

# The Policy Context and Public Consultation: A Consideration of Transgenic Salmon

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## 1 Introduction

As elucidated by other papers in this volume, public consultation about science and technology is a subject of serious study and much time has been devoted to outlining methods, goals and appropriate uses. Public consultation is ultimately intended as a tool to inform and benefit a more democratic society as it examines and adopts new technologies. We applaud the contributions of these studies. However, in our view, too little time has been spent examining one element of public consultations—namely, the link between such consultations and the policy arena.

The goal of this paper is to begin to tease out the complexity of the relationship between policymaking and consultations in the U.S. and Canada. We do this in the context of genetically modified (GM) salmon, which involves a particularly entangled set of regulatory regimes. In exploring this relationship, we seek to lay the groundwork for demonstrating that the design, implementation, interpretation, and evaluation of public consultations need to take account of the policy arena. We use the term “policy” broadly here to refer to both legislative and administrative regimes designed to manage or implement a technology. We do not posit here that the policy regime should determine the public consultation. Rather, just as the underlying science is important to the design of the public consultation, so too is the policy regime. Thus, we think it necessary to take account of the policy arena they aim to influence in the same manner that designers of public consultation take some account of the science underlying the

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issues.<sup>1</sup> The questions that drive this research are many and include:

1. How do the scope and character of public consultations vary as a function of the convening authority?
2. What is the most efficient—and thus “appropriate”—breadth to public consultations? What are the costs and benefits of allowing a full spectrum of issues to be discussed? Conversely, what results from limiting discussion to a defined set of technical issues?
3. To what degree should public consultations be a component of a policy context? Alternatively, are consultations more revealing if they take place outside the policy context?

In posing these questions, we recognize that they raise a large number of issues that are neither simple nor straightforward to answer. We state emphatically that this paper is intended only as a first step in an effort to map the issue with respect to transgenic salmon and outline the direction for further study.

In the following section ([Section 2](#)) we briefly address the scientific innovation underlying transgenic salmon. In subsequent sections ([Subsection 3.2](#) and [Subsection 3.3](#)) we present the respective regulatory contexts in the U.S. and Canada and review representative public consultations that have taken place in each of these jurisdictions. In so doing, we are acutely conscious that the governmental structures of the two countries differ in multifarious ways. Nevertheless, in the two jurisdictions there are comparable federal regulatory bodies that are among the key institutions developing, and certainly implementing, policy in the matter of transgenic salmon.<sup>2</sup> Finally, in [Section 4](#), we outline preliminary thoughts about the relationship between policymaking for a complex issue and public consultation. The paper does not reach conclusions about policymaking and consultation. Instead, we end with observations from our research and conclude by urging more comprehensive study concerning the relationship between policymaking and consultations.

## 2 The Underlying Innovation

The innovation<sup>3</sup> on which this paper is based is best exemplified by a fifth-generation transgenic animal developed by Aqua Bounty Farms known as AquAd-

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<sup>1</sup>“Taking account” of the policy arena does not require total immersion into regulatory system any more than taking account of the science requires mastering the scientific corpus.

<sup>2</sup>In both countries there are municipal and regional bodies as well provincial/state bodies that can affect policy within their jurisdictions. Nevertheless, in both cases it is the federal level which is the primary policy setters; the main actions open to other jurisdictions are to opt out of, or otherwise modify, federal policy. E.g., in Canada even if transgenic salmon were approved federally, a provincial government might be able to severely restrict the location of aquaculture.

<sup>3</sup>In the realm of basic scientific research, genomics is the “study of genes and their function.” Various branches of genomics concentrate upon gene mapping, genetic evolution, and gene function and expression. As such, discoveries in salmon genomics could be applied to understanding, diagnosing, and treating fish pathologies; identifying and tracking sub-populations;

vantage™ salmon. We will confine our attention to what are commonly called GM or transgenic salmon. We use both terms to denote the transplantation of a foreign gene (the transgene) into the germ line of an organism.<sup>4</sup>

This salmon, currently being considered for approval by the United States Food and Drug Administration (FDA) (1999) and Canadian regulators (CBC News, Dec 8, 2004), is a candidate for becoming the first transgenic animal available to Americans and Canadians for human consumption. AquAdvantage™ salmon are produced by a two-fold modification of the Atlantic salmon genome: a growth hormone gene from a Pacific Chinook salmon and a promoter sequence derived from the ocean pout (cold water fish) are inserted. This is referred to as an “all fish transgene” process because all the material is derived from the DNA of fish, which are, in this case, already available to consumers. The pout promoter gene is used because it acts to stimulate the production of the inserted growth hormones year round. The new promoter thus disrupts the salmon’s normal growth cycle, which produces growth hormones only during the warmer summer months.

As a whole, the modifications work by making the salmon growth cycle continuous rather than seasonal, as is the case in unaltered varieties. The result causes the fish to grow to a marketable size within eighteen months, which is about half the time required by unaltered farmed salmon. The process does not actually produce a bigger fish; the AquAdvantage™ salmon end up being about the same size as their non transgenic counterparts by the time they are ready for market. However, the 50% reduction in time to market represents a significant market advantage. The introduction of this novel fish is intended to increase the potential profitability of salmon farming and could eventually make on-land systems an economic possibility as overall production costs are reduced.<sup>5</sup> In addition, Aqua Bounty has designed the system so that these transgenic fish are sterile (all female, triploid), and thus may be less harmful to wild stocks if and when they escape from ocean netpens.

While the science behind the Aqua Bounty salmon may be relatively straightforward, the regulatory status of the fish in both the U.S. and Canada has been more problematic. In the next section of the article, we review how the potential introduction of the transgenic salmon has thus far been handled by regulatory structures in both countries. Within this discussion, we survey the relevant consultations that have taken place.

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and modifying the salmon genome to create an organism more suitable for aquaculture. We fully recognize that the latter is only one of the applications and that the focus of basic scientists is less on applications than on understanding. (Oak Ridge National Laboratory, 2006).

<sup>4</sup>When a foreign gene (the transgene) is transplanted into the germ line of an organism, the transgenic organism will then express the gene product of the inserted DNA. Our definition of genetically modified organism is sourced from Oxford Dictionary of Biology (n.d.).

<sup>5</sup>To date, on-land salmon farms have not been widely pursued, largely because they are so expensive to run. Many, however, feel on-land systems would provide a good alternative to netpen salmon farms because the environmental risks are not as great.

