY038 was approved in Canada in 2006[132] but has not been commercialized anywhere in the world).

Health Canada does not require any animal feeding studies on GM food. Some companies may choose to conduct such tests and submit them for government safety assessment but these experiments are not mandatory in Canada. Without this requirement, it appears that very few animal feeding trials have been provided to Health Canada for GM food safety assessments. Health Canada says that, "Given that the application of genetic modification does not introduce unique risks, the potential for long term effects of these foods are no different than that for conventional foods which have been safely part of the Canadian diet for a long time. Therefore, there is no current evidence to indicate that long term studies are needed to ensure the safety of foods produced using this technology."[133]

In 2000, University of Guelph associate professor E. Ann Clark examined Health Canada's summary Decision Documents and determined that 70% of the GM crops approved "have not been subjected to any actual lab or animal toxicity testing" and that the remaining 30% included trials using single purified proteins (not GM feed).[134] Additionally, none of the studies appear to have been published in the refereed literature. Since then, we have learned, for example, that there were no animal feeding trials conducted to investigate possible risks from eating the GM non-browning apple, which was approved in 2015. (This information was confirmed to CBAN by the company Okanagan Specialty Fruits.)[135] There are very few long-term animal feeding tests that correspond with any of the GM foods currently on the market.[136] In the case of Monsanto's corn NK603, such trials were conducted years after Canadian regulators approved the product (see box, page 27).

In 2013, the European Commission made 90-day feeding trials mandatory for GM food safety assessments.[137]

For further discussion, see the GMO Inquiry report "Are GM Foods Better for Consumers?"

Case: Corn NK603

Health Canada approved the GM corn NK603 in 2001, four years before Monsanto published its own peer-reviewed 90-day animal feeding trial, and a decade before Gilles-Éric Séralini's team published the results of the first-ever long-term feeding study.[138]

Health Canada's Decision Document on NK603 does not indicate the use of data from any animal feeding trials.[139] When CBAN asked Health Canada if regulators had access to feeding tests from Monsanto, an official responded, "Regarding your specific request on NK 603, I cannot provide you with information beyond what is presented in our decision document.[140]

The same letter to CBAN confirms Health Canada's approach to animal feeding trials: "Health Canada does not have an explicit requirement for whole food feeding studies (such as the one presented) in the assessment of GM foods, given their limitation in providing useful toxicological information. If such a study was provided as part of a GM food submission, it would be reviewed, but it would be of limited usefulness in the overall weight of evidence."

For a discussion on the question of animal feeding trials and the implications for safety, see the GMO Inquiry report "Are GM Foods Better for Consumers?"

"SCIENCE-BASED" REGULATION EXCLUDES ECONOMIC AND SOCIAL CONCERNS

> In order to protect the scientific integrity of the assessment process, socio-economic factors, such as potential market reaction, are not considered in the decision-making process with respect to novel products. — Health Canada, 2015[141]

> Consideration of social or economic factors are outside of the Agency's mandate. — President, CFIA, 2012[142]

> The Canadian Food Inspection Agency and Health Canada regulate for safety and efficacy of these products, but are not responsible for evaluating need. The issue of whether or not these products are "necessary" is left to the market place to determine. — CFIA, 2015[143]

> By intentionally excluding everything but a few very simple measurements, government has made the value judgment that market implications, religious beliefs, or the societal implications of concentration of power are not important.
>
> — E. Ann Clark, 2004[144]

The reason why Canada calls its regulation "science-based" is to make it clear that government regulation is not based on "non-science" questions like the impacts on farmers or consumers. **Questions like: "What could the impacts of a new GM crop be on Canada's export markets?" and "Do Canadians want to eat this GM food?" are not considered**. Farmers and consumers are not consulted. The process of government GMO risk assessment is closed to public participation and the "science-based" focus of regulation is one structure that achieves this closure.

This "science-based" regulation prioritizes predictability for industry. The biotechnology industry argues that democratic debate and public participation would take more time and create an unpredictable environment for industry: "The industry feels that the licensing and approval process is absolutely critical to the future development and growth of the industry, and should focus on a science-based approach rather than one that is weighted by social and political concerns."[145] In 1994, the Industrial Biotechnology Association of Canada argued that including non-scientific concerns would be "inviting opposition to biotechnology"[146] and the President of Ag-West Biotech Inc. said, "Science must continue to be the basis of regulations. Other issues are too variable and could be used by industry opponents to hold up the approval of new products indefinitely."[147] Globally, our government advertises that, "international companies investing in Canada's ag-biotech sector will find a predictable and effective regulatory environment."[148]

