CHAPTER 8

Public Inclusion and Responsiveness in Governance of Genetically Engineered Animals

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Introduction

In 2016, Canada approved the first genetically engineered (GE) animal for sale on the food market, the AquAdvantage Salmon (AAS). AAS is genetically engineered to grow to adulthood in half the time in comparison to the wild-type Atlantic salmon. Developers inserted genes for the growth hormone gene from Chinook salmon and a promoter gene from the ocean pout to achieve this more rapid growth. The Canadian AAS case is the first time that a GE animal has been approved for human consumption and sold in the marketplace.

GE animals in the food supply are even more controversial than GE plants, and the AAS continues to face significant opposition from

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consumers, nongovernmental organizations (NGOs), and retailers (Halliday 2020). Surveys suggest that the public is more significantly concerned about GE animals for food than GE crops (Frewer et al. 2014; Cuite et al. 2005; Hoban 1998; Halliday 2020; Martin-Collado et al. 2022). GE animals are viewed as the most negative of various food technologies—even more so than pesticides and hormones (Henson et al. 2008). Deeply held attitudes, values, and beliefs often underlie this negativity. For example, measures of "disgust sensitivity" are strongly correlated with resistance to GE animals (Scott et al. 2016), and genetically engineering animals provoke diverse ethical concerns outside of scientific safety (Thompson 1997). Nep and O'Doherty (2013) also found in focus groups that there is significant distrust among Canadian consumers with regard to governance of GE salmon by companies and government.

GE foods are not labeled in Canada and there is a lack of public awareness that AAS has entered the market. The lack of transparency and labeling of GE foods derived from animals may fuel consumer distrust (Nep & O'Doherty 2013). In the words of one biotechnology expert, "There's a lack of transparency across the board in the industry...ordinary consumers don't really understand what genetic engineering is all about…animals make for a whole other layer of complexity…This biotechnology in food has arrived without any sort of social consent provided by consumers" (S. Charlebois, quoted in Halliday 2020). An NGO representative summarizes the shortcomings in public participation in decision-making about AAS as "There's no consultation with the public…no consultation with fisherfolk or farmers. They don't look at the questions, 'Do we need or want this technology?' The regulatory system looks only at the question of safety and excludes those questions" (L. Sharratt, as quoted in Halliday 2020).

In this chapter, we examine the regulatory decision-making for AAS up until its market introduction in 2017. We seek to understand whether, where, when, and how there are opportunities for public participation and values-discussions within the Canadian governance system for GE animals. Where there are opportunities to articulate values in the Canadian governance system, we examine how decision-makers respond to and incorporate broader concerns about AAS. The AAS case serves as a current example for governance of GE food animals and an instructive case for future governance of GE and gene-edited animals and their food products.

We frame our evaluation on two principles of responsible innovation (RI)—*inclusion and responsiveness*—the public-facing endeavors of RRI. First, we look at the regulatory approval process for AAS to examine when there were opportunities for public and stakeholder participation in decision-making (*inclusion*). Second, we report on findings from our study which utilized textual analysis of one public participation window—a series of Parliamentary hearings associated with GE animal oversight in Canada in 2016. Here, we examine whether decision-makers incorporated the diverse stakeholder perspectives and concerns voiced at the hearings into their final reports (*responsiveness*). Finally, we identify barriers to putting inclusion and responsiveness into practice in risk governance of GE organisms and discuss ways to overcome these barriers to facilitate responsible innovation practices in oversight systems for emerging technologies.

Responsible Research and Innovation

The framework of responsible research and innovation (RRI) may provide a way forward for biotechnology developers to act on their desires for greater public trust and legitimacy (Kuzma 2018) and to address the public concerns about lack of consultation in GE approval processes and the AAS case more specifically (Halliday 2020). RRI has been proposed in the last decade to better align science and technological development with democratic engagement processes, public values, and societal goals (e.g., Gardezi et al. 2022; Owen et al. 2012, 2013; Stilgoe et al. 2013). RRI arose out of a longer history of work on the ethical, legal, and social implications/aspects of scientific research and technology development (Felt 2018).

Although RRI as a framework is continually evolving, its most-cited conception centers around four principles: anticipation, inclusion, reflexivity, and responsiveness (Stilgoe et al. 2013). *Reflexivity* moves governance of science and technology away from solely a risk-based approach to one that encompasses reflection on the underlying goals, motivations, limits of knowledge, assumptions, and alternative framings of problems. *Anticipation* incorporates a forward-looking dimension where potential consequences are explored and analyzed before technologies are fully developed in order to anticipate downstream potential risks and impacts. *Inclusion* involves citizens and publics, in addition to stakeholders, in

governance of research and innovation, opening up processes of reflexivity and anticipation to voices beyond those of subject-matter experts. Finally, *responsiveness* requires a capacity to change shape or direction of innovation in response to stakeholder and public values (discovered by anticipation, inclusion, and reflexivity), as well as new or changing information or circumstances. The RRI framework based on these 4 principles is "deemed to be characteristic of a more responsible vision of innovation" than other frameworks centering on research ethics, diversity, and inclusion in STEM fields, and interdisciplinarity (Wittrock et al. 2021, p. xi) and has been "operationalized by national funding bodies" and "integrated in research practice" in the EU (Wittrock et al. 2021, p. xi).