## 3 Regulation

### 3.1 General

Understanding the current framework for regulation is critical to any assessment of the public consultations that have taken place. Both the U.S. and Canada organize regulatory systems according to area of expertise, with different bodies or agencies responsible for identified areas such as environmental, agricultural, food, and animal health. A single technology or product may impact human health, environmental health, and animal health. Each of these aspects will—by dint of this organizing principle—be subject to the regulatory jurisdiction of different agencies. The net result, often, is that policy-making occurs in a piecemeal fashion with the issues broken down and assigned to bodies with very different mandates. In some cases, the sum of the regulatory parts may not cover the whole range of issues being raised.<sup>6</sup> In other situations, as we note below with respect to Canada, the net result may be that analogous issues are addressed in different fashion by multiple regulatory bodies. Ultimately, while the compartmentalized approach to regulation certainly has benefits in directing expertise, it can result in a situation where issues that are of concern are not satisfactorily addressed because of the very structure of the governing regulatory systems. These phenomena can be discerned in the ways the U.S. and Canadian regulatory systems handle the matter of transgenic salmon. As the following sections demonstrate, these gaps and duplications are echoed in consultations undertaken.

Salmon genomics raises issues that cross local, regional, and even national regulatory regimes. Moreover, ocean netpen farmed transgenic<sup>7</sup> salmon potentially have environmental, economic, and social impacts in addition to those traditionally attributable to farmed fish. In North America, there is confusion as to which national and sub-national bodies are actually regulating cultured fish and what the relationships among these bodies are or ought to be. In addition, the impacts of transgenic salmon cross national boundaries, yet there is currently no joint international U.S.-Canadian institution to regulate these transboundary consequences (McDaniels et al., 2005). We acknowledge the international regulatory dimensions of transgenic salmon and believe that they should also be addressed. Note, however, that in this paper we focus primarily on national regulatory regimes.

The regulatory systems in both the U.S. and Canada are struggling to keep pace with the fierce rate of change maintained within the agricultural biotech-

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<sup>6</sup>This is certainly the case with respect to transgenic crops under the Coordinated Framework for Biotechnology in the U.S. For a good discussion along these lines see Mandel (2004).

<sup>7</sup>For the purposes of this paper, we define transgenic in accordance with the RSC Expert Panel Report on the Future of Food Biotechnology in Canada as a process in which genes are “altered and transposed between organisms by processes that would not occur ‘naturally,’ crossing species and kingdom barriers and producing life forms (transgenic plants and animals) that would not be produced by the ‘natural’ processes of evolution.” (Royal Society of Canada, 2001) In the media, the transgenic terminology is mostly used, but not necessarily technically correct.

nology industry. Although the case that motivates this paper is the AquAdvantage™ salmon, North America has already had a transgenic fish slip through the regulation system with very little reaction. The GloFish™ is a pet, not intended for human consumption. It glows in the dark thanks to an artificially introduced sea coral gene. In 2003, the U.S. FDA reported that these GM zebra danio fish do not pose “any more threat to the environment than their unmodified counterparts, which have long been widely sold in the U.S.” and they were released into the consumer environment (U.S. FDA, Dec. 9, 2003). They were also imported into Canada and sold to consumers despite the fact that Environment Canada (EC) had not approved this endeavor. When EC was alerted to the fact that transgenic fluorescent fish were being sold in Canada, all importers or producers of these animals were asked to freeze dead specimens and retain fish that had not been sold (Environment Canada, 2004). The GloFish™ example illustrates the ease by which transgenic animals can enter the environment and the necessity of focusing on regulatory provisions as well as public awareness of the developments.

## 3.2 United States

In the U.S., transgenic salmon are subject to a regulatory system that was devised before the emergence of biotechnology. Thus, there are a number of statutes and regulatory agencies that could potentially impact policy on transgenic salmon. However, there has been one agency, namely FDA, that has claimed primary jurisdiction over the fish, while other agencies have declined to take such initiative.

Consultations carried out by the U.S. government are reflective of the current regulatory situation. Thus, despite the fact that FDA jurisdiction does not appear to give the agency authority over the entire range of issues raised by the salmon, this agency is the only government body to undertake or involve itself in consultations.

### 3.2.1 Regulatory Background

The U.S. government has consistently taken the approach that the products of agricultural biotechnology should be regulated based on their end uses; e.g., a GM tomato should be regulated like other tomatoes as long as it is “substantially equivalent” to an existing product, rather than in a special category for products that have undergone genetic modification. Based on this product-based philosophy, U.S. authorities have not enacted new laws or regulations to address the products of biotechnology.

This approach to agricultural biotechnology was developed in 1986 with the “Coordinated Framework for Regulation of Biotechnology” (“US Coordinated Framework”), which introduced a policy of regulating GM products strictly according to measurable scientific risks. In so doing, regulators expressly stated that biotechnology was on a spectrum with other forms of breeding and thus should be regulated in the same way. Extrapolating this view to a legal frame-

Table 1: Division of responsibilities

Agency	Products Regulated	Reviews for Safety
FDA	Food, feed, food additives, veterinary drugs	Safe to eat
USDA	Plant pests, plants, veterinary biologic	Safe to grow as agriculture or livestock
EPA	Microbial/plant pesticides, new uses of existing pesticides, novel microorganisms	Safe for the environment. Safety of a new use of a companion herbicide

work, the U.S. Coordinated Framework proposed that new biotechnology products be regulated under the existing web of federal statutory authority and regulation ([U.S. Federal Register, Dec. 31, 1984](#)) on grounds that “existing statutes seem adequate to deal with the emerging processes and products of [genetic modification].” ([U.S. Federal Register, June 26, 1986](#))

The agency assignments outlined were consistent with existing federal exercise of jurisdiction. Thus, the FDA was to have responsibility for regulating food and feeds modified via genetic modification. The United States Department of Agriculture (USDA) would regulate importation, interstate movement, and environmental release of transgenic plants or animals with an aim of protecting existing crops or livestock from hazards ([U.S. Federal Register, June 26, 1986](#)). Finally, the Environmental Protection Agency (EPA) would register certain pesticidal aspects (components) of products in transgenic organisms prior to their distribution and sale and would establish pesticide tolerances for residues in foods ([McGarity, 1987](#)). The federal government assigned the division of responsibilities to agencies as shown in [Table 1](#).

Animal biotechnology is the latest challenge to the U.S. Coordinated Framework and has only recently begun being considered by the Federal government. Consistent with the U.S. Coordinated Framework, there are no federal laws that directly regulate the use or release of GM fish or other transgenic animals. ([Council on Environmental Quality and Office of Science and Technology Policy, 2001](#)) Moreover, as the reality of transgenic animals has emerged, both EPA and USDA determined that they lack regulatory authority under their authorizing statutes. Thus neither USDA nor EPA plans to evaluate transgenic salmon or any other transgenic animal.<sup>8</sup> FDA is the only regulatory agency to have asserted authority, which it has done pursuant to the Federal Food Drug and Cosmetics Act (FFDCA).