There are no mechanisms for considering ethical issues and cultural, social or economic impacts at any stage in federal regulation of GM crops, foods or animals and this includes a total absence of consultations with consumers and farmers. In the case of the GM apple, apple producer associations in Canada opposed approval "due to possible market backlash that could impact all apples."[149] After approval, in answer to the question "Why is this product needed when there are other ways to stop an apple from browning?" the CFIA said, "The potential market demand for any new product is a matter of business judgment. It is up to Okanagan Specialty Fruits Inc. [the company that owns the GM apple] to determine whether there is sufficient customer demand to merit commercializing Arctic apple."[150]

Apple producers in British Columbia point out the contradiction of the government leaving market forces to decide the acceptability of GMOs without providing the tool of mandatory labelling to enable consumers to make this decision. As Fred Steele, President of the BC Fruit Growers Association said, "The government has always used the saying that the market will decide, but at present there is no distinction in the marketplace between genetically modified or genetically engineered food and conventional food. The market should have a reference point to make a choice and to protect conventional producers from possible harm."[151]

The depth of the political commitment to exclude non-scientific criteria in regulation was made clear by the 2011 defeat of Private Members Bill C-474 that would have required the government to include an assessment of export market harm before any new GM crop was introduced.[152] In the debate over the bill, farmer organizations representing forage growers strongly supported the need for the inclusion of market considerations before the release of GM alfalfa. Kelvin Einarson, Director and Secretary Treasurer of the Manitoba Forage Seed Association Inc. told House of Commons agriculture committee hearings that, "Bill C-474 is the first step in offering some protection in the future for Canadian family farms. Market acceptance must be made part of the evaluation process and incorporated into the Seeds Regulation Act."[153] Jim Lintott, Chairman of

the Manitoba Forage Council also said, "The point is that from the producer's point of view, we have attempted to express our need to stop Roundup Ready alfalfa. Clearly, the regulations and the laws in place fail miserably on this point. We need a regulation that gets us there."

The lack of consideration for non-scientific impacts also narrows the scope of scientific evaluation. For example, without consulting farmers, the full risks of GM contamination are not evaluated, nor are the long-term environmental and agronomic impacts of using new GM crops (as discussed in the following section in relation to herbicide-tolerant crops). The Royal Society of Canada's Expert Panel said that health and environmental safety issues "though largely scientific in nature, often cannot be addressed fully without reference to broader ethical, political and social issues and assumptions."[154] The Panel also argued that questions about potential hazards, though primarily scientific, are not purely scientific because they involve value judgments, for example in defining the scope of the risk issue and what levels of risk are acceptable.[155]

In 2013, two Ontario farmers requested a provincial environmental assessment of genetically modified alfalfa because "the risks to the Ontario environment and economy were not assessed by the Canadian Food Inspection Agency."[156] In his Annual Report, the Environmental Commissioner of Ontario agreed that, "the applicants raised several valid issues that clearly fall outside the scope of the narrow federal safety assessment. Issues related to sustainable and organic agriculture, increased herbicide use, and related social and economic effects play no role in the federal approval process for GE crops."[157]

LONG-TERM ENVIRONMENTAL IMPACTS

Environmental regulation of GMOs in Canada is restricted to a limited set of questions with little room to evaluate the potential long-term, system-wide consequences of introducing new GM crops. **For example, Canada approved GM 2,4-D- and dicamba-tolerant crops in 2012 but there is no evidence that Canadian regulators assessed how these crops would further increase the use of herbicides in agriculture**. This is despite the fact that these products were expressly developed to deal with the environmental and agronomic problems created by the use of previous herbicide-tolerant GM crops (see box, pages 30-31). *The consequences of using GM herbicide-tolerant crops are documented in the GMO Inquiry reports "Are GM Crops Better for the Environment?" and "Are GM Crops Better for Farmers?"*

In 2004, Canada's Auditor General concluded an investigation into CFIA's regulation and said, "it was not transparent how the Agency evaluates the long-term environmental effects before authorizing unconfined release as legally required."[158] The Auditor General recommended that the CFIA "define more explicitly how its evaluation process considers the long-term effects on the environment" and "ensure that it has documentary evidence in its files showing how it is evaluating the environmental effects of plants with novel traits, including the long-term effects."

The CFIA asks companies to answer the question: "Will the cultivation practices (land preparation, weed and pest control, harvest, and post-harvest protocols) involved in growing the PNT [Plant with Novel Trait] vary from those traditionally used?" Companies are asked to provide information showing the effect of these changes on sustainability, especially with respect to pesticide use, frequency of tillage, soil erosion and consequential changes in energy and soil conservation. This includes the question "Will volunteer plants [crop plants from the previous season that grow unwanted in fields, as weeds] of the PNT result in altered cultivation practices for succeeding crops?"[159] How these questions are answered and how the answers influence the environmental assessment is unknown.