We evaluate the oversight process for AAS according to two of these four principles—inclusion and responsivity. We choose these two as they are more public-facing endeavors of RRI, putting public engagement and the incorporation of societal values into the process of biotechnology innovation. Below we consider whether the government approval processes for AAS in Canada provided opportunities for meaningful, bi-directional public engagement and input (e.g., as those suggested in NASEM 2016 for gene drives).

Inclusion in Risk Governance for GE Animals

In late 2013, AAS was approved for commercial production in Canada, and in 2016, AAS was also approved for human consumption in Canada (Fig. 8.1). In 2017, AquaBounty technologies announced that it had already sold 4.5 tons of AquAdvantage Salmon (AAS) (Waltz 2017). Current labeling laws in Canada are based on voluntary labeling standards, so much of the Canadian public was and remains unaware that salmon on the market could be genetically engineered (Halliday 2020). For the initial production of AAS, eggs were fertilized in a facility on Prince Edward Island (PEI) and then shipped to the Panamanian highlands for "grow-out" where the GE salmon were grown to full size in a land-locked location using recirculating aquaculture tanks. Once AAS were grown to full size in Panama, they were transported to food distributors in Canada for sale in food markets. The initial parameters for Canadian approval of AAS were specific to being grown out in Panama, but since, AAS has been approved for grow-out in both the U.S. and Canada (AquaBounty 2019; Callegari & Mikhailova 2021). Below we

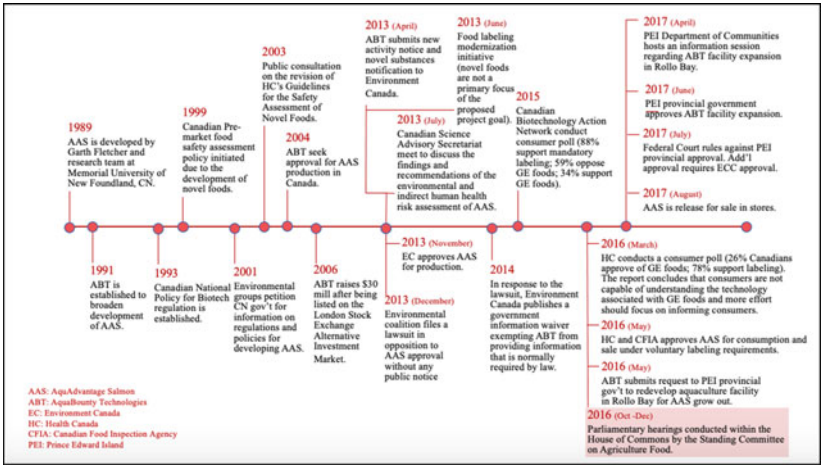

Fig. 8.1 Timeline of GE Salmon in Canada

describe the regulatory approval process from 2013 to 2017 for AAS in Canada to investigate places where the public was informed or engaged.

AAS Regulatory Approval: Living Organisms

The Canadian Environmental Protection Act 1999 (CEPA 1999), administered by Environment Canada (EC) and Health Canada (HC), is the key authority for novel organisms like the AAS. The regulatory process for novel organisms focuses extensively on the assessment of risks to human health and the environment, as the Government of Canada ensures that all new substances, including organisms, are assessed for their potential harm to the environment and human health. The New Substances Notification Regulations (Organisms) [NSNR (Organisms)] under CEPA 1999 prescribe the information that must be provided to Environment Canada (EC) prior to the import to or manufacture in Canada of new organisms that are living products of biotechnology, including fish like the AAS (Government of Canada 2005, 2010).

The Department of Fisheries and Oceans Canada (DFO), EC and HC signed a Memorandum of Understanding to implement the NSNR (Organisms) for fish (Department of Fisheries and Ocean 2013). DFO assists by conducting an environmental and indirect human health risk

assessment for GE fish like AAS and recommending any necessary measures to manage risks. The risk assessments evaluate whether the notified fish product of biotechnology is "CEPA toxic": a substance is toxic if it may enter the environment and (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity; (b) constitute or may constitute a danger to the environment on which life depends; or (c) constitute or may constitute a danger in Canada to human life or health.