It is worth noting that several other federal agencies and state environmental controls apply to farmed fish, regardless of whether those fish are transgenic. Coastal zone management authorities in the states, the Army Corps of Engi-

<sup>8</sup>Some have argued that the EPA could assert regulatory authority over GM fish by defining the products of the inserted genes as “new chemical substances” pursuant to the Toxic Substances Control Act (TSCA). EPA, however, has not exercised this authority and there is some question regarding whether such an interpretation would be upheld ([Pew Initiative on Food and Biotechnology, 2003](#)).

neers, the Fish and Wildlife Service, and the National Marine Fisheries Service<sup>9</sup> are all involved with site selection and permitting of netpens and hatcheries. The EPA and individual states enforce the Clean Water Act, regulating the potential harm that may be caused by fish wastes and disposal of the new animal drugs used on fish ([Council on Environmental Quality and Office of Science and Technology Policy, 2001](#)). Some states have been more active, with a number passing legislation barring transgenic fish from being grown, or requiring labeling.<sup>10</sup>

### 3.2.2 Transgenic salmon

Within the U.S. Coordinated Framework, even FDA's asserted regulatory authority had to depend on a somewhat novel application of the FFDCa. FDA's authority extends to human and animal foods, human and animal drugs, medical devices, biologics and cosmetics. Thus, to be subject to FDA regulation, a transgenic animal would need to fit within one of these categories. Category determination is historically and currently determined by the intended use of the product.

To many, it seemed clear that, if anything, GM salmon and other GM animals intended for human consumption should be regarded as foods and considered under food laws and regulations. Many in and outside FDA were, however, concerned that the food category would not provide adequate opportunity for regulatory review.<sup>11</sup> Indeed, under U.S. law, foods are not subject to premarket review. Instead they are only subject to regulatory action if it "contains any poisonous or deleterious substance which may render it injurious to health." ([United States Congress, n.d.b](#), (a)(1)) Moreover, new food ingredients are not subject to pre-market government review or approval unless they are characterized as a food additive that is not 'generally recognized as safe' (GRAS). Importantly, the manufacturer of the food makes the first determination of whether the food would be subject to FDA food additive review.<sup>12</sup> In the absence of ingredients subject to food additive review, no FDA premarket review is required.

In light of this reality, FDA wanted to find a broader authority for review.

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<sup>9</sup>None of these federal agencies have held consultations on transgenic fish

<sup>10</sup>As of 2003, 15 states in the U.S. had adopted regulations concerning uncontained uses of transgenic fish and other transgenic marine organisms ([Pew Initiative on Food and Biotechnology, 2003](#)).

<sup>11</sup>It is interesting to observe that the regulatory attention to the first GM fish is analogous to the regulatory attention given to the Calgene Flavr-Savr tomato, which was introduced in 1992 as the first GM food. At that time, Calgene and FDA agreed that the genetic modification in the tomato would be reviewed as a "food additive" affording FDA the most stringent pre-market review available for food products. Subsequent entries to the GM food category have been subject only to voluntary pre-market consultations with the agency under the presumption that most genetic modifications result in foods that are "substantially equivalent" to existing product, and therefore are technically exempt from any mandatory agency review ([Marden, 2003](#)).

<sup>12</sup>For a more detailed discussion of regulation of GM foods under existing food law and regulation in the U.S. ([Marden, 2003](#)).

The agency thus took the position that a transgenic fish—or any transgenic animal—would instead be regulated as an animal drug (Miller & Matheson III, 1996). To reach this conclusion, FDA identified the transgenic fish as an “article(s) (other than food) intended to affect the structure or function of the body of man or other animals” (United States Congress, n.d.a, (g)(1)(c)). Subject to regulation under the New Animal Drug Application (NADA) regulation, FDA then stated it was regulating the substance produced by a genetic modification, “not the altered fish itself because the genetic modification changed the function of the salmon’s genome” (Miller & Matheson III, 1996). This regulatory contortion was taken in order—in FDA’s words—to subject the novel fish to the most stringent regulatory review available<sup>13</sup> and to ensure that the genetic modification was safe for the fish and for humans. FDA has also taken the position that certain environmental effects come within FDA’s jurisdiction over animal drugs (Council on Environmental Quality and Office of Science and Technology Policy, 2001).

There are certain limitations associated with being considered as a new animal drug with respect to public consultation; namely, there is no transparency. In fact, FDA is not authorized to even disclose the fact that a New Animal Drug Application (NADA) has been filed, unless this fact is publicly acknowledged first by the sponsor of the product. Moreover, FDA’s authority to consider environmental issues is not well established and has not typically been a significant aspect of NADA approvals either of human or of animal drugs.<sup>14</sup>

FDA made its most revealing statements on how it planned to carry out its regulatory authority in a 2000 report issued for the Clinton White House’s Council on Environmental Quality (CEQ), an Executive branch advisory body (Council on Environmental Quality and Office of Science and Technology Policy, 2001). In the CEQ case study on GM salmon, FDA stated that it was aware of the lack of transparency and the concerns about environmental issues (Mandel, 2004). The FDA promised that it would ensure that the review of GM salmon was as broad as possible, would undertake public consultations and would work with the sponsor of the product to disclose as much information as possible (Council on Environmental Quality and Office of Science and Technology Policy, 2001).

Non-governmental organizations (NGOs) have pressed FDA on these promises in a Citizen Petition filed with the agency by the Center for Food Safety (CFS) in Washington DC, in cooperation with a large number of other consumer, environmental, and fisheries NGOs (Center for Food Safety, May 9, 2001). The petition asks that FDA adequately conduct a thorough environmental review, and that public concerns about impacts beyond health and safety be addressed.

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<sup>13</sup>The FFDCA defines “drug” to include “articles... intended to affect the structure or any function of the body of man or other animals.” (United States Congress, n.d.a, (s))

Under the FFDCA, a new animal drug’s safety is determined with “reference to the health of man or animal.” (United States Congress, n.d.a, (u)) FDA interprets this statutory language to include “environmental effects that directly or indirectly affect the health of humans or animals.” (Council on Environmental Quality and Office of Science and Technology Policy, 2001).

<sup>14</sup>See comments by FDA attorney Fred Degnan (Pew Initiative on Biotechnology, 2002).

Under FDA regulations, the agency has an obligation to respond to Citizen Petitions within 180 days of their filing. However, no response has been forthcoming,<sup>15</sup> despite the fact that there were news reports suggesting that FDA would act on the Aqua Bounty salmon NADA as early as 2005 (Volz, 2005).

