

The impact of genetically modified salmon: from risk assessment to quality evaluation

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Abstract. In this paper we address the complex and controversial issue of the possible commercialization of a genetically engineered (GE) salmon for human consumption: the AquAdvantage Salmon®, by one of the leading US aquaculture corporations, AquaBounty Technologies Inc (ABT). This analysis follows and deepens our reflections on the notion of impact assessment, in the framework of biotechnology for food production. In the first part, we consider the epistemic and normative implications involved in the regulatory process of the transgenic salmon, starting with a review of the scientific research on genetic engineering applied to the taxonomic family Salmonidae. We explore the inextricable relationship between facts and values, and their mutual dependence on the high stakes implied in the controversy. In the second part, we challenge the identification of impact assessment with future developments, the risks and promises of the GE salmon. We propose a shift to from prediction to diagnosis, and we provide a brief account of the driving forces that bring the transgenic fish into the world, along the path-dependent trajectory of technoscientific innovation. We conclude by proposing to open a collective space for reflection about the criteria for evaluating the quality of GE salmon in our present.

Keywords: impact assessment, genetically engineered salmon, biotechnology for food production, quality, innovation

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1. Introduction

The word “impact” entails the idea that something is already into the world and it is “pressing” against a target¹. In the still dominant, modern ideal, assessing the impact of technoscientific open-field experimentations means identifying the target and evaluating the consequences of this pressure, on the basis of scientific evidence collected by purposely-selected experts, for the needed regulatory aims. In this model, the certain, objective and exhaustive scientific evidence speak for themselves and rational decisions about the governance of technology can be made in the form of logical deductions (Wildavsky 1979).

In our previous work, we have discussed some of the inadequacies of this framework in the context of biotechnology for food production (Benessia and Barbiero 2012, Guarnieri et al. 2008). By focusing on the research, implementation and regulation of genetically modified organisms in industrial agriculture, we have shown that this modern model can be applied only at the price of selectively obscuring the normative dimension inherent in the process of impact assessment. Indeed, the framing of what constitutes an evidence, the ways in which the designated significant data are collected and evaluated, the questions to be answered and the conclusions to be drawn are intrinsically value-based practices, embedded in the technical, scientific procedures. The needed expertise and the corresponding epistemic culture of the actual experts do not automatically emerge from a predefined laboratory setting in which the impact is set up to happen (Hardin 2004, Knorr Cetina

1999). They are the result of choices, based on specific aims, and they produce a plurality of perspectives