

## Article

# RRI and Corporate Stakeholder Engagement: The Aquadvantage Salmon Case

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**Abstract:** Declining public trust in science and innovation triggered the emergence and development of the responsible research and innovation (RRI) concept among policymakers and academics. Engaging stakeholders in the early phases of innovation processes has been identified as a major driver of inclusive, responsible, and sustainable development. Firms however have often adopted practices entirely opposite to those being advocated within the RRI framework, namely, reducing external interaction with stakeholders, focusing on exclusive communication with the scientific community and legal authorities while avoiding the social spotlight. We illustrate these practices, their causes and consequences using the case of the Aquadvantage salmon, the first genetically modified (GM) animal approved to petition for the United States (US) Food and Drug Administration (FDA) approval for human consumption. We find that such practices heighten the risk of social backlash, being undesirable from the perspective of both the organizations involved and society at large. Stakeholder engagement remains necessary in order to gain the minimum social acceptance required for contentious innovative products to enter the market. However, stakeholder engagement must be selective, focused on pragmatic organizations whose aims and interests are sufficiently broad to potentially align with corporate interests. Strategic stakeholder engagement offers a meeting point between the transformative aspirations of RRI framework proponents and legitimate business interests.

**Keywords:** RRI; stakeholder engagement; responsible innovation process; commercialization process; biotechnology; GM animal regulation



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## 1. Introduction

Scientific progress constantly pushes onwards the boundaries of the possible, as we struggle to understand the implications and cope with the consequences. The new vistas opened by innovation, however, change according to the perspective adopted. As the world changes beyond the ability of anyone to keep up, trust in policymakers, scientists, entrepreneurs and innovators is necessary for social consensus to maintain. It is precisely this trust, however, that has been eroding at an accelerating pace in the last decades, a worrying process that does not seem to be stopping anytime soon. Responsible research and innovation (RRI) is a framework developed to support regulators, policymakers, academic entities, and corporations in constructively facing this issue and contributing to slow or even reverse the worrying trend.

While only recently introduced [1,2], the concept has proven very popular within the academic community, resulting in an explosive number of contributions in the last few years [3–6]. However, actual change in terms of practice has been more modest in scope [7]. One of the key challenges currently facing researchers active in this area is to improve our understanding of how to translate the principles into practice, and how to implement such practice in the world of policy, regulation, academia, and corporate operations. Our study focuses on a specific aspect of RRI-inspired practice, namely, the

constructive involvement of stakeholders within corporate innovation processes. Recent research on RRI and corporate practices has found numerous stumbling blocks preventing a satisfactory implementation of stakeholder engagement practices within corporate settings [8]. Furthermore, stakeholder inclusion tends to take place at the very last phases of the innovation process, as part of the marketing process, revealing a severe misalignment between RRI principles and actual corporate practices [9]. While researchers have investigated how to develop effective pre-engagement tools to ensure earlier stakeholder engagement [10], stakeholder engagement in the pre-marketing phases remains relatively under-researched. This research gap has motivated our research question: which factors prevent the implementation of RRI-inspired principles of stakeholder engagement within actual corporate settings? Our study aims to contribute to the identification of the key factors responsible for the lack of stakeholder engagement, defined as corporate practices to involve stakeholders in a positive manner in organizational activities [11], in current corporate practices, distinguishing between structural features of the market economy and contingent limitation of RRI-informed guidelines. The results so obtained are used to derive practical implications aiming to improve the actual feasibility of RRI integration within the corporate world.

We investigate this problem by analyzing the case of the first GM animal commercialized for human consumption, the AquAdvantage salmon, and the difficult road that this controversial technology and its proponents have traveled in the last decades. We find that the decision of the company to avoid stakeholder engagement, while not unreasonable, has resulted in decades of legal strife and unprofitability, the resolution of which is still in the future, and not necessarily promising. This negative result confirms the practical relevance and potential benefit of RRI-inspired practices of stakeholder integration, but also highlights the current gap between RRI principles and their implementation. We confirm that demand for early and meaningful stakeholder integration clashes with the aim of innovation benefits appropriation, and the related need for corporate information management [8]. Furthermore, stakeholder engagement cannot solve the problem of widespread social distrust towards specific scientific techniques, or, more precisely, towards the ethical orientation held by those engaged in development, exploitation and regulation of such techniques [12]. We find that stakeholder engagement must be strategic, focused on those stakeholders whose aims are broad enough to be potentially compatible with the technological path pursued by the firm. The aim cannot be the creation of a social consensus, which is beyond the scope of corporate practice, but the definition of a coalition of interests sufficient to persuade regulators and public alike. Thus, the enduring diversity of visions, aims and values that characterizes a pluralistic society [13] is not compressed into an artificial broad consensus, but rather expressed by a plurality of heterogeneous, both collaborating and conflicting actors.

The paper is structured as follows. Section 2 reviews the relevant literature in order to introduce the key concepts used in this study. Section 3 provides an empirical description of the case of the AquAdvantage salmon. Section 4 analyzes the case from a theoretical perspective, drawing its consequences for the further development of RRI as a practical approach. Section 5 concludes.

## 2. Literature Review

RRI has arisen as a science policy measure to establish codes of responsible conduct in science and to enable inclusive and sustainable research and innovation processes [1,4,14]. This policy-driven initiative was introduced to tackle lack of public faith in science and evidence-based policy-making, as well as to increase the ability of democratic societies to address challenges associated with emerging and disruptive technologies [15].

The aim of RRI at a high level is to redraw the contours of what responsibility means for researchers, developers, and innovators [16] and to enhance the societal embeddedness of the innovation process [17]. RRI is purposefully designed as an integrative framework to allow inclusion of various initiatives that helps societal actors to collaborate and to achieve

the alignment of the innovation process with societal needs, values, and expectations [1]. As a result, RRI can be interpreted and applied in a variety of ways [18] since the dynamics of interface and interplay between actors vary across countries and sectors. The crucial element of RRI, however, is to establish collective stewardship for the future [14] through anticipation, reflexivity, inclusion, and responsiveness in the present [2]. We define inclusion as the exchange of views between stakeholders, based on shared information and evaluation criteria, supporting stakeholders' decision-making on the innovation process and/or its results [19].