### 3.2.3 Regulatory Actions and Public Consultation

Many of the key consultations carried out on transgenic animals or fish in the U.S. are documented in [Table 2](#). The extent and nature of the public consultations reflect the current state of policy-making in the U.S. As discussed above, there are a number of agencies with the potential to regulate transgenic animals under the cobbled-together regulatory framework that exists. With the exception of FDA, none of these agencies has interpreted their authorizing statutes to allow such consideration.

FDA's sole ventures into public consultation of transgenics have come in the area of agricultural biotechnology and animal cloning. FDA's 1999 agricultural biotechnology hearings were held to address the budding controversy over foods containing GM organisms. While the hearings were directed at plants, the breadth of permissible comments was open and a number of comments expressed sentiments about transgenic animals. FDA's more recent Veterinary Medicine Advisory Committee (VMAC) hearing on animal cloning was of a more limited nature and focused on technical aspects of cloning safety. In addition, FDA asked the NAS to undertake a science based risk assessment of transgenic animals with the aim of advising the agency how to proceed. Finally, the Pew Initiative for Biotechnology funded its own set of discussions of animal biotech with the aim of fostering public discussion and thus more democratic regulation.

Although FDA has stated that other agencies, including EPA, the Fish and Wildlife Service and the National Marine Fisheries Service, have a voice in its policy ([Council on Environmental Quality and Office of Science and Technology Policy, 2001](#)), there is no evidence of this cooperative arrangement in the consultations that take place. The most commonly voiced concern by experts and the public alike is whether FDA, alone, has the capacity and/or authority to consider environmental, social, and ethical issues that are not technically in its mandate. A number of expert panelists go so far as to ask the FDA to acknowledge that it does not have jurisdiction over these issues, so that other agencies (or Congress) take up the issue.

## 3.3 Canada

This section provides an analogous overview of the multi-faceted policy landscape in Canada concerning transgenic salmon. Canadian and U.S. regulatory

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<sup>15</sup>In recognition of the absence of clarity on regulatory authority over the fish, CFS also filed Citizen Petitions with USDA and the Commerce Department, asking those entities to enforce regulations—such as the Endangered Species Act—that could have a bearing on the presence of GM salmon on the market.

Table 2: Selective list of U.S. Consultations concerning biotechnology topics

Date	Organisation	Meetings:	Mandate	Result	Public Consultation Component
Dec., 1999	FDA, Public Biotechnology in the Year 2000 and Beyond	As discussed above, FDA has some claim to regulatory authority to regulate transgenic salmon.	As discussed above, FDA has some claim to regulatory authority to regulate transgenic salmon.	FDA invited members of the public to air their concerns about agricultural biotechnology. FDA ultimately made transcripts available and published summaries of concerns voiced. FDA did follow up consultations on labeling of GM food products, in response to the widespread nature of public concern.	The consultations afforded the public an open forum to express concerns on everything relating to agricultural impacts, to ethics, to cost factors to the need for labeling. It is difficult to estimate whether the consultations had any impact on FDA policy because most of the comments were on issues that are outside the agency's mandate, which is limited to health and safety. FDA has not explicitly incorporated the comments into any policy.
Aug., 2002	National Academy of Sciences: Animal Biotechnology, Science Based Concerns ( <a href="#">National Academy of Sciences, 2002</a> )	NAS has no legal authority over transgenic salmon. Instead, it is a government funded expert body that is occasionally asked to review and issue findings on scientific topics.	NAS has no legal authority over transgenic salmon. Instead, it is a government funded expert body that is occasionally asked to review and issue findings on scientific topics.	NAS was asked by FDA to produce a science-based risk assessment of animal biotechnology. NAS issued a book-length report on its findings, which included a thorough review of the science with the conclusion that there needs to be further scientific study on certain aspects of the technology. On its own initiative, the NAS panel expressed concern that there were significant ethical/social/religious issues tied up with transgenic animals, and that these issues did not appear to have a place in the consideration of various regulatory bodies.	FDA has acknowledged receipt of the report but not responded to it. It is possible that the Veterinary Medicine Advisory Committee (VMAC) meeting was convened as a direct result of the NAS report, though FDA has not explicitly acknowledged this fact. As discussed above, FDA has yet to issue an approval on a transgenic animal for food or drug use.
2003	Pew Initiative on Biotechnology: "Biotech in the Barryard: Implications of Genetically Engineered Animals" ( <a href="#">Pew Initiative on Biotechnology, 2002</a> )	The Pew Foundation is an entirely private organization with no legal authority over transgenic salmon.	The Pew Foundation is an entirely private organization with no legal authority over transgenic salmon.	The Pew Initiative attempts to foster public discussion and reasoned policy on biotechnology. The Initiative has no formal role in regulation and no submission was made to any regulatory body. Panelists raised a number of issues, from the potential medical and food value of transgenic animals, to the gaps in the regulatory structure, and the lack of consideration being given to ethical issues.	The consultation included consumers and other individuals openly critical of government regulatory capacity of transgenic animals.
Nov., 2003	FDA Veterinary Medicine Advisory Committee (VMAC) on Animal Cloning	The VMAC is an advisory body convened by FDA to give input on relevant matters. FDA is under no legal obligation to act upon the VMAC's advice, but in reality, often does so.	The VMAC is an advisory body convened by FDA to give input on relevant matters. FDA is under no legal obligation to act upon the VMAC's advice, but in reality, often does so.	VMAC, a scientific advisory body to FDA on veterinary issues, was asked to consider whether FDA's internal risk assessment of animal cloning had adequately addressed hazards and risks for both animal and human health. The public was invited to make comments after FDA's presentations on the science were concluded. FDA's Center for Veterinary Medicine intended to take VMAC's response into consideration as it continued drafting a policy on animal cloning. FDA has not acted on the animal cloning issue since the meeting, except to say that the issue is still under consideration. ( <a href="#">US Food and Drug Administration, June 22, 2005</a> )	The hearing was quite limited to very technical matters relating to the safety of cloning for both animals and for secondary human drug and food use of cloned animal products. We have no information indicating that social or ethical issues relating to cloned animals were raised in any capacity.

authorities wrestle with many similar issues, such as notions of substantial equivalence and the regulation of product, rather than of process. The key distinction is that many Canadian agencies are actively involved in the regulation of transgenic salmon, whereas in the U.S., the FDA is the lead agency.