A notification under the NSNR (Organisms) was submitted to EC by AquaBounty Technologies in April 2013. DFO conducted an environmental and indirect human health risk assessment to make recommendations to EC and the Minister of the Environment about any necessary risk management measures for the AAS. A review of the DFO risk assessment was conducted under the National Science Response Process, Canadian Science Advisory Secretariat (CSAS) in July 2013. The purpose of this meeting was to peer-review the conclusions presented in DFO's preliminary comprehensive Environmental and Indirect Human Health Risk Assessment for AAS. However, only 3 of 23 participants were from outside of the government sector. Sixteen out of 23 participants were from DFO itself, 3 from other federal government. Agencies (HC and EC), 1 from the PEI Provincial government, and only 3 from outside government (1 consultant, 1 academic, and 1 from the Atlantic Salmon Foundation) (Department of Fisheries and Oceans 2013).

Both the risk assessment process under DFO and the meeting to review the risk assessment were generally closed to the public. No public comment period was conducted, and decision-making was conducted between the federal agencies and the developers of AAS. The public was not directly solicited for input on the decision-making process for the approval of AAS production under the NSNR (Organisms) process. Up until this point, there would be little if any information available to the public on the approval of AAS in Canada.

The federal Ministers of the Environment and Health ultimately approved the commercial production of AAS eggs in a notice published in the Canada Gazette on November 23, 2013 (Goldenberg 2013). The decision allowed AquaBounty to proceed with the production of the GE salmon eggs in PEI, Canada for shipping to Panama for grow-out and processing. Once the approval under CEPA and the NSNR process was made, however, Ecology Action Centre (EAC) and Living Oceans (LOS), took the federal government to court in 2014 over substantive portions

of the review and legal requirements. This opposition to AAS approval included the argument that the review did not include an assessment of "whether the genetically engineered salmon could become invasive, potentially putting ecosystems and species such as wild salmon at risk" (Wristen 2014). These NGOs also objected to the permits EC granted for "unassessed uses" of AAS at the time such as its grow-out in Canada (Wristen 2014). One NGO leader involved in the suit also bemoaned the lack of transparency and public consultation in the decision-making process stating that "this is the world's first genetically modified food animal to go into production…this was done without any public debate at all and under circumstances that look like a deliberate attempt to prevent public comment. Canadians have a right to know about decisions like this in advance of them being made" (Wristen 2014). In the end, the court ruled in the favor of the federal government's approval, but at the time, it also restricted AquaBounty egg production to a single facility in PEI and did not grant permission to grow out the GE salmon at other locations (note: grow-out was ultimately approved in Rollo Bay, PEI in 2019—see Evans 2019). The court also ruled that the federal government's current practices of issuing waivers for grow-out without public notification could not be continued.

In spring 2018, we interviewed several decision-makers in Canada involved in the assessment and approval of AAS who confirmed the lack of public consultation on the approval.

In contrast to the Canadian approval, the U.S. has requirements under the Administrative Procedures Act (APA) for notice and public comment in rulemaking and these were invoked for the AAS approval under the U.S. Food and Drug Administration. The draft environmental assessment was available for public comment in the U.S. prior to the approval decision being made. In addition, the U.S. FDA convened its Veterinary Medicine Advisory Committee, an external advisory committee (no government employees) to review the assessment of AAS and deliberate in an open public meeting. Although the U.S. process for AAS was far from the ideal forms of public engagement discussed in the scholarly literature and suggested by the RRI principle of inclusion, there were multiple windows of opportunity to obtain and incorporate public feedback for the AAS decision (Stilgoe et al. 2013; Callegari & Mikhailova 2021). In contrast, in Canada, the public was not solicited for input on the decision-making process for the approval of AAS production under the NSNR (Organisms) process. The process lacked public transparency

and no public information was available until the 2013 final AAS approval was published in the Canada Gazette and NGOs announced they were taking the federal government to court for the approval.

AAS Regulatory Approval: Food and Feed

For food and feed approval of AAS, two additional separate assessments were conducted. In addition to the DFO assessment for EC's NSNR regulation, Health Canada assessed the safety and nutrition of AquAdvantage Salmon for use as food (Health Canada 2016a) and the Canadian Food Inspection Agency (CFIA) assessed the safety and nutrition of AquAdvantage Salmon for use as a livestock feed (CFIA 2016). In Canada, genetically engineered foods like AAS fall under the category of "novel foods." According to the Food and Drugs Act (Health Canada 1985), novel foods are described as food that have been produced through new processes, that do not have a history of safe use as a food, or that have been modified by genetic manipulation (Health Canada 2006). The guidelines for the safety assessment of novel foods stipulate that approval requests for the production and sale of novel foods be made to the Health Products and Food Branch (Health Canada 2006). These foods are subjected to a food safety and nutrition assessment that is based on substantial equivalence. Substantial equivalence is the argument that the novel food product is equivalent to conventional foods in terms of safety and nutritional standards (Health Canada 2006). Health Canada's assessment of AAS was conducted based on the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (UN FAO 2008). CFIA assessed the safety and nutrition of AquAdvantage Salmon for use as a livestock feed to establish the safety of feed ingredients derived from AAS.