The implementation of RRI practices has been evaluated in several different contexts, including biotechnology [20,21] and nanotechnology [22], information and communications technology [23–25], synthetic biology [26], and private sector in general [27,28]. However, at the moment RRI remains primarily focused on (semi-) public, non-profit/not for profit organizations [29]. The definition of a responsible company, and of corporate responsible innovation practices remain challenging [30,31]. Bolz and Volkmann [32] has proposed four principles of responsible bioentrepreneurship: transparency, dialogue, awareness, and self-reflection. How these principles can be translated in corporate practice, however, needs to be explored. For Lubberink, et al. [33] what RRI means in a business context remains mostly unknown.

Despite these limitations, however, a consensus is emerging on the need to implement new channels and expand existing facilities and practices dedicated to the integration of public opinion on science and innovation in scientific, policy, and industry communities [34,35]. Specifically, what is called for is “broad, collective deliberation through processes of dialogue, engagement and debate, inviting and listening to wider perspectives from publics and diverse stakeholders” [16] (p. 755). These normative considerations are acknowledged by Noorman, et al. [36] as one of the key principles defining RRI, and by Bolz and Volkmann [32] as a key aim of responsible bioentrepreneurship practices.

The implementation of such principles in practice has proven somewhat challenging. While Montoliu, et al. [37] have illustrated how comprehension and endorsement of experiments on animals in laboratory can benefit from openness and transparency, the result of Bremer, et al. [38] experimental engagement with the full spectrum of aquaculture stakeholders are more nuanced. Starting from the normative principle that responsible decisions can be made solely by engaging with the multiplicity of ethical concerns, the researcher assembled 27 types of stakeholders, including individuals and organization representing, or claiming to represent, producers, the scientific community, the aquaculture industry at large, including input suppliers, processors, retail distributor, consumers, the environment and even the fish themselves. The research highlighted the tremendous diversity hidden in the concept of stakeholder, the efforts required to garner a truly comprehensive stakeholder perspective, and the impossibility of achieving a general consensus.

The fact that technological uncertainties can either be attenuated or amplified through dialogue between stakeholders has long been known [39]. Dialogue can also be simply ineffective. Bruce and Bruce [40] describe an initiative undertaken by several US biotech companies that between 2000 and 2001 organized a series of meetings with various stakeholders, amongst them skeptical non-governmental organizations (NGOs), to establish shared ethical principles for how to proceed with GM crop development. This initiative failed to deliver any tangible impact. Bolz and Volkmann [32] illustrates how debate on controversial technologies, and especially biotechnologies, generally rests on two deadlocked viewpoints, pro or against, with little space for constructive compromise.

Describing these and other experiences, Bruce and Bruce [40] highlight that time and resources are of essence in regard to engaging with various stakeholders on emerging controversial technologies. Furthermore, the practice of engagement is necessarily limited to a modest amount of people. In terms of impact mass media outlets and social media can facilitate wider communication, but are unlikely to result in actual, constructive debate. Both information and disinformation can be diffused through media, but they are unlikely to provide an effective conduit for generating meaningful feedback for policy-

makers and corporate entities. The lack of representation of public opinion may mislead researchers and policymakers in regard to the actual community sentiment on novel and disruptive technologies.

Keeping pace with the forefront development and achievements in science can be very demanding for audiences with no special or expert knowledge. As a consequence, their judgement rely on knowledge of established technologies and previous debates [41]. Therefore, public attitude towards breakthrough technologies is framed by dominant ideologies, existing stances, and presumptions, something that should be accounted for by scientists and regulators [42]. However, in both academic and societal environments, researchers consistently affirm superiority of knowledge development over reflective evaluative appraisal of ethical concerns in relation to practical application of this knowledge [2]. Thus, regulators and experts may be ignorant about diverse apprehensions in relation to a certain emerging technology [43]. Paradoxically, however, it is precisely in the technological frontier that a decision-making process deliberately based on scientific evidence cannot be applied. This is because on one hand the prediction of all potential consequences of a certain technology use is unattainable and on the other the social and ethical considerations exceed the purely scientific domain [38].

The engagement of a diverse range of stakeholders is meant to mitigate these tendencies. However, as Weisenfeld [31] illustrates, while a stakeholder-focused approach may succeed, the choice of stakeholders assisting an organization in fulfilling its responsibility persists to be the core problem for stakeholder engagement practices. Ethical and normative distance between stakeholders implies that any discussion will not develop on a purely factual basis. Consequently, power distribution among stakeholders will be mirrored in the result of their discussions. Stakeholders may be more effective at expressing their prepossessions rather than marking the boundaries of social responsibility. The moment of stakeholder selection will therefore define the process of development and fulfilment of corporate and regulatory responsibility.

From a corporate perspective, stakeholder selectivity is a necessity due to the costs involved in any stakeholder integration effort. In fact, both Flipse, et al. [44] and Sonck, et al. [45] observe that such practices are relatively rare in the context of R&D industry projects. Van de Poel and Sand [46] stress how RRI practices in R&D teams introduce new routines for researchers implying increasing responsibilities. While many activities endorsed in the RRI framework are already mainstream in companies, albeit in limited forms, RRI as an integral, systematic approach has yet to be implemented in the corporate setting [17]. Davies, et al. [47] explains this outcome with two factors defining industry formulation of responsibility: “the logic of the bottom line, and the practical limitations of actors’ agency and social milieu” (p.155). While connecting risk management and financial stability is straightforward, RRI practices with a broader scope, such as social transparency, public discussions, and sociotechnical synthesis remain more difficult to integrate in corporate reality [48].