### 3.3.1 Regulatory Background

A series of stakeholder consultations helped to form the Canadian Biotechnology Strategy (CBS) of 1998, which expanded on the National Biotechnology Strategy (NBS) of 1983. One of the goals of the CBS is to maintain standards based on the Federal Regulatory Framework for Biotechnology (Canadian Framework), including the commitment to public involvement. The government introduced the Canadian Framework for the regulation of biotechnology products in 1993, seven years after the U.S. developed its “Coordinated Framework for Regulation of Biotechnology”. Just as in the U.S., the Canadian Framework encourages regulatory bodies to use “existing laws and regulatory departments to avoid duplication” in order to protect the health and safety of Canadians and the Canadian environment ([Health Canada, 2006b](#)). As an illustration of this fact, in May 2004, Fisheries and Oceans Canada (DFO), Environment Canada (EC), and Health Canada (HC) created a Memorandum of Understanding (MOU) that determined how the departments would regulate transgenic aquatic organisms until new regulations concerning transgenic fish became established under the Fisheries Act ([Health Canada, 2005](#)). Until these new regulations are in place, transgenic fish intended for human consumption will fall under HC’s Novel Food Regulations<sup>16</sup> ([Fisheries and Oceans Canada, 2004](#)). Environment Canada will conduct assessments of transgenic animals,<sup>17</sup> and DFO will take the lead on drafting new regulations pertaining to transgenic fish. These regulations will cover manufacturing and research aspects of transgenic fish, among other things.<sup>18</sup> Assessments of indirect human health impacts, as well as environmental impacts, will continue in the interim to be authorized under the Canadian Environmental Protection Act ([Department of Justice Canada, 1999](#)), the key authority for ensuring the safety of all new substances.<sup>19</sup> The Canadian Framework therefore results in a situation in which a number of federal government departments and agencies are granted authority over Canadian biotechnology products, including transgenic fish, though no agency has taken or been given a leading role.

Yet the regulatory realities are actually much more complex than suggested in the 2004 MOU (see [Table 3](#)). For example, under the current regulatory

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<sup>16</sup>It is still not clear when these regulations will be established under the Fisheries Act.

<sup>17</sup>Examples of documents created through guidance from the Animal Biotechnology Unit (ABU) include Notification Guidelines for the Environmental Assessment of Biotechnology-Derived Livestock Animals

<sup>18</sup>It appears that DFO is still in the process of developing these new regulations

<sup>19</sup>It is important to note that although CEPA 1999 is the key authority for ensuring the safety (in terms of both human and environmental health) of new substances, substances regulated by other Acts are exempt from the New Substance Notification requirements in order to reduce regulatory overlap.

system, multiple bodies have oversight over closely related or overlapping issues while other agencies are, in the views of some, stepping outside their mandated authority. Environmental aspects, in particular, are subject to multiple and distinct layers of regulation. For example, HC must assess the various human health risks associated with biotechnology food products. However, the department is also one among many bodies that will help address the environmental risks posed by transgenic fish. The department must conduct environmental assessments of transgenic, and other, food products regulated under the Food and Drugs Act due to responsibilities established under the New Substance Notification Regulations of CEPA 1999.<sup>20</sup> Environment Canada will conduct assessments of transgenic animals with guidance from The Canadian Food Inspection Agency's (CFIA) Animal Biotechnology Unit (ABU) through requirements under 1999 CEPA and the New Substances Notification Regulations. The CFIA regulates biotech products such as animal feeds and fertilizers while also examining the environmental risks associated with transgenic plants. In addition, this body monitors trials, import permits, and others issues regarding the registration of these products. Lastly, DFO will also share responsibility for environmental assessments of transgenic fish ([Fisheries and Oceans Canada, 2004](#)).

The role of DFO is further confused. The historic mandate of DFO was the management of wild Canadian fisheries. As such, many view their position as a regulator of aquaculture development as a conflict of interest with their original mandate ([Auditor General of Canada, 2001](#)).<sup>21</sup> Similar objections can also be directed at the Fisheries Act. As reported by the Commissioner for Aquaculture Development and referred to by Melanie Powers in her paper on salmon aquaculture, genomics, and ethics,

... Many of the regulations under the Fisheries Act are not well adapted or directly relevant to aquaculture—a situation that results in the aquaculture industry being managed as a subset of the traditional fisheries. This is analogous to equating traditional livestock and crop agriculture to the hunting and gathering of animals and plants. ([Power, 2003](#), p. 1)<sup>22</sup>

With the appearance of transgenic fish, as with aquaculture generally, the Fisheries Act will be required to stretch its regulatory power to cover issues that could not possibly have been conceived of when it was originally drafted.

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<sup>20</sup>Health Canada may create new assessment regulations with EC concerning the impact that new products may have on human health and the environment.

<sup>21</sup>For example, scientists at DFO are currently conducting research to determine and minimize any risks that transgenic fish may pose to wild stocks and the natural environment. This activity is taking place in spite of there being a tension in the RSC Report between the Panel's call for a moratorium on GM fish in ocean netpens and their call for more research on GM fish.

<sup>22</sup>Original quote referenced from [Office of the Commissioner for Aquaculture Development \(2001\)](#).

Table 3: Overview of Canadian regulatory bodies responsible for transgenic salmon (until such time as new regulations are established under the Fisheries Act for transgenic fish)

Regulatory Body	Responsibility
HC	<ul style="list-style-type: none"> <li>• Assessing the various human health risks associated with biotechnology food products</li> <li>• Helping to address the environmental risks posed by transgenic fish by conducting environmental assessments of transgenic, and other, food products regulated under the Food and Drugs Act due to responsibilities established under the New Substance Notification Regulations of 1999 CEPA</li> </ul>
EC	<ul style="list-style-type: none"> <li>• Conducting assessments of transgenic animals with guidance from CFIA's ABU</li> </ul>
DFO	<ul style="list-style-type: none"> <li>• Regulating wild Canadian fisheries (historic mandate)</li> <li>• Conducting research to determine and minimize any risks that transgenic fish may pose to wild stocks and the natural environment</li> <li>• Helping to draft new regulations pertaining to transgenic fish</li> <li>• Sharing responsibility for environmental assessments of transgenic fish</li> </ul>
CFIA's ABU	<ul style="list-style-type: none"> <li>• Helping EC to conduct assessments of transgenic animals through requirements under the 1999 CEPA and New Substances Notification Regulations</li> </ul>

### 3.3.2 Regulatory Actions and Public Consultation

This policy and regulatory discussion of transgenic salmon takes place against the backdrop of two influential biotechnology related documents: “Novel Foods Regulations” ([Government of Canada, 1999](#)) and the “Royal Society of Canada Expert Panel Report on the Future of Food Biotechnology” ([Royal Society of Canada, 2001](#)). In October, 1999, HC published the Novel Foods Regulations in the Canada Gazette, Part II ([Government of Canada, 1999](#)). These regulations required “pre-market notification and review for all novel foods including foods derived from biotechnology” ([Health Canada, 2006b](#)). The safety assessments addressed in this document refer to guidelines used since 1994 and are currently under revision. Environment Canada revised the New Substances<sup>23</sup> documentation in 2002 and began working on a tracking system for transgenic livestock and fish in conjunction with Agriculture and Agri-Food Canada (AAFC) through the Interdepartmental Working Group on Transgenic Animals, including Fish.