The true environmental impacts of GM crops can only be seen once they are released into the environment. Small-scale field trials can only offer limited information about what might really happen

when a plant is released into the environment, and when (how) farmers start growing it. The long–term impacts of such a technology can only be observed in the long term, and **it is therefore necessary to assess and reassess the impacts over time, based on experiences in the field**.

In discussing the use of substantial equivalence in Canadian regulation, Barrett and Abergel argued that, "the acceptability of industrial agriculture is embedded in the current regulatory framework: GE crops are 'safe enough' if they are sufficiently similar to existing food and agricultural standards."[160]

They pointed out that the effects of monoculture, agrochemicals, globalized agricultural trade and patenting are therefore not considered in this regulation. The Royal Society of Canada's Expert Panel similarly warned of possible environmental impacts if genetic engineering led to "the expansion of the range of conditions in which agriculture can be practiced."[161] (An illustrative example is the observed role of GM herbicide-tolerant corn in the expansion of corn production and glyphosate use in the US cornbelt, resulting in a critical decrease in monarch butterfly habitat.[162]) *See the GMO Inquiry report "Are GM Crops Better for the Environment?"*

Case: GM herbicide-tolerant crops

In its environmental safety assessment criteria, the CFIA mentions that it assesses "longer term environmental effects" but in the case of herbicide-tolerant and insect-resistant traits, it **leaves these risks to be managed through industry plans, and off-loads responsibility to farmers**: *"As part of the … assessment of longer term environmental effects, the [Plant Biosafety Office's] decision with regards to authorizing the release of a PNT expressing either a novel herbicide tolerance or a novel insect resistance will take into consideration whether or not the applicant has provided a stewardship plan addressing the need for the responsible deployment of the novel crop into the environment."*[163]

The CFIA says that the development of herbicide tolerance management plans are "the applicant's responsibility" and they should contain elements that address:

1. "the control of volunteers, more specifically, any changes in usual agronomic practices that may arise from the novel herbicide tolerance and which could result in reduced sustainability or have significant impacts on soil conservation;;
2. the selection of herbicide tolerance in weeds resulting from the potential continued application of the same herbicide in subsequent rotations;
3. the introgression of novel trait into related species;
4. the management of the herbicide tolerant crop during the growing season, particularly where multiple herbicide tolerances, due to cross pollination, could arise in subsequent growing seasons;
5. communication to growers as well as an efficient mechanism allowing growers to report problems to developer;
6. the monitoring of effectiveness of the stewardship plan."[164]

Such stewardship plans are voluntary except for certain required measures, such as insect resistance management.

In its Decision Document for Monsanto's GM herbicide-tolerant alfalfa, for example, the CFIA noted that the use of more herbicide-tolerant crops could lead to unwanted (volunteer) herbicide-tolerant crop plants, making some herbicides useless. However, the issue is left to management plans drafted by companies:

continued…

"A longer term consideration, if there is general adoption of several different crop species and specific herbicide weed management systems (i.e. numerous combinations of crop species and tolerances to different herbicides), is the potential development of crop volunteers with a combination of novel tolerances to different herbicides. ***This could result in the loss of the use of these herbicides and any of their potential benefits****. Therefore, Monsanto Canada Inc. will make their stewardship plan readily available to growers and agriculture extension personnel, in both private and public sectors, to promote the careful management practices, such as use of alternate control tools as appropriate to achieve complete control, recommended to help minimize the development of resistant weed populations."*[165] (Emphasis added)

In its summary of the 2005 decision to approve GM alfalfa, the CFIA anticipated the problem of glyphosate-tolerant volunteers and the need to use non-glyphosate herbicides to control them: "Volunteer alfalfa containing glyphosate tolerance, originating from previous crop years or cross pollination (i.e. wind or bee mediated), can still be managed by growers through the use of alternative herbicides with different modes of action, or cultivation practices which do not involve the use of herbicides."[166] Despite having identified this problem, GM alfalfa was approved.

On GM alfalfa, the CFIA said that, "The agronomic stewardship plan, which contains a herbicide tolerance management plan, submitted by Monsanto Canada Inc. was evaluated by the CFIA and determined to be satisfactory."[167] This determination was, however, made three years before the discovery of the first of five glyphosate-resistant weeds in Canada and the obvious failure of industry management plans to prevent them.[168] **The decision has not been revised in light of the evolution and spread of these new weeds, and no wider assessment of the environmental impacts of the herbicide-tolerant cropping system as a whole has been triggered**.