A key factor behind limited stakeholder inclusion is the difference in values held by different stakeholders [43]. These differences can promote conflict, leading to the marginalization of stakeholders holding value frames radically different from those held by firms [49]. Managers can mitigate these issues through efforts aimed to align stakeholders’ expectations [50]; more commonly, however, conflict must simply be accepted [51]. These considerations are problematic from both a theoretical and practical perspective. Is the inevitability of conflict compatible with the RRI goals of promoting a harmonious approach to the innovation process? Moreover, how can corporate practitioners constructively engage with stakeholders that may legitimately never approve nor support their actions? More research is needed to understand if and how such obstacles can be circumvented, and how can more feasible practical recommendations for corporate actors be developed while maintaining fidelity to the fundamental RRI principles. We have studied this problem in the context of the biotechnology field, an area that has attracted the attention of RRI scholars due to its great potential for further development [20] and its socially and politically

controversial nature [21]. Animal genetic engineering for food production in particular has become a point of contention for many large-scale political discussions both within industry and society at large [52–54]. These characteristics make the actual developments taking place both among regulators and corporate entities particularly relevant for the development, testing and integration of RRI practices. It is to the study of one of these processes that we now turn.

### 3. Method

According to Yin [55], a case study is the preferred strategy when focusing on a contemporary phenomenon in a real-life context, having the potential to provide significant contribution to theory development and extension. We used purposive sampling to select a case rich in information [56] to study how engagement and integration of stakeholders, including competitors, NGOs, governmental organizations, and the society at large can help companies to negotiate their responsibility throughout innovation process. By sampling in a strategic way, we ensure that the case is information-rich which can give a more in-depth understanding of the phenomenon we are studying [57]. We have selected AquaAdvantage, the first and only approved GM fish for human consumption, as a case study. The reasons for this choice are manifold.

First, the RRI framework addresses social and ethical concerns during the early phases of innovation to ensure that these concerns are anticipated, integrated and reflected upon from the beginning [2]. The innovation process of AquaBounty salmon began in the early 1970s, yet the GM fish has yet to reach the US stores, offering the opportunity to explore the dialogue between the AquaBounty company, Massachusetts, USA and a heterogeneous set of stakeholders as it developed over an extended period of time. Second, while stakeholder analysis literature has presumed that stakeholders are self-evident and exogenously given [58], our literature review suggests that the choice of stakeholders to engage with is essential as it influences the outcome of the negotiation process through which the company's responsibility is defined. By studying the contested development of the AquaAdvantage innovative process we gain insight both into corporate strategies of stakeholder selection and stakeholder strategies aimed at influencing corporate decision-making. Third, according to Van de Poel, et al. [59], fully understanding the context is highly relevant for establishing useful RRI practices and strategies yet the definition of what to include within the analytical context remains open. Using a single case study approach [60] enables us to provide answers to "how" questions about phenomena in settings without clear boundaries between the context and the phenomenon [56]. Fourth, according to Stahl, et al. [61], there are certain industries "where numerous innovation processes can be highly regulated" (p.4) that have specific relevance of alignment with RRI values. In the case of gene-engineering, the impact of transformative technologies on society is tremendous. For this reason, stakeholder engagement is a potentially crucial practice for corporate entities active in the field of genetic modification for human consumption.

As typical for cases oriented on thick description of the process and where existent theories need to be refined, we used qualitative data collection and analysis [62]. Our primary data is drawn from extant texts. Conducting a systematic search for relevant documents we reviewed documentary evidence including various announcements, minutes of meetings, and other written reports of events, formal studies, and evaluations related to AquaAdvantage case, news accounts from sources based in both the US and Canada (list of documents is provided in Supplementary Materials). To better represent the company's perspective, our data also included an interview and comments of AquaBounty's representatives in which they described their experiences in relation to the events of GM fish innovation process. We scrutinized the purpose of each document and evaluated the audience to which it was addressed in order to critically interpret the content of documents, what Yin [55] called being "a vicarious observer" (p. 108). The data is presented within its context of reference, including the other texts being referred and responded to, in order to highlight the significance of these materials for the actors involved, their underlying



motives and aims [63]. In conjunction with documents, we included insights from broader national discourse analysis of legitimacy and sustainability of GM fish production in the US to provide a more nuanced representation of different stakeholders' contribution to negotiation of the AquAdvantage responsibility. By collecting information on multiple aspects of phenomena and documenting viewpoints of the key stakeholders we strive to reveal and explore social relationships within a continuously evolving social context.

Consistently with the transdisciplinary nature of RRI [64], we have adopted a critical discourse analysis approach based on a critical realist social ontology [65]. We have analyzed the contested process of negotiated legitimization of the AquAdvantage salmon as a process of recontextualization [66], as AquaBounty, the FDA, and several NGOs attempted to fit the facts of innovation within existing narratives of consumers advantage, product regulation and environmental protection. Accordingly, we have first analyzed the data by identifying the dominant narrative frames explicitly invoked and/or implied by the texts. The performative nature of the discourse, exemplified by key regulatory passages, implied an operationalization dimension which we attempted to disclose by coding each text with its intended performative aims, explicit, and implicit. Both tasks have been performed by the authors separately and harmonized after an internal reflexive discussion.

The purpose of our analytic strategy is to link the AquAdvantage case study data to stakeholder engagement and RRI framework. Following George and Bennett [67] we first present a detailed narrative of our case history in chronicle form, making no explicit use of theoretical concepts. The historical narrative of the case is then followed by an analytical explanation couched in explicit theoretical forms aiming to identify general patterns and mechanisms. The four key dimensions of the AREA (anticipation, reflection, engagement, and action) framework introduced by Owen, Macnaghten and Stilgoe [16] gave us a sense of direction in analyzing the data and specifying on "how" or "why" the events unfolded in a certain way. We analyzed the company's ability to engage in dialogue with relevant stakeholders (inclusiveness), respond to their insights (responsiveness), and reflect on the GM fish impact on society throughout the process (reflexivity). Finally, the identified mechanisms are used to develop an explicit contribution to existing theoretical debates.