A second major document, the Future of Food Biotechnology report, was produced in 2001 by an expert panel convened by the Royal Society of Canada (RSC) at the request of HC, CFIA, and EC. The Panel evaluated the safety of biotechnology derived food products, and its report spawned a series of responses and activities from both government agencies and NGOs.

Many Canadian regulatory agencies involved with transgenic salmon have demonstrated a strong interest in public consultation. For example, HC, AAFC, CFIA, EC, and DFO began to draft an “Issue Identification Paper” on food from cloned animals in 2002. After drafting this document, HC requested public input concerning foods derived from cloned animals and ultimately created the Food Directorate Interim Policy on Foods from Cloned Animals on September 24, 2003. ([Health Canada, 2003](#)) Yet despite the interest that Canadian regulators show in public consultation, the range of consultations actually carried out reflects the piecemeal nature of regulation; as such, the scope of questions addressed by each consultation is often limited. [Table 4](#) provides a brief overview of a selection of biotechnology related public consultations that have been conducted in Canada since 1999. As shown in this table, many of the consultations deal with technical issues concerning transgenic products and few specifically focus on ethical or moral considerations held by members of the general public. For example, Health Canada’s July 2003 consultation report focuses specifically on evaluating regulatory possibilities for the environmental assessments of products falling under the Food and Drugs Act.<sup>24</sup>

The CBAC and Canadian Biotechnology Secretariat (CBSec) appear to be making the strongest attempt to include the public in their consultation processes. The CBAC was initiated in 1998<sup>25</sup> as a core component of the CBS,

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<sup>23</sup>A “New Substance” is a substance that cannot be found on the Domestic Substances List (DSL) including transgenic, genetically modified, cloned, or chimeric animals ([Environment Canada, 2004](#)).

<sup>24</sup>The document was posted on the Environmental Impact Initiative web site in order to allow for 60 days of public commentary and additional meetings or sessions followed.

<sup>25</sup>Although the CBAC and CBSec were both initiated in 1998, CBAC was not fully functioning until 1999.

which is supported by the CBSec. The 2001 Citizen Engagement Plan was created to “increase awareness of the Committee and its work and of biotechnology in general; to encourage participation in CBAC activities; and to build a partnership network to amplify its outreach endeavors” ([Canadian Biotechnology Advisory Committee, 2001](#)). The Committee also reports using various initiatives (i.e., the SchoolNet Partnership initiative) to address youth, communities, stakeholders, the media, and the general public. Members of CBAC participate in conferences and workshops and are active in tracking public opinion through feedback mechanisms which include a toll-free telephone line, e-mail correspondence, and web site reactions. In addition, the Committee consistently monitors other GM opinion studies. Since 1999, the CBSec and its partners have tracked public opinion research, organized thirteen public opinion surveys of their own, and conducted over one hundred focus groups concerning attitudes toward biotechnology and biotechnology policies.

Ultimately, however, the mission of CBAC is to “provide expert advice to the federal government on ethical, social, regulatory, economic, scientific, environmental, and health aspects of biotechnology” ([Canadian Biotechnology Advisory Committee, 2005a](#)). As such, CBAC consultations often include expert stakeholder groups and are not exclusively directed at the general public. For example, although the CBAC multi-city 2001 roundtable meetings included a discussion of ethical considerations, the individuals that were present primarily represented stakeholders outside the general population (NGO/Consumer Groups, Government, Industry, Academia, and the Health Industry). Documents like the “Acceptability Spectrum” for GM Foods included participation from the general public, but this cohort constituted a small portion of the sample. The Spectrum study was conducted with four stakeholder groups which included: (1) NGOs/ENGOS and representatives from Health and Faith communities; (2) Consumers; (3) GM biotechnology developers; and (4) Supply chain organizations and firms: farm producers, food manufacturers and distributors. Public concerns within the Consumer cohort may be lost within a diverse group that also represents special interest groups and experts.

## 4 Discussion

The foregoing investigation outlines the regulatory framework applicable to transgenic salmon in the U.S. and Canada and notes many of the relevant consultations that have taken place on this issue. The aim of this paper is to examine the relationship between this regulatory framework and the consultations that have been carried out, and conversely, the relationship between the types of consultations carried out and the regulatory stances taken. In so doing, we hope to draw attention to the interaction between policy and public consultation as an understudied area.

Before we outline our observations, it is critical to note the obvious fact that public consultations take many different forms. To speak intelligently about how a public consultation can be tied in to policy making, we first have to be able

Table 4: Selective list of national public consultations concerning biotechnology, including transgenic salmon