Both HC and the CFIA published the summaries of their AAS assessments on May 19, 2016, in which it was determined AAS were as safe and nutritious as other farmed Atlantic salmon and that there were no feed safety concerns (CFIA 2016; Health Canada 2016a) (Fig. 8.1). Once again, however, there were not opportunities for public comment or open meetings through which to solicit public feedback on AAS approval for the Canadian food market. It is notable that the complete risk assessments for the CEPA NSNR process, the HC novel foods and CFIA novel feeds were not published online for public viewing, but rather just summaries are posted on the HC and EC websites. In contrast,

in the U.S., one can obtain the risk assessment documents for biotech products online in most cases, and thus see how the data is interpreted (e.g., Meghani & Kuzma 2018). In the U.S., there are also mandates for public comment periods on regulatory decisions, sometimes involving the approval of individual GE food animals, in addition to broader policies on how to regulate. This is a key weakness in transparency for Canada—external academics and stakeholders with subject-matter knowledge, and other interested publics, cannot judge the data, its interpretation, and risk conclusions from just a summary. One could argue that this lack of *external* peer review and scrutiny is harmful to both public legitimacy and the scientific enterprise. Without external eyes and drawing upon a wide expertise of various publics and stakeholders, scholars have argued that the analyses will suffer from a deficit of important standpoints (Meghani & Kuzma 2011)—quality may suffer, and public legitimacy of decisions may decrease. Ultimately, the lack of inclusive processes, as suggested by the RRI framework, may jeopardize the future of GE animal-based foods.

Barriers to Inclusion for AAS Approval

In informal interviews with biotech stakeholders,[1] we found that at the time of the AAS approval, regulators struggled with broader goals to engage the public in decision-making and increase transparency for biotechnology product decisions. Agency staff recognized that GE animal products are controversial and that there will soon be an explosion of them as gene-editing and CRISPR make genetic modification on animals easier to perform. They agreed that greater public inclusion should be a goal. However, agency managers also noted significant barriers to increasing public transparency and participation in GE animal approvals. One is the need to protect confidential business information (CBI) in biotech product submissions. At the time of the AAS approval, NSNR (Organisms) notifications and assessments for GE animals did not have to be posted prior to approval (unlike for new chemical substances under the same law). The rationale in designing the closed process for NSNR (Organisms) was that there would need to be a higher degree of intellectual property (IP) protection given the novelty of genetically engineered

[1] One author spent 4 months in Ottawa Canada in Spring 2018 meeting and speaking with regulators, innovators, trade organization representatives, government leaders, NGOs, and other stakeholders associated with GE animal policies.

animals (compared to chemicals). Protecting CBI was deemed as important, although it came at the expense of public transparency during regulatory review. Balancing the protection of IP and CBI with openness was considered a significant challenge for GE animals and AAS oversight.

The second challenge Canadian regulators noted is that there is little capacity and experience among the regulatory staff with the public comment and rulemaking process. Regulators expressed concern about comments falling outside of their jurisdiction and worried about the possible high volume and low relevance of public comments. The agency staff felt constrained in not being able to consider "non-scientific" concerns and expected most comments to contain information not relevant to the technical scope of their decision-making which centers around plausible health and environmental risks. Broader public concerns about social, cultural, or economic harms or social values about "naturalness" and sustainability are likely to be expressed in public comment or input processes, yet lie outside the authorities granted by the regulations public administrators are tasked with administrating.

Shortly after the AAS approval, the agencies were being asked by Parliament to implement public participation processes and operate under greater transparency. For example, the Standing Committee on Environment and Sustainable Development (ENVI) in the Parliament's House of Commons published a report in June 2017 with two specific recommendations for NSNR (Organisms) (House of Commons 2017): (1) Recommendation 26: "The Committee recommends that CEPA be amended to establish a more open, inclusive and transparent risk assessment process that better enables public participation in the evaluation of new living modified organisms" and (2) Recommendation 28: "The Committee recommends that CEPA be amended to ensure that provisions that set out a requirement for consultation with the provinces and territories also require consultation with Indigenous peoples." While waiting for CEPA to be amended by Parliament (which it ultimately was in April 2021), regulators expressed plans to design a voluntary process for developers to notify the public of NSNR (Organisms) submissions for GE animals. In this process, developers would have the option to publish a non-confidential summary of their product on the EC website when they submit a GE animal or microbe to EC NSNR division. EC NSNR would then solicit public comments on what types of environmental and health risks are of concern to people for that GE animal or microbial product.