#### 4. Case

Biotechnology is expected to play a significant role in the future of agri- and aquaculture for food safety, animal health, and welfare, and the enhancement of nutritional quality of various foods [68–70]. Bioengineering took off in the late 80s, with the first GM animals, transgenic pigs, sheep, and rabbits produced by microinjection, reported in 1985 [71]. Since then, the amount of GM farm animals and fish developed in experimental laboratories has continuously increased [70]: few of them have reached the market however. The situation will not change as long as the potential benefits of genetic engineering are overshadowed by the substantial ethical, environmental, and economic concerns it evokes.

As a direct result of these concerns, numerous processes of commercialization of GE products have been suspended. Wrubel, et al. [72] described two cases where innovators halted commercialization of GE microbes due to burdensome and unclear regulatory requirements. Another example is the termination of the project with GM salmon by New Zealand King Salmon Company. Innovation activities were abandoned in 2000 due to an adversarial climate of opinion about the experiments and the consolidation of government controls [73]. Learning from this experience, other major salmon aquaculture producing nations, like Chile and Norway, have rejected commercial production of GM salmon. Despite a more lenient attitude towards GM products in the US compared to the rest of the world [73,74], US authorities have proven to be cautious in regard to the regulation of GM animals for human consumption.

The twisted journey of GM salmon through the US regulatory system illustrates many of the challenges that RRI practices are supposed to address. Seeking approval for the GM fish application was foreseeably a complex process due to its controversial nature, involving

to the same extent optics and politics, as well as science and food safety. Early during the process it became clear that scientific progress had outpaced regulatory capacity [73]. Corporate actors, public authorities and NGOs struggled to push their agenda, developing new practices in the process.

The foundation for the AquAdvantage technology was laid in the early 1970s, when Dr. Garth Fletcher, working together with Dr. Choy Hew and Peter Davies, experimented on proteins that facilitated survival of fish in sub-zero waters. The experiments did not succeed in their intended aim; however, they led to the discovery of a “antifreeze” gene effect on a salmon’s growth-hormone gene, leading to significant increase in the growth rate of Atlantic salmon (5–6 times faster in early months). Following such discovery, “A/F Protein Canada Inc” company was established in 1991 in Waltham, Massachusetts by the scientists who participated in the initial research. This company proceeded to develop a fast-growing transgenic fish, resulting from the replacement of a growth hormone-regulating gene in the Atlantic salmon with the one from the fast-growing Pacific Chinook salmon and a promoter sequence from an Ocean Pout. This modification allowed salmon to grow consistently through the whole year rather than exclusively in spring and summer [75]. The prospect of shortening the time to marketable size was very promising from a commercial perspective, leading A/F Protein to initiate a conversation with the FDA agency about regulatory guidelines for AquAdvantage salmon patent application in 1993. In March 1994 a patent application was filed for the transgenic Atlantic salmon, and on 13 August 1996 Choy Hew and Garth Fletcher were issued United States patent 5,545,808 titled “Transgenic Salmonoid Fish Expressing Exogenous Salmonoid Growth Hormone” [76]. United States Patent 5,545,808 comprised seven claims related to genetically engineered (GE) Atlantic salmon containing the functioning growth hormone. In 1996, a license to the AquAdvantage® and the methods of increasing the growth rate of Atlantic salmon were acquired by A/F Protein from the University of Toronto and Memorial University of Newfoundland in St. John’s, Canada. On September 14, 1995 the company opened an investigation aiming at commercialization of the AquAdvantage salmon. At that point no clear regulatory instructions were written for GE animals. It was decided that GE animals for human consumption should follow the existing regulatory pathway for drugs evaluation in the United States. However, the FDA agency had yet to define the process of approval and its requirements.

In 2000, A/F Protein was reorganized into two independent companies, one of which, A/F Protein, kept possession of the antifreeze protein technology, while the other one, AquaBounty Farms got hold of the AquAdvantage® technology and was renamed into AquaBounty Technologies in 2004. In 2001 the firm had already developed 10,000 to 20,000 GM salmon in 136 tanks in three different locations in Maritime Provinces of Canada with the intent of further commercial distribution of eggs to aquaculture facilities in New Zealand, Chile, the US, and Canada itself [53]. In the meantime, the FDA attempted to initiate an open dialog with different stakeholders to achieve a consensus about the procedure to regulate GE animals. The FDA also sought expert opinion for risk assessment and consulted with other regulatory agencies [77]. The approach was later criticized by the CEO of AquaBounty as too lengthy and ultimately unsuccessful: “There may be areas where that’s possible. But when it comes to the review of scientific applications [...] it can’t be by referendum. It can’t be by consensus.” [77]. As a result of these choices by the FDA, the time span without defined regulatory guidelines extended to much longer than anticipated. In January 2009, almost eight years after AquaBounty first submitted a New Animal Drug Application (NADA), the FDA released a “Final Guidance Document” on the premarket approval process applied to GE animals developed for human consumption.

GE animals were confirmed to be handled as a “new animal drug” following the Federal Food, Drug, and Cosmetic Act enforced by the FDA. GE animals nominated as a source of food are to be evaluated in regard to their nutritional differences with baseline counterparts. Applicants must also submit an assessment of its environmental impacts according to the National Environmental Policy Act (NEPA), which contains

evaluation of conditions suggested for the GE animal raising process [53]. If all criteria are met, a Finding of No Significant Impact (FONSI) is issued by the agency, allowing commercialization to proceed. The responsibility of demonstrating that the GE product fits safety and effectiveness criteria lies solely with the applicant.