Date	Organisation (& partners)	Mandate	Result	Public Consultation Component
1999-present	CBSee (& partners)	Manages the CBS, which is intended to "promote the scientifically-sound development, application and export of biotechnology through strategic investments" while "engaging Canadians directly in shaping relevant policies" among other things. (Government of Canada Biotechnology 2006)	Various reports available on the CBS website.	Track public opinion polls and research and organized 13 of its own public opinion surveys and over 100 focus groups concerning attitudes of biotechnology and biotechnology policies.
Jan, 2001	RSC Expert Panel at the request of HC, CFIA, & EC.	Created in order to "promote learning and research in the arts and sciences" (The Royal Society of Canada, 2006)	Evaluated the safety of biotechnology derived food products. The report spawned a series of responses and activities from both government agencies and non governmental organizations.	Submissions from the public. The Panel made numerous recommendations that dealt specifically with consultation issues such as public access to information and calls for transparency. However the Panel said that philosophical and metaphysical issues fall outside their mandate
Sept, 2001	HC	Federal department responsible for maintaining and improving the health of all Canadians. (Health Canada, 2006a)	Proposed the Environmental Impact Initiative (EII) for new substances regulated under the F&D Act (e.g., genetic therapies and novel foods).	Intention to promote an "open and consultative" process during its development.
2001	CBAC	"Provides expert advice to the federal government on ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology." (Canadian Biotechnology Advisory Committee, 2005f)	Series of roundtable discussions about biotechnology in various cities across Canada produced a number of consultation documents available on the CBAC website	Stakeholders (i.e., NGO/Consumer Group, Government, Industry, Academia, Health Industry) discussed various issues including good governance, intellectual property, and ethics.
2001	CBAC	See above.	Citizen engagement plan to "increase awareness of the Committee and its work and of biotechnology in general; to encourage participation in CBAC activities; and to build a partnership network to amplify its outreach endeavors."	Includes initiatives like the SchoolNet Partnership to address the public (i.e., youth, communities, stakeholders, the media and the general public). CBAC members also participate in conferences and workshops and track public opinion through various feedback mechanisms (e.g., toll-free telephone line, e-mail, and web site). They also monitor other public opinion research about GM food regulation and commissioned a multi year review of such research.
Feb, 2002	CBAC	See above.	Document describing Exploratory Committee Examines an "Acceptability Spectrum" for GM Foods.	Conducted with four stakeholder groups: (1) NGOs/ENGOS, and representatives from Health and Faith communities; (2) Consumers; (3) GM biotechnology developers; and (4) Supply chain organizations and firms: farm producers, food manufacturers and distributors.
2002	HC, AAFC, CFIA, EC, & DFO	HC: see above. AAFC: "Provides information, research and technology, and policies and programs to achieve security of the food system, health of the environment and innovation for growth." (Agriculture and Agri-Food Canada, 2005) CFIA: "Safeguards Canada's food supply and the plants and animals upon which safe and high-quality food depends." (Canadian Food Inspection Agency, 2005b) EC: "Preserve and enhance the quality of the natural environment" by enforcing environmental rules and coordinating relevant programs and policies. (Environment Canada, 2005) DFO: "Federal agency responsible for developing and implementing policies and programs in support of Canada's economic, ecological and scientific interests in oceans and inland waters." (Fisheries and Oceans Canada, 2006)	Began to draft the "Issue Identification Paper" on food from cloned animals.	Consultations included discussions with the Expert Panel and "others."
March, 2003	CFIA's ABU	"Responsible for establishing animal health standards and augmenting regulatory controls for the development of biotechnology-derived animals." (Canadian Food Inspection Agency, 2005a)	2003 Animal Biotechnology Focus Group Meetings.	Consultation with animal industry groups and other stakeholders. Participants received a summary report on compact disc. (Canadian Food Inspection Agency, 2004)
Sept, 2003	HC	See above.	Created the Food Directorate Interim Policy on Foods from Cloned Animals.	Requested public input concerning foods derived from cloned animals.
Feb, 2004	CFIA's ABU	See above.	2004 Consultation on Animal Biotechnology and tracking.	Consultation with animal industry groups and other stakeholders. Participants received a summary report on compact disc. Results available on the Web (January 16, 2006).

to characterize the breadth and depth of the consultation itself. In addition to the vast literature analyzing particular instances of public consultations, there have been numerous suggestions about how to classify and evaluate types of public consultations. For example, James Fishkin identified eight forms of public consultation (Fishkin, 2005). Interestingly, the public hearing was not among the eight and it is one of the main types of consultation employed in the cases we mention above.<sup>26</sup> A more standard classification scheme is offered by Rowe and Frewer (Rowe & Frewer, 2000). They too have eight types, including the public hearing. The features that they identify for distinguishing a public hearing are these:

**Participants:** true participants are experts, but interested citizens may also participate;

**Time scale/duration:** may last weeks, months or even years.

**Mechanisms:** “Entails presentations by agencies regarding plans in open forum. Public may voice opinions but have no direct impact on recommendation.”<sup>27</sup> (Rowe & Frewer, 2000)

The main thrust of Rowe and Frewer’s article is to propose, defend, and attempt to apply both acceptance and process criteria for evaluating the types of consultation they have identified. Among the criteria are representativeness and independence of participants, influence of the consultation on final policy, stage at which consultation takes place, transparency, task definition, and cost effectiveness. These criteria could well be refined and supplemented, and then applied to the various instances of consultation that we have cited. We have not undertaken this task here; instead we offer, in a preliminary way, some observations about what we have found in the context of transgenic salmon.

#### 4.1 Context of Consultation

First, we note that it is critical to look at the context of the consultation, and to carefully identify the authority raising the issues, the mandate of the agency, and the timing of the consultation vis-à-vis any regulatory decision-making that may take place. That is, just as the designers of public consultation have to take some account of the science underlying the issues, we think it necessary to take some account of the policy arena they aim to influence.

The consultations on transgenic salmon and related issues suggest an inverse relationship between the breadth of issues identified and the decision-making power of the body convening the consultation. As an example, we note the scope of the issues addressed by the RSC Expert Panel which has an advisory

<sup>26</sup>Rather than criticizing Fishkin, we believe that he is simply looking beyond most of the traditional modes of public consultation.

<sup>27</sup>An anonymous referee asked, “What would be the point of attending a hearing if there is no expected direct impact on policy recommendation?” We think this is a very good question and it raises our main issue: consultations and the policy context must be considered as two parts of a whole.

role and no direct regulatory authority. At its first meeting, the Panel initiated a discussion about the scope of its mandate with the sponsoring government departments:

The discussion with the sponsors made it evident that, although the focus of the Expert Panel's enquiry was on the scientific aspects of the new technologies and their effective regulation, the Panel would need to address many peripheral issues that touch on the question of the appropriate use of science in the regulation of risks . . . [I]t is important to understand that answers to questions not specifically within our mandate are often relevant to, and influence answers to questions that are within it. The health and environmental safety issues posed to the Panel in the Terms of Reference, though largely scientific in nature, often cannot be addressed fully without reference to broader ethical, political and social issues and assumptions. ([Royal Society of Canada, 2001](#))

The US National Academy of Sciences, which is also strictly an advisory body, reached a similar point.

While policy issues might be considered beyond the scope of this study, the committee took account of their existence in identifying science-based concerns about animal biotechnology. ([National Academy of Sciences, 2002](#))

In contrast, regulatory agencies such as CFIA's ABU and FDA, which are actually engaged in the assessment of transgenic salmon (CFIA's ABU) or have authority to issue approvals of transgenic salmon (FDA), have thus far directed consultations primarily to expert analysis of narrowly defined technical issues. Even if these bodies engage in more wide-ranging consultations prior to issuing approvals, it is unlikely that they will openly discuss free-ranging ethical considerations, as these issues are not technically part of their mandates. For example, in setting out its task in the Veterinary Medicine Advisory Committee meeting on animal cloning, FDA states repeatedly that its task is science based risk assessment and not anything else.

Risk assessment . . . is science based. It identifies hazards and risks. And we will talk about the difference between the two in a couple of minutes. It's relatively value free, but never entirely value free, because we do make assumptions, but we try to be very clear about what those assumptions are. And finally, it provides a framework for risk management decisions.

Risk management, on the other hand, which will come farther along in the process, is the identification and evaluation of alternative strategies and the selection among them based on some set of preestablished criteria.