After the AAS approval, HC placed increasing emphasis on openness and transparency for novel foods like those derived from AAS. These are reflected in Health Canada's Regulatory Transparency and Openness Framework (Health Canada 2019). They have adopted digital methods (i.e., online consultation, online comment submissions) to foster public participation. This has provided novel approaches to allow Canadians to provide public input and interact with the Government of Canada. Health Canada and the Public Health Agency of Canada also published Guidelines on Public Engagement to strengthen their public engagement efforts and capacity by providing staff with guidance on sound principles, practical tools and templates, best practices, and the use of innovative technologies for engagement (Health Canada 2016b).

AAS Post-approval Inclusion

Despite a lack of public participation during the federal regulatory process for AAS, there was a significant point *after* the regulatory approval in which public and stakeholder input was sought via Parliamentary hearings focused on Canadian policy toward GE animals (Fig. 8.1). In the next section, we use this window of participation to explore public concerns and values associated with risk governance and oversight for AAS and GE animals. As an indicator of RRI's principle of responsiveness, we also examine whether decision-makers incorporated the diverse perspectives expressed in the hearings in their final reports.

Responsiveness in Risk Governance for GE Animals

Soon after CFIA and HC made their decisions on feed and novel-food approval for AAS, Parliament's House of Commons Committee on Agriculture and Agri-Food was asked by the Minister of Agriculture and Agri-Food to examine the legal and regulatory framework around GE animals more generally and their increasing availability for human consumption. On 1 June 2016, the Committee agreed to investigate GM animals for food and the issues around regulatory approval in Canada beyond health and safety, as well as steps to provide the public with information about the market entry of GM animal-based products (House of Commons 2016). The Committee was to release its report to the House by December 8, 2016 (ibid.).

The Committee held four public hearings in fall 2016, soliciting input from representatives of the agriculture and agri-food sector, regulatory authorities, and civil society about the issues raised by the arrival of GE animals for human consumption. Stakeholders were invited to present their viewpoints at these committee hearings. In December 2016, Parliament's summary report was released and became available online along with full transcripts of the meetings (House of Commons 2016). In April 2017, the government agencies involved in AAS approvals and GE animal regulation more broadly responded to the report.

These reports and transcripts of the meetings provided a window of participation into regulatory policy-setting for GE animals in Canada. Although it occurred after the formal regulatory decision to approve AAS, given the lack of other venues for public comment, we used it to examine narrative frames and stakeholder attitudes toward governance policy for GE animals and how those concerns were considered in the final reports written by either Parliament or by the federal agencies in response to the hearings. Here, we use the reflection of public and stakeholder narratives and concerns in the Parliament and agency reports as evidence for "policy uptake" or "responsiveness" to public and stakeholder concerns. Below, we briefly summarize our findings, and more details on the methodologies and results can be found in Williams (2019).

Stakeholder Comments and Cultural Worldviews

Our textual analysis of the Parliamentary hearings involved categorizing each comment by stakeholder group and cultural worldview (Williams 2019). Cultural worldviews were assessed using cultural theory (Douglas & Wildavsky 1982) which has a long history of explaining how people perceive risks from emerging technologies (Finucane & Holup 2005; Jones & Song 2014; Kahan et al. 2011). The four cultural types identified by cultural theory are egalitarian, hierarchical, individualistic, and fatalistic (Douglas & Wildavsky 1982; Kahan et al. 2011; Jones & Song 2014; Thompson et al. 2018). Previous research has used these four cultural types to examine the way that issues concerning risk are framed as narratives (i.e., stories) depending on the cultural worldview (Jones & Song 2014). Figure 8.2 describes how we translated this prior work and applied it to identify cultural narratives in the Parliamentary hearings for the GE salmon and GE animals (for more details, see Williams 2019). Table 8.1 shows the results of the comments displayed during

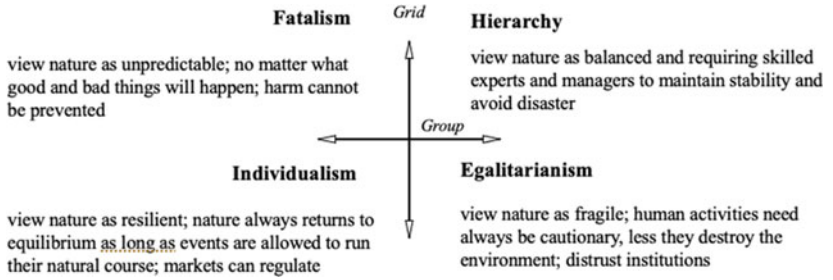

Fig. 8.2 Four cultural archetypes and narratives about technology, risk, and governance

the Parliamentary hearings by stakeholder affiliation and these cultural worldviews. Notably, those with greater hierarchical worldviews tended to be in the federal agency positions, positions of authority and decision-making for AAS, while those with egalitarian views were in the advocacy sector. Members of Parliament, industry, and trade groups displayed a more even breakdown of hierarchical (H), individualistic (I), and egalitarian (E) worldviews. Fatalistic worldviews were not identified in the hearings.