The final version was issued after considering almost 29,000 public remarks received during a 60 days period allocated for public comments following the publication of the document draft in 2008 [53]. An unrivaled share of comments (approximately 28,000 letters and general statements) expressed an aversion towards raising GE animals for human consumption. Only sixty proposals from the rest of the comments were deemed substantive by the FDA. These comments focused on issues ranging from the fitness between formal requirements of NADA provisions and the implementation of better regulation efforts towards GE animals; the fairness and sufficiency of FDA's efforts to deal with food security, animal welfare and environmental vulnerability; and the urgency of openness and public participation in innovation governance. In the Final Guidance Document, the FDA declared its interest in increasing the transparency of the process by arranging public meetings of the advisory committees prior to the final approval of any GE animal. AquaBounty submitted their final study to the FDA a few months after the Final Guidance Document was released. AquaBounty, which was already operating significant salmon hatching operations in Prince Island at the time, estimated that, in case of a positive outcome of the presentation to the FDA advisory committee, the GM fish would be in the grocery stores by the end of 2012. The company also requested for the AquAdvantage fish to not be labeled as genetically engineered, arguing that no nutritionally relevant difference existed with a natural salmon, and that "the label could even be misleading because it implies a difference that doesn't exist", as the CEO put it [78].

Interviewed by CBC news, John Buchanan, AquaBounty's R&D director, offered his perspective on the process [79]. First, he argued that, given the extensive research carried over the years on the AquAdvantage salmon, the call for additional studies arising from some members of the public were specious, essentially amounting to dilatory tactics. He also argued that the commercial benefits of the new fish could offset some of the costs involved in the transition towards land-based fish farming, a desirable shift from an environmental perspective. Cheaper production costs would also contribute to meeting the United Nations forecast of tripled seafood production by 2030. From a public relations perspective, Buchanan expressed satisfaction about the approach taken by large media, restricting his criticism to NGOs-controlled outlets.

In the meantime, opposition started to mount in both Canada and the US. A coalition of Canadian NGOs, led by the Council of Canadians, called for an environmental assessment for GE fish eggs, asking for more public involvement in the process. The coalition, including the Prince Edward Island (PEI) Health Coalition, Earth Action PEI and the Canadian Biotechnology Action Network requested to share with the public any updates on environmental assessment status of AquAdvantage from Environment Canada. In the US, growing opposition from Congressional representatives delayed the FDA final decision on AquaBounty's NADA. The FDA commissioner received two letters, one written by 11 US Senators primarily from the Pacific Northwest, and another by 29 delegators of the US House of Representatives. Both letters expressed concern over the FDA's process of GE animal regulation, particularly pointing at the need for openness and possibility for public engagement in the process. The latter highlighted that approval of the AquAdvantage salmon could endanger the living conditions of native salmon populations, referring to it as the "Trojan gene effect" [53]. A budget amendment restraining the FDA from using funds to support the GE salmon approval process was reached on 16 June 2001. A representative from Alaska, Don Young, presented the amendment as protecting the interests of the large industry of wild salmon fisheries, which considered GE salmon as a competitor. This amendment was introduced by Rep. Don Young from Alaska, a state with a large wild caught salmon industry. In support of the amendment, Young argued that AquAdvantage salmon would compete with Alaska-based wild salmon fisheries. The amendment was



voted on by a few House members and failed to become law. Aqua Bounty CEO Ron Stotish described the move as “a public relations ploy and an attempt to generate negative publicity” [80]. The move failed to stop the FDA from declaring on 3 September 2010 that the AquaAdvantage Salmon is similar in nutritional terms to the conventional Atlantic salmon, and therefore safe for human consumption.

Two public meetings were scheduled to take place from 19th to the 21st September, organized by the FDA’s Veterinary Medicine Advisory Committee (VMAC). Public notice of the meetings was published three and a half weeks ahead of the meeting. The FDA presented their findings to VMAC and recommended approval. These findings consisted of a 171 pages document summarizing all the data regarding the health and safety of the AquaAdvantage salmon that could be made publicly available and an 84-page environmental assessment. Both documents were released to the public half a month prior to the public VMAC meeting. Complaints about insufficient transparency and limited scope of public participation permitted by the approval process started to mount. Rogers, representing the US Alliance for Natural Health, complained that only a selection of the data had been released to the public, and also excessively late, making it “impossible for the public and experts to assess whether scientific burdens have been met” [81] (p. 282). Hanson from the Center for Food Safety, claimed that the public could get hold of the data only 10 days before comments were due, too little time for proper comments and criticism to be developed [82]. From the FDA perspective, however, releasing the data package to the public was already an exceptional concession to openness.

During the hearings, critics expressed two main concerns—the safety of GM salmon consumption by humans in terms of dangerous allergens and the environmental effect of GE salmon that can be caused by intermingling with the wild salmon population. A broad range of groups concerned with environmental issues, food safety, and consumer rights requested more publicly funded studies of GE salmon. The existing FDA process was criticized as it allowed companies to conceal information: “Consumers have a right to know what FDA is trying to allow into our food supply” [83]. The CEO of AquaBounty, Ron Stoish, disputed that the AquaAdvantage salmon investigation was more thorough compared to most food. Independent experts representing industry, academia and various NGOs were invited as members of the VMAC committee to evaluate FDA’s findings. This committee confirmed the FDA’s decision to the effect that (1) AquaAdvantage salmon was comparable to the farmed Atlantic salmon in terms of food safety for human consumption and (2) did not impose any danger for the environment [84]. Despite a net loss of \$2.8 m in the first two quarters of 2011, AquaBounty company received half a million dollars grant from the US Department of Agriculture for research. The decision did not satisfy critics on both sides of the frontier. The Canadian Biotechnology Action Network involving representatives from Ottawa, PEI and Washington, led an Atlantic forum in opposition to AquaBounty. The coordinator of this network, Lucy Sharratt, opposed AquaBounty plans to sell its eggs worldwide, arguing that multiple rearing locations, in diverse environmental conditions, and potentially insufficient monitoring and enforcement of regulations would result in a severe threat for the wild Atlantic salmon. AquaBounty countered by arguing that existing regulations and risk assessment processes would prove sufficient to the task at hand. In early February 2012, several organizations, including Consumer Union, Food and Water Watch, and the Center for Food Safety, sent a formal request to the FDA to assess the GE salmon not as a new animal drug, but as a food additive instead. Additionally, they insisted on requiring a study to evaluate the consequences of GE salmon escape in terms of disease spread and procreation with non-transgenic species. As a result of these demands, the FDA approval remained limited to the original application locations. Despite the initial positive declaration, the FDA did not take any further decision, frustrating AquaBounty commercialization plans.