In accordance with directives offered at the beginning of these assessments, this is a scientific risk assessment, underscored by scientific biases. They are not moral or ethical biases which are more appropriately addressed during the risk management component of this overall process. ([US Center for Veterinary Medicine, November 4, 2003](#))

## 4.2 Aims of Consultation

Second, we observe that those holding public consultations—and well as those receiving these results—struggle with of the benefits of having information about public positions. Is it inherently valuable to compel policymakers to be presented with issues beyond their mandate? Or alternatively, are there times where—for the sake of enacting effect technical responses to technology—we need to limit the breadth of public commentary in the process?

One of the recurring complaints about the way the policy establishment organizes public input is that the terms of the debate are set by the establishment and not by the public. Thus, for example, the option not to pursue a particular technology is often not an option. See for example [Wynne \(2001\)](#) and [Levidow & Carr \(1997\)](#). A protracted analysis of this point is made by [Glover \(2003\)](#), who analyzes several nations' efforts to comply with a requirement in the Cartagena Protocol to consult their citizens in constructing their national biosafety protocols. [Glover](#) claims that it is difficult if not impossible to confine public consultation to the technical discussion of biosafety; instead, publics insist on debating a wide range of issues based in biotechnology policy in general.<sup>28</sup>

There are echoes of this tension in our discussion. Actual policymaking bodies, such as FDA, carefully defined the terms of debate by stating that their mandate was to hear issues raised by scientific risk assessment and *not* non-technical issues, which they promise will be addressed in other contexts. In contrast, the RSC Panel in Canada suspected at the outset that their terms of reference had to be widened, and their subsequent experience confirmed that suspicion. Similarly, the U.S. National Academy of Sciences felt compelled to add a section in its report on environmental, social, and ethical issues even though such topics were clearly outside the scope of what they were requested to do.

Ultimately, the utility of broad public input is an understudied area that needs much further attention. On the one hand, some maintain that we should broaden public consultations to address the entire range of potential issues and that in this way, we will support and promote democratic investment in decision-making on science and technology issues. Public consultations initiated by the

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<sup>28</sup>Others maintain that the effort by regulatory authorities to constrain debate may ultimately have negative repercussions. Without a forum for expressing concerns about religious, ethical, or social issues, safety discussions may become a proxy for broader issues—intensifying debate in a manner that may defy satisfactory resolution based on technical issues alone. This theme is repeated throughout the articles contained in Dorothy Nelkin's edited volume ([Nelkin, 1992](#)).

Government of Canada's CBSec seem to reflect this line of reasoning. Since its inception in 1999, the Secretariat and its partners have conducted and continue to study public opinion research in what has become "North America's largest and most comprehensive investigation into attitudes about biotechnology and the public policy that surrounds it" ([Government of Canada Biostrategy, 2006](#)). In their December 2004 Statement on Renewal of the CBS and the Evolving Role of CBAC, the CBAC reported similar sentiments in comments concerning their work.

Our work on the Regulation of Genetically Modified Food and Feed, for example, was informed by the Royal Society's Expert Panel Report on the scientific aspects of this topic. We related that work to a broader investigation of the social, ethical and economic issues involved and their policy implications—an investigation that involved broad public and stakeholder consultations. The latter activities resulted in the "spin-off" of a process that led to the creation of a "dialogue tool" for facilitating debate on controversial topics. One can readily envision CBAC exercising its meta-advisory role in relation to the assessments that might be undertaken, at the request of the government, by the nascent Canadian Academies of Sciences. ([Canadian Biotechnology Advisory Committee, 2004](#))

Those who promote broad consultations may assert that such efforts will prevent issues from falling through the cracks in the process of disaggregating problems to fit the mandates of agencies that convene public consultations. In so doing, it can be argued, public consultation can serve as a corrective to the overly restrictive scope of agency considerations of policy.

The alternative position is that there are times when limitations on public consultations are entirely justified on the grounds that overarching decisions have been addressed in other venues and the issue at hand requires deep and detailed investigation. In this context, we wonder whether there are public consultations that can be judged as effective and even exemplary, even though their scope is limited and some would charge that certain underlying issues were papered over or not addressed at all.

For example, the VMAC hearing is explicitly limited to science based risk assessment. But in undertaking this task, the Committee is cognizant that this step is a necessary element of later risk management and risk communication steps that will be taken. Thus, it seems that this kind of narrow consultation plays an important role in the process of deciding on questions of policy and should not be eliminated in favor of broad consultations that always explicitly include broad ethical and social questions.

Does the risk assessment or what we have discussed today change CVM's position on food derived from clones or their progeny? The answer is no. This is just the science portion of the process. So only through risk management would we change the policy.

Would there be any change in the position? Some of the risk management actions that are available to FDA include things as simple as guidances for industry. Policy statements. Regulations. Even compliance policy guides which are instructions to the field for how to inspect.

A few words about the risk management process itself. This is the stage where burden comes into place versus the benefits. And the tolerance for uncertainty from the risk manager's point of view. What level of uncertainty are you willing to live with? These are all non-science issues really. ([US Center for Veterinary Medicine, November 4, 2003](#))

It is worth noting that there have been occasions where, in spite of authorities' efforts to limit discussions, the public forces views to be heard. A good example is the discussions of DNA in the 1970s. While many in the regulatory and scientific communities attempted to limit the breadth of debate, interested parties used alternative force—including city council meetings—to ensure that a wide range of concerns entered the public domain ([Krimsky, 1992](#)).

## 5 Conclusion

This paper does not reach any grand conclusions on the breadth or role of public consultation in public policy creation. Rather, it is intended to stand as a step toward a more comprehensive study of the nexus between policy and consultation. From our brief study, it is clear that in the case of transgenic salmon in North America, the complexity of regulations (the “policy” regime) has directly affected the types of consultations made available. The policy making bodies seem to limit the terms of consultations based on their regulatory mandates. Interestingly, the inverse seems to be true for those bodies that do not have an actual mandate to effect policy: for example both the NAS in the U.S. and the RSC Expert Panel, in Canada, broadened consultations to include issues beyond narrowly construed science-based ones.

The material discussed also illustrates that the policymaking context is critical not only to the type of public consultation but also to the types of issues that can be effectively considered. Policy and consultation are thus invariably linked together and yet, beneficial forms of public consultation have not been well defined, and there is very little explicit recognition of how, where, when and what quantity of information gained from such consultations will be used in policy. Certainly, these questions are not easy to answer. Policymaking is already cluttered with input from the regulated industry, lobbyists, NGOs, and many others. Further, the appropriate type of consultation in any given situation will necessarily need to reflect the types of decisions to be made, parties involved, level of technical detail, timeframe, and many other factors.

We conclude, then, with a hope that further study will be dedicated toward mutual understanding of policy and consultative arenas, structures, limitations, and challenges.

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