Comments by "Science-Based" or "Science-Plus"

In addition to tracking the cultural worldviews and stakeholder groups, we probed whether the points and issues raised in the hearings are related to strictly "science-based" concerns (such as direct toxicity or allergenicity of the product) or "science plus" which includes broader concerns about potential impacts or issues (including social, economic, cultural, political, or indirect ecosystem impacts). We found that egalitarian and individualistic commentators were much more likely to expand the scope of the issues beyond "science-only" to "science plus"; however, hierarchs were more likely to contract the scope of GE animals to "science only" (Table 8.2) (see also Williams 2019; Williams & Kuzma 2022).[2]

We also found differences in the cultural groups as to *how* "science-only" or "science-plus" arguments were used (Williams 2019; Williams &

[2] These relationships were statistically significant at $p < 0.05$ as reported in Williams (2019) and Williams and Kuzma (2022).

Table 8.1 Parliamentary hearing comments according to stakeholder and cultural groups

	Stakeholder Group	*Cultural Group*						*Total* n = *269 (100%)*
		Hierarchical n = *121(45%)*		Individualist n = *65 (24%)*		Egalitarian n = *83 (31%)*		
Liberal, Conservative, NDP	Member of Parliament	53	(45%)	25	(22%)	39	(33%)	117 (100%)
Canadian Cattlemen's association, BioteCanada	Alliance/Coalition	29	(37%)	30	(39%)	19	(24%)	78 (100%)
AquaBounty Technologies, Canadian Aquaculture Industry Alliance	Fishing industry	5	(31%)	3	(19%)	8	(50%)	16 (100%)
Department of Agriculture and Agri-Food, Canadian Food Inspection Agency, Department of Health	Agency official	30	(83%)	6	(17%)	0	(0%)	36 (100%)
Canadian Biotechnology Action Network, CropLife Canada, Ecology Action Centre, Vigilance OGM	Advocacy group	2	(11%)	0	(0%)	17	(89%)	19 (100%)

	Stakeholder Group	*Cultural Group*						*Total* n = *269 (100%)*
		Hierarchical n = *121(45%)*		Individualist n = *65 (24%)*		Egalitarian n = *83 (31%)*		
University professor/Board member of AquaBounty	Researcher/Scientist	2	(67%)	1	(33%)	0	(0%)	3 (100%)

Reading across the rows, for that stakeholder group, the number and % of comments falling into each cultural group is shown. Across all stakeholder groups (n = 269), cultural group representation in the comments is Hierarchical 45% (n = 121), Individualist 24% (n= 65), and Egalitarian 31% (n = 83)

Kuzma 2022). Egalitarian comments tended to be against GE animal approval ($n = 18$ comments for approval and $n = 59$ comments against approval) and used "science plus" arguments more frequently than "science-only" arguments both to support their positions and to refute opposing positions (Table 8.2). In contrast to egalitarians, individualists were generally in favor of GE animal approval ($n = 60$ comments for and $n = 3$ comments against approval). However, like egalitarians, individualists also used "science plus" more frequently than "science-only" both to support their arguments and to refute opposing arguments (Table 8.2). In contrast, hierarchical comments, which were mostly in favor of GE animal approval ($n = 109$ comments for and $n = 9$ comments against), shifted the use of "science plus" arguments or "science-only" arguments depending on whether they were arguing for their own position in favor of GE animals or refuting other's arguments against GE animals. As shown in the highlighted cells in Table 8.2, hierarchs with a pro-GE position tended to use "science-only" to refute arguments against the release of GE salmon ($n = 16$ "science plus" vs $n = 48$ "science-only") but expanded to "science plus" when arguing in favor of GE animal release ($n = 32$ "science plus" vs $n = 13$ "science-only").

The last finding was interesting to us in the context of prior literature that describes the marginalization of perspectives that are not "science-based" in the biotechnology debates (e.g., see Thompson 2007; Meghani & Kuzma 2011). The predisposition of those in positions of regulatory authority (largely hierarchs—see Table 8.1) is to go beyond the science when arguing *for* the approval of GE animals by making appeals to the economy, markets, or sustainability, but to refute arguments of those who oppose GE animals by forcing them to stick to the scientific risks (i.e., objections to GE animals must be "science-based"). In other words, hierarchs, and those in favor of GE animals seem to reject arguments against GE animal approval that appeal to the economy, cultural, or sustainability, yet use these same appeals to support their position for GE animals.

Policy Uptake of Stakeholder Concerns by Science/Science-Plus and Cultural Worldview

To get at responsiveness to diverse public concerns, we next analyzed whether the Parliamentary hearing final report and the federal agency response reports reflected the arguments we saw in the hearing transcripts.