Few companies have the financial resources to survive more than a decade in regulatory uncertainty. AquaBounty came close to bankruptcy several times. According to an article published in The New York Times, AquaBounty had a bad financial year in 2011,

and had to downsize its personnel from 27 to 12. However, in March 2012, the company managed to raise \$2 million of funding, enough to survive until the end of the year. Another US company in synthetic biology, Intrexon, stepped in in October 2012 after Kakha Bendukidze, an important private investor who controlled nearly half of AquaBounty's stock (47.6%), bailed. Intrexon proposed to acquire the rest of the shares and invest half a million dollars to fulfill company's needs for the capital. Finally, in December 2012, both the FONSI and the FDA's environmental evaluation became available for public comments. These documents stated that raising AquaAdvantage salmon in accordance to the conditions indicated in the application was environmentally safe [84]. In 2013 Intrexon acquired majority ownership of AquaBounty. The same year Environment Canada approved an increase of salmon eggs production from research quantity to commercial volume. Despite the company's net losses (\$4.4 million in 2012 and \$2.7 million in 2011) AquaBounty felt confident about AquaAdvantage salmon reaching the market in the US.

Critics complained about the absence of public consultation by the Canadian government regarding the approval of AquaBounty hatchery located in Bay Fortune. Stotish provided a Manichean reply: "Are you going to believe the professionals, the skilled scientists, or the people that are constantly beating the drum that there is some sort of conspiracy between the government and industry to somehow damage the environment?" [85]. The CEO added that the hatchery would not scale up to commercial production without AquaBounty getting permission from Health Canada. Stotish affirmed that this permission allowed the company to make headway with FDA application, especially since the Canadian review was scrupulous. The Canadian review included risk assessment of the Department of Fisheries and Oceans (DFO), which identified that the risk to the PEI environment from the operations at the hatchery was with reasonable certainty low. However, there is also a record in the report stating that an escape of fish into the wild could cause significant environmental danger. To avoid procreation of GE salmon with wild salmon species, AquaBounty plan to raise only triploid females, ensuring that 99 percent of the population is reproductively sterile. However, AquaBounty cannot guarantee 100 percent sterility. Consequently, in case of further developments Environment Canada will launch a new review process. AquaBounty's Ron Stotish described the Canadian facility as "perhaps the most scrutinized facility in the history of fisheries", being visited "on a continuing basis, and it's probably a dozen times a year between DFO, Environment Canada and other agencies" [85].

The American FDA approved AquaAdvantage salmon application in November 2015. As a condition of the approval, AquaBounty's facilities were restrained to the physically contained freshwater culture facilities as indicated in the NADA: the Bay Fortune egg production facility on PEI, and a grow-out facility in Panama for hatching, growing and harvesting fish eggs. Canada was decided to be the primary market for the AquaAdvantage Salmon grown for human food use in Rollo Bay. Meanwhile AquaBounty Technologies was planning to seek US FDA approval to enable AquaAdvantage Salmon grown in the Rollo Bay Grow out Unit to be harvested and exported to the U.S.

The FDA subsequently issued an alert to prevent eggs import into the US before the guidelines for GE food concerning information disclosure were in place. US lawmakers instructed the FDA to temporarily forbid the sale of food containing GE salmon, due to the appropriations bill rider filed by Alaska Senator Murkowski. Murkowski was driven by the threat of competition facing Alaskan fishers when she claimed that wild salmon fisheries located in the Pacific Northwest are endangered by the fast-growing transgenic salmon. According to the US, as well as Canadian national policy at that time, GM food did not require a label when its composition was not considerably divergent from conventional equivalent or when no health effect was documented, although several US states (Vermont, Connecticut, and Maine) independently enacted laws for labelling GE food. AquaBounty claimed that GM salmon did not need to be labelled because there was no significant difference from Atlantic salmon. The FDA announcement that food being genetically modified was not sufficient to warrant labelling, was challenged by the Alaskan authorities

and as a result of negotiations, labeling of GM food became regulated by the national Public Law 114–214 in July 2016. Murkowski, together with three other senators, worked their way through to ensure that the AquaAdvantage salmon will be labeled as “genetically engineered,” and will undergo environmental review. These actions kept GM salmon out of the US market.

While the US market was closed for the import of the GM salmon, AquaAdvantage was approved for food and feed by Health Canada. The Canadian authorities requested three reports from AquaBounty: an environmental risk evaluation, a safety and nutrition assessment for human consumption, and a separate assessment for use as a livestock food source. In 2017, AquaBounty sold 5 tons of GM salmon filets in Canada, where no additional label is required for AquaAdvantage salmon. That led to very modest revenues of \$138,000 over the period 2017–2018. With the start of sales operations, the company planned expansion, submitting an Indiana rearing facility application to the FDA, approved in 2018. While all documents were in order, the import alert enacted in 2016 was still banning the product from the US. On March 8, 2019 the U.S. FDA lifted the ban as a result of the enactment of labeling guidelines for “bioengineered” foods by the US Department of Agriculture. Shortly after, recirculating aquaculture system facilities in Indiana were certified by state authorities and began production.