Twenty years of GM herbicide-tolerant crops in Canada have led to the emergence and spread of glyphosate-tolerant weeds, causing increased costs and complications for farmers[169] and leading to the increased use of herbicides.[170] **Rather than assess these emerging problems, in 2012 the CFIA approved GM 2,4-D- and dicamba-tolerant crops that will perpetuate the increasing use of herbicides and the spread of herbicide-resistant weeds**.

For more information on herbicide-tolerant crops and the related issues of herbicide use and herbicide-resistant weeds, see the GMO Inquiry reports "Are GM Crops Better for the Environment?" and "Are GM Crops Better for Farmers?"

CORPORATE INFLUENCE IN REGULATION?

Corporations – and other product patent holders (some universities in Canada have developed GMOs) – are the only non-governmental parties that have access to the regulatory process in Canada. **Companies are privy to information about the regulatory process that the public is not, and they have an official role inside that process**. **Companies have exclusive access to and direct lines of communications with regulators**.

The Royal Society of Canada's Expert Panel commented on regulators negotiating away openness "in exchange for cordial and supportive relationships with the industries being regulated."[171] The Panel said that the responses of regulators to questions about transparency and confidentiality "uniformly stressed the importance of maintaining a favourable climate for the biotechnology industry to develop new products and submit them for approval on the Canadian market…Several managers referred to the importance of maintaining a relationship of trust between the industry and the regulators."[172]

For the public, the outcome of this direct communication between companies and regulators is approved – and unlabelled – GM crops and foods. Fifteen years ago however, the Canadian public gained rare access to some internal discussions behind product assessment in the case of the government's review of Monsanto's recombinant Bovine Growth Hormone (BGH), the company's first GM agricultural product approval request. This case offered the public an unprecedented window into the regulatory process, and warned of the real possibility of corporate influence.

In 1998, six scientists in the Bureau of Veterinary Drugs at Health Canada filed a complaint with their union alleging that they were moved off their work on the BGH file in order to expedite approval of the product (a veterinary drug injected into dairy cows to make them produce more milk).[173] Three of the six later testified at Senate committee hearings, including Dr. Shiv Chopra who told senators, "**we have been pressured and coerced to pass drugs of questionable safety, including [BGH]**."[174] The scientists had questions about BGH's safety for both animals and humans. They alleged that their concerns, including concerns with the methodology of studies submitted by Monsanto and their desire to see more data, were suppressed by departmental managers in favor of product approval because of industry pressure.[175]

A memo obtained by CBC TV's *The Fifth Estate*, revealed that one of the scientists, Dr. Margaret Haydon, filed a complaint about a 1990 meeting where she says Monsanto representatives offered Health Canada "one to two million dollars with the condition that the company receive approval to market their drug in Canada without being required to submit data from any further studies or trials."[176] This offer was confirmed by Health Canada's Director General who was also at the meeting and who interpreted it as an attempted bribe.[177] Monsanto later said that the offer was one of research funds.[178]

The movement of government regulators to become employees of biotechnology industry lobby groups also raises questions about the impact of regulator-industry relationships built over years of product assessment. The concept of the "revolving door" describes the phenomenon of industry employees leaving to work for government and vice-versa, implying the possibility of a sustained, direct relationship between industry and government through the exchange of personnel. This phenomenon exists in Canada at both a regulatory and political level (see table on page 33). University, industry and government are the three sectors that can provide careers for people with relevant scientific expertise, and because Canada has a relatively small community, it is logical to see some movement of qualified people back and forth between the public and private sectors. However, this movement becomes a problem when regulation is closed to the public. While the revolving door is not itself an explanation for corporate influence in

regulation – companies already have direct access to regulators and politicians – **it is one symptom of a possible larger problem** in a decision-making process that is closed to the public.

Federal government ethics rules prohibit public officials from working as lobbyists for one year after leaving government. This timeframe was not respected in the cases of Ted Menzies[179] and John Dossetor,[180] named in the table below.