Table 8.2 Use of science-plus and science-only arguments by cultural type in Parliamentary hearings

Cultural type	*Scope*	*To support their own position*		*To refute opponent's position*		Total
		Comment with: Pro-GE stance	Anti-GE stance	Comment with: Pro-GE stance	Anti-GE stance	
Egalitarian $n = 77$	*Science PLUS*	13	45	3	14	75 (97%)
	Science ONLY	1	0	1	0	2 (3%)
Individualist $n = 63$	*Science PLUS*	31	1	14	0	46 (73%)
	Science ONLY	4	1	11	1	17 (27%)
Hierarchical $n = 118$	*Science PLUS*	32	5	16	4	57 (48%)
	Science ONLY	13	0	48	0	61 (52%)

Source Authors. Note: the hierarchical row shows the shift that hierarchs, who are largely in favor of GE animals, make from "science-plus" in arguing for their position in comparison with "science-only" to arguing against an opponent's position, as discussed in the text

We examined the two reports for the cultural worldviews expressed in the reports and the appeals to "science-only" or "science-plus" concerns to compare them to these appeals in the hearing transcripts. Figure 8.3 shows that although a significant number of comments in the hearings went beyond science and were "science-plus" (69%), both the Parliament report (49%) and to a greater extent the federal agency report (13%) reduced these appeals, focusing more on "science-only" issues. We interpret this result as an indicator of low responsivity to concerns outside of direct scientific risk in the public policy process for GE animals.

Likewise, we tracked and compared the cultural types of arguments among the hearings, Parliament report, and federal agency response report. Figure 8.4 shows that the uptake of cultural worldviews in Parliament's report after the hearings largely reflected the comments in the hearings. However, the federal agency report tended to overemphasize hierarchical worldviews at the expense of individualistic worldviews. As expected, the results in Table 8.1 indicate that hierarchical worldviews

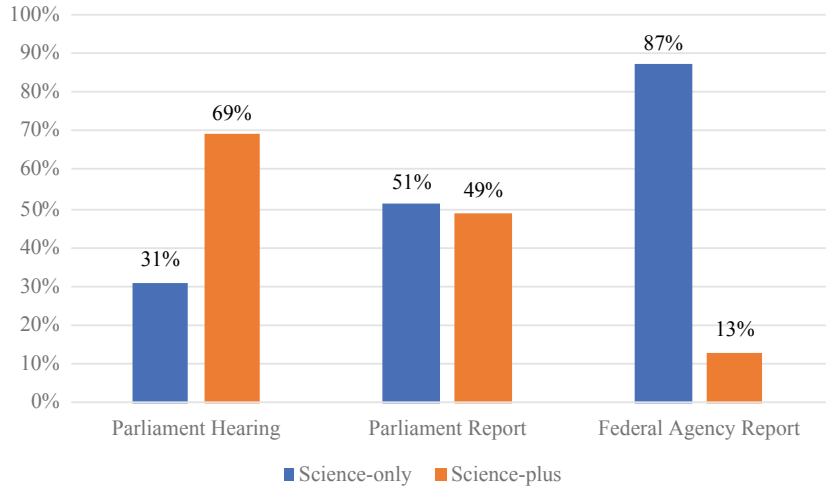

Fig. 8.3 Responsiveness to science-only versus science-plus concerns—uptake in final reports

were more dominant in federal agency representative comments. Egalitarian worldviews shared a similar percentage across the hearings and both reports. We interpret this result as a better indication of responsivity to diverse cultural perspectives in comparison to the minimal uptake of science-plus concerns in the final reports.

Although there are limitations to textual analysis, we present it here as a potential novel way to look at responsivity or policy-uptake from participatory events. Future research could build upon and validate such approaches.

Barriers and Opportunities for Inclusion and Responsiveness

As previously mentioned, in our conversations with decision-makers for GE animals in Canada, they highlighted two key barriers to public inclusion in the regulation of GE animals: protecting intellectual property and lack of capacity for dealing with public comments. Previous work in the U.S. on stakeholder attitudes to RRI in biotech innovation systems