AquaBounty’s stock price shot up after receiving the go-ahead from the FDA to import Canadian-grown eggs of AquaAdvantage salmon into the US. The company raised \$13.25 million in 2019 alone to kickstart production operations and hire production staff for commercial sale in the US. By that time, cumulative financial losses since inception had reached \$119 million. Commercialization proved challenging. Some organic-type chains like Whole Foods and Trader Joe’s have rejected GM salmon already in 2015 after the FDA approval. AquaBounty plans to pursue both retail and foodservice opportunities closer to the harvesting time; however, restaurants and grocery chains remain unsure about the public willingness to accept the GM salmon. The International Salmon Farmers Association expressed their concerns about public perception of GM fish and the effect of GM fish on the whole industry, voicing widespread concerns about the commercial viability of the product. Due to these uncertainties, even though AquaBounty already expanded their facilities in Canada, the productive capability in Indiana is 1200 metric tons; relatively small volumes compared to US import of salmon.

In addition to commercialization, legal issues are still present. A coalition of GMO labeling advocates recently sued the federal government to force changes to the federal GMO labeling law—to use the more common terminology “genetically modified” or “genetically engineered” instead of “Bioengineered” or “Derived from Bioengineering”. In November 2020, a San Franciscan federal judge rejected the lawsuit seeking to vacate the agency’s approval of the salmon filed by environmental groups. The NGOs involved claimed that they would continue their legal battle against AquaAdvantage. The judge, however, instructed the FDA to thoroughly re-assess the consequences of GM salmon escaping from fish farms and establishing in the wild for the native salmon population. The FDA concluded that the salmon were unlikely to escape from the fish farms where they would be housed, and that if they escaped, they would be unlikely to survive. “Even if this scenario was unlikely, the FDA was still required to assess the consequences of it coming to pass”, the judge wrote [86]. “This is especially true because the FDA knew that the company’s salmon operations would likely grow, with additional facilities being used for farming” [87]. The new CEO of AquaBounty, Sylvia Wulf, claimed that the decision would not affect operations. The legal struggle is set to continue for the foreseeable future.

## 5. Analysis

While AquaAdvantage may yet prove to be a commercial success, from a RRI perspective it cannot be seen as anything but a failure. After decades of protracted engagement, neither AquaBounty nor the FDA appear to have managed to win over the trust of neither the general public nor the NGOs who became involved in the process of regulating the

first GE animal for human consumption. However, this is not a simple case of failing to adhere to desirable RRI practices and reaping the consequences, as it could be argued that at least the FDA attempted to adopt more open and inclusive practices, although ultimately unsuccessfully. Furthermore, the approach adopted by AquaBounty, arguably quite removed from RRI principles, should be analyzed to understand the drivers behind their choices, and what their experiences could teach those aiming to integrate the RRI perspective with corporate practices.

A byproduct of scientific research aimed for commercial purposes, AquaBounty and its predecessor, A/F Protein Canada Inc, St John's Canada, reflect a precise ethical value configuration, prioritizing scientific consensus over social concerns and experimental data over precautionary principles. This approach has been commonly found among technological actors, who tend to create "us vs them" discourses, featuring enlightened innovators on one side and a public to be educated on the other [88]. This perspective that has supported the bold project of commercializing the first GE animal for human consumption, in the absence of any regulatory framework and support from the general public. The only asset that AquaBounty could leverage were the conviction in the ability of the AquAdvantage salmon to pass any scientific test that could be asked by the authorities, and its commercial viability once legalized. The firm never attempted to win over either the general public or the NGOs protesting against its activities. Their communication efforts have been steadily aimed at the regulatory agencies, the scientific community and the business arena, both prospective investors and large-scale customers. Their general media strategy has been reactive at best, consisting in a series of interviews disputing the criticism advanced by NGOs against their product as unsubstantiated at best, and specious at worst, painting the corporation as the victim of an overlong and undeserved harassment campaign.

The same attitude has motivated the long-term strategy to avoid GE labelling. The supporting argument is the following. Since the AquAdvantage salmon has been declared by the FDA nutritionally equivalent to the Atlantic salmon, a GE label would suggest to the public a substantial difference that does not exist, thus leading to the paradoxical outcome of an informational instrument spreading disinformation. The argument, however, is based on the assumption that consumers care exclusively about nutritional content and that they may have ethical and/or environmental concerns regarding the consumption of GE products, or that such concerns are undeserving of consideration. The first assumption is blatantly false; given the high profile of debates surrounding GMOs, it is unlikely that the firm could believe such assumption to be based in actual facts [89]. The second reflects a rather narrow ethical orientation. Quite simply, given the current general public opposition to GE products, the latter are likely to be considered inferior products, and consequently sold in lesser quantities and/or at a lower price. To prevent the GE labelling of the AquAdvantage salmon is equivalent to deprive the consumers of the possibility to decide to consume or avoid GE products, in order to increase AquaBounty's future profitability; a textbook example of information asymmetry exploitation, a key issue plaguing RRI [90].

RRI frameworks would instead support the embrace of labelling, as an expression of openness towards the customers, meant to build awareness of the characteristics of the innovative product. Awareness, however, has little to do with acceptance. If AquaBounty were a large firm, with a wide variety of product lines, perhaps the losses inevitably accrued on the labelled AquAdvantage salmon could be seen as an investment in building consumer trust, which could translate in market shares solidification over more conventional products offered to the market. In the actual case of a small, innovative firm built around a single ambitious project, however, such considerations cannot apply. In this case, promoting awareness entails a net corporate loss, hardly justifiable to investors, whose patience has already been sorely tested. In these cases, as in all cases in which RRI practices imply a net loss, implementation will not take place, as commonly acknowledged by innovation management literature addressing the needs and practices of innovation-oriented businesses that have profit generation as their primary aim [8,91].