Canada's Industry–Government "Revolving Door"

PERSON	PREVIOUS POSITION	LATER POSITIONS
Ted Menzies	Government of Canada, Minister of State for Finance 2011 – 2013	CropLife Canada, President 2014 – present
Steven Yarrow	CFIA (including Director, Field Crops Division) 1992 – 2011	CropLife Canada, Vice President, Plant Biotechnology 2011 – present
Ian Affleck	CFIA (including Manager, Governance and Outreach) 2004 – 2014	CropLife Canada, Managing Director, Science and Regulatory Affairs 2014 – present
Janice Tranberg	CropLife Canada, Vice President, Western Canada 2007 – 2013	SaskCanola, Executive Director 2015 – present Government of Saskatchewan. Ministry of Agriculture, Assistant Deputy Minister, Regulatory and Innovation, 2014-2015
JoAnne Buth	Canola Council of Canada, Vice President 1999 – 2007 President 2007 – 2012	Canadian International Grains Institute, CEO, 2014 – present Senate of Canada, Senator, 2002 – 2014
John Dossetor	Government of Canada, Senior Policy Advisor to the Minister of Health 1997 – 2001	Monsanto, Vice President, Government Affairs 2001 – unknown
Simon Barber	CFIA (including Chief, Plant Biotechnology Office) 1990 – 1997	Syngenta 2009 – present EuropaBio 1999 – 2007 Organization for Economic Co-operation and Development 1997 – 1999

REMOVING THE "REGULATORY BURDEN"

While the industry relies on government regulation of GMOs to communicate safety to the public and get products to market, companies also view this regulation as costly and time-consuming. The biotechnology industry often refers to this treatment as a "regulatory burden".[181] For example, in 2013, Monsanto encouraged Peter Phillips, a policy professor at University of Saskatchewan, to write about "over burdensome regulation of GMO crops and food."[182] In his subsequent article, "Economic Consequences of Regulations of GM Crops," Phillips argued that "Regulatory programs that ensure timely review and public policy approaches that provide stability in the process will incentivize innovative companies of all sizes to pursue ongoing advances in biotechnology innovation and research."[183]

In Canada, there already are some GM crops and foods that are not subject to safety assessment.

- The Canadian government does not assess the safety of combining ("stacking") multiple GM traits together in one organism if each of the individual GM traits have already been approved. For example, Monsanto's "Smartstax" corn has eight different GM traits – six insect-resistant traits and two herbicide-tolerance traits – but was not assessed for safety by Health Canada.[184]
- The Canadian government, under the Canadian Environmental Protection Act, does not regulate GMO research conducted in contained facilities.[185] For example, GM plants such as GM purple tomatoes in greenhouses in Ontario and GM animals such as AquaBounty's research and development of GM salmon eggs in PEI. The government does not issue permits for such activities and relies on companies to report any accidental GMO escapes.

To reduce the "regulatory burden" on companies, industry proposes harmonized regulations across the world where, as CropLife Canada proposes, "Canada could consider and recognize the conclusions of risk assessments completed in other countries with reliable regulatory systems."[186] Agriculture and Agri-Food Canada has been developing a policy called "Low Level Presence" (LLP) that would take a major step towards this goal. LLP would create exceptions to Health Canada's risk assessment of some GM foods and rely on approvals from other governments instead. It would allow a certain percent of contamination in imports to Canada from GM foods that have not yet been approved as safe by Health Canada, if the contamination comes from a country whose regulatory system Health Canada says is trustworthy. This policy would mean that Canada's regulation of GM foods would no longer be applied to all the GM foods that Canadians eat. See www.cban.ca/llp

CONCLUSION

> The federal government maintains that Canada had to take this giant leap into biotech so that it would not miss the bus. But in the rush to get on board, no one asked us where we wanted to go or informed us about where the bus would be going.
>
> — Devlin Kuyek, 2002[187]

The government had an opportunity to make meaningful regulatory change when The Royal Society of Canada's *Expert Panel on the Future of Food Biotechnology* presented its 53 recommendations in 2001. However, the government failed to respond with any significant change. In the fifteen years since, many new GM foods and crops, and the world's first GM animals, have been approved using this same flawed system.

Canadian government regulation of GMOs is closed to the public. The science behind government approvals is not disclosed to the public or the scientific community, and the precise process by which the safety of GMOs is determined remains unclear. Canadian regulation does not consider any non-scientific concerns and does not include any consultations with farmers or consumers. These fundamental constraints have created a regulatory system that is predictable for industry but is closed to public participation.

These limitations also mean that Canadian regulatory agencies are reviewing GM products that may have little or no social worth or economic benefit. In the absence of democratic process, companies are submitting products for approval, such as the GM non-browning apple and GM herbicide-tolerant alfalfa, that have little social utility and, on the contrary, pose enormous risks for many Canadian farmers.

After twenty years of regulating GM foods, crops and animals, we need a national evaluation of the impacts and risks of GMOs, along with a national conversation about their future role in food and farming. Once there has been this full assessment and democratic debate, the goals and structure of the regulatory system should be re-evaluated.

MORE RESOURCES

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