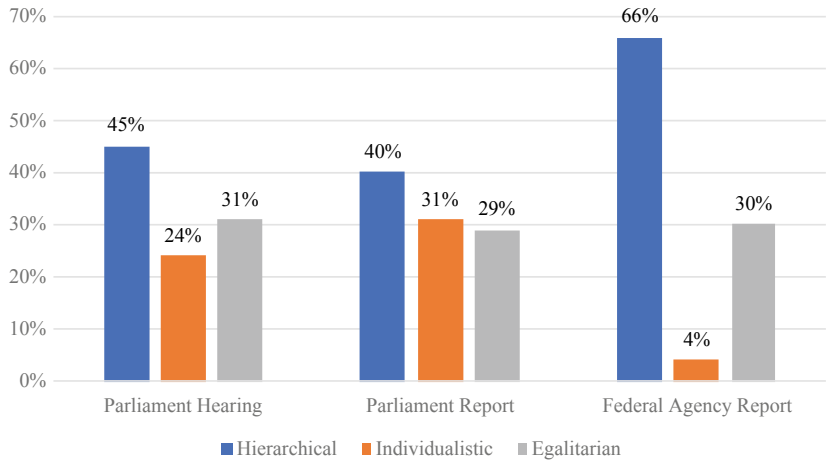

Fig. 8.4 Responsiveness to cultural worldviews—uptake in final reports

also uncovered barriers to RRI, especially for the principles of inclusion and responsiveness. Roberts et al. (2020) analyzed the attitudes of different biotechnology stakeholders toward principles and practices of RRI with a mixed-method approach. Homogenous focus groups (by stakeholder affiliation) and pre- and post-focus group surveys were used to measure sector attitudes toward RRI. Significant differences were found in stakeholder reactions to practices to implement RRI. In comparison to government and consumer groups, industry, trade organizations, and academics had more negative reactions to RRI practices that relinquish control to people outside of technology development, namely practices of inclusion and responsiveness (Roberts et al. 2020). Qualitative analysis of focus-group conversations revealed barriers to RRI associated with institutional goals and cultures. Regarding inclusion and responsiveness, innovators were cynical about including external voices in innovation pathways due to the inflexibility of funding programs which leads to constraints on their work, and they were also concerned about these RRI practices causing potential delays to innovation given the highly competitive national and international environments for financing and patents (Roberts et al. 2020).

Our conversations with Canadian regulators and innovators from industry also expressed these fears and barriers to greater public inclusion

and responsiveness and fell into a few general categories. In addition to the issues of IP protection and capacity previously discussed, government and industry representatives mentioned that greater public inclusion and transparency may increase public fear of AAS and GE animal-based foods. In the words of one industry representative, greater public engagement or transparency through GE animal food labeling may lead to "picketing in front of grocery stores" where AAS is sold. Marris (2015) coins the term "biotechphobia-phobia" to describe this expert fear of public fear of biotechnology. In contrast, Nep and O'Doherty (2013) found that Canadian consumers view labeling as a way to enhance consumer transparency and trust in GE salmon.

Second, like the US biotech innovators interviewed in Roberts et al. (2020), Canadian government and biotech industry stakeholders for AAS were motivated to protect the pace and standards of innovation. Their views were optimistic about the contribution of genetic engineering to society (techno-optimistic), and they expressed concern about the delays to innovation that would likely result from greater public inclusion and responsiveness. Finally, they pointed out that there would be threats to science-based decision-making if broader socioeconomic and cultural perspectives were incorporated (as public responsiveness a la Stilgoe et al. 2013 would likely require).

In prior work, Callegari and Mikhailova (2021) also explore RRI as a framework in investigating AAS governance, but in the U.S. They found that companies adopt practices "entirely opposite to those being advocated within the RRI framework" and focus on "exclusive communication with the scientific community and legal authorities" (p. 1). They conclude that these practices are "undesirable from the perspective of both the organizations involved and society at large" (p. 1). Both they and Roberts et al. (2020) recognize that fulfilling RRI ideals from the scholarly literature (e.g., Stilgoe et al. 2013) may present too many practical barriers to innovators and regulators, and they suggest compromise in taking smaller steps toward public and stakeholder inclusion and responsiveness. Roberts et al. (2020) suggest the co-design of RRI pathways that include biotech innovators and other stakeholders to consider the very practical limitations that innovators face (e.g., with respect to CBI, IP, and competitiveness of innovation and funding systems). They also propose that institutional incentives for incorporating RRI practices be developed to encourage government regulators and innovators to adopt greater inclusion and responsiveness. Callegari and Mikhailova (2021)

suggest that as a step toward RRI, stakeholder engagement should be "strategic and selective" (p. 14), and at first, limited to stakeholders that are willing to compromise to accommodate the goals of biotech innovators. Both Roberts et al. (2020) and Callegari and Mikhailova (2021) recognize that these accommodations may not be considered true to the scholarly visions of RRI, however, if RRI is to advance at all beyond an academic set of ideal principles, incremental steps should be the near-term focus.

In the context of regulatory decision-making and GE animals, these incremental steps could include: (1) the formation of a supra-agency federal body that convenes stakeholders and publics in dialogue about GE animal foods, allowing for the consideration of concerns and benefits that go beyond individual and narrow federal regulatory jurisdictions to include socioeconomic issues, indirect risks, and cultural impacts (see for example NASEM 2017, p. 9); (2) federal incentives provided to innovators for incorporating RRI practices in upstream innovation of GE animals to encourage openness and transparency with the public and stakeholders; and (3) funding and capacity-building for government regulators in Canada to open up public comment periods on every federal regulatory decision for GE animals, engage in public hearings on a regular basis, and convene public and stakeholder workshops and focus groups. These steps will not achieve the pure vision of RRI articulated by scholars, but will go a long way toward building greater public legitimacy and trust, even if opposition to GE animal foods is likely to remain.

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