The other stark contrast between AquaBounty actions and RRI principles can be found in regard to stakeholder engagement. Since its inception, AquaBounty has not attempted to mollify the opposition advanced by NGOs and other activists, apparently considering their positions incompatible with the firm and its operations. These stakeholders, identified *ex ante* as disruptive, have been systematically excluded, rather than included [49]. The approach has proven costly, as time and again the firm's plans have been delayed and disrupted by the effective resistance organized by its critics, which has taken place through both legal and media channels. While the firm could ignore such complaints, regulatory agencies could not, leading to exceedingly slow and contradictory regulatory action, resulting in a discontinuous flow of costly requests that almost bankrupted AquaBounty on more than one occasion. Even today, the long-awaited US commercialization may have been put in jeopardy by the unexpected consequences of the latest lawsuit. Since the approach has resulted in a decade of losses and may even lead to the end of the firm, it cannot be considered successful. Can the RRI framework offer a solution?

The suggestion to integrate stakeholders within the decision-making process appears particularly challenging in the case under study. A firm dedicated to the commercialization of GE animals can invite the representatives of an NGO dedicated to stopping animal bioengineering for a meeting, but the result is unlikely to be particularly constructive. Quite simply, for many of the NGOs and the activists behind the successful resistance to the AquaAdvantage salmon, the commercial activities of AquaBounty are undesirable. While discussion can take place, constructive resolution is impossible, for both AquaBounty and the activists would simply desire the counterpart to cease their activities. The inclusion of these stakeholders, defined as an exchange of views [9] would simply lead to the realization that these views are incompatible. Consequently, the integration of such perspectives within the decision-making process would simply see the latter grind into a halt [19]. Under such conditions, it is unclear what could be achieved through discussion and an open attitude; in a corporate context in which resources are costly, such approaches will not be taken.

However, this does not imply that no improvement is possible. Stakeholder engagement remains a promising set of practices, although its implementation requires selectivity [8,21]. While existentially adverse stakeholders cannot be meaningfully integrated within corporate decision-making processes, there are a number of groups whose opposition is neither necessary nor immutable. These are the groups whose objectives are significantly wide to be potentially compatible with at least some of AquaBounty commercial activities, namely, consumer interests and broad environmental groups. While some consumers will reject GE products, others may be interested in them, and many would benefit from healthy proteins being offered at a more affordable price. Although environmental concerns about the AquaAdvantage salmon exist, it is true that land-based approaches to seafood farming may alleviate the environmental blueprint of the sector. In brief, these groups can potentially see GE products as offering a tradeoff to the groups whose interests they represent, and are therefore theoretically amenable to negotiation, and constructive stakeholder engagement.

The downside, however, is that as a result of their broader focus, these organizations are unlikely to pay immediate and significant attention to the specific innovation process, as their resources are likely tied up over numerous fronts at the same time. Consequently, a purely reactive strategy will likely ignore these organizations, while failing to appease the more active, hostile entities described above. A RRI-inspired corporate strategy would instead advocate that the innovative firm initiate contact with these organizations, attracting their attention and negotiating for their support in the ensuing disputes. While such an approach is certainly expensive, and potentially risky, its viability should be assessed in comparison to the passive approach, whose existential risks have been sufficiently illustrated by the case of AquaBounty.

Our analysis finds that the integration of RRI-inspired principles of stakeholder engagement within corporate settings requires a currently missing set of guidelines. To the principle of stakeholder selectivity, we add that a necessary first step to be taken by firms



aiming to constructively engage public concerns is identifying organizations dedicated to the promotion of the welfare, understood in broad terms, of relevant stakeholder groups, and selectively engage them in the early stages of the innovation process. The initial goal of this engagement should be to co-define shared aims which the current innovation process may positively contribute to, and problematic areas to which attention should be paid from the beginning to mitigate the social conflict that transformative technological change necessarily entails. While the inclusion of such type of stakeholders within the decision-making process may be initially limited, repeated practice may over time lead to the development of those organizational capabilities, currently missing on both sides, required to gradually give life to the RRI vision of a socially inclusive and responsible innovation process.

## 6. Conclusions

The key principle of RRI, stakeholder engagement, appears vindicated by the rocky road faced by AquaBounty in their daring attempt to commercialize the first GM animal for human consumption. However, the integration of this principle within a corporate context appears to require two important qualifiers. First, stakeholder engagement must be strategic and selective, as already argued by previous research [11,27,92]. Second, stakeholder selection must be predicated on the possibility of compromise, identifying those organizations whose aims are sufficiently broad to potentially accommodate the relevant innovation. Such organizations are those whose goals are expressed in terms of benefits to be accrued by specific groups, rather than in terms of means and approaches through which such benefits are to be gained. Only these pragmatic organizations can be integrated in current corporate responsible innovation practices, as the costs involved in the required outreach initiatives are likely to be recouped in terms of regulatory support and market penetration. The nature of these organizations implies that stakeholder engagement [8] will be initially limited to practices of stakeholder inclusion [9]. However, these practices may allow for the gradual development of now missing organizational capabilities required for stakeholder integration to develop further in the future.

It may be argued that this is an insufficient realization of RRI principles. The claim can hardly be rejected: if RRI is collective husbandry of technological development and innovation [2,7,21], then selective stakeholder inclusion, rather than engagement, is not RRI. However, if RRI is to become a practice, rather than a contested set of principles, research should be focused first on which elements can be reasonably expected to be integrated within today's current practices. This has been the focus of this research. It is not argued, however, that RRI could not strive for loftier goals in the future. Once the, perhaps narrow, perimeter of the possible responsible corporate innovative practices of the present has been defined, it will be possible to identify which factors constrain such perimeter, and how they can be relaxed, for a more comprehensive and meaningful RRI framework to become reality. While RRI may be difficult to implement and likely resulting in a slower pace of innovation in the earlier stages, it is the only currently existing approach that can reveal and potentially mitigate social issues, minimizing risks for innovators and society alike.

This research has been limited to a single case in the field of biotechnology. However, it can be argued that the themes of stakeholder engagement, social acceptance, and public interaction are not specific to this specific technological setting. More research is needed to test if the practice of strategic, selective, and pragmatic stakeholder interaction can be fruitfully pursued within different sectors, and if such practice can achieve the ambitious aim of providing tangible benefits to corporate entities, while simultaneously ameliorating the social governance of the innovation process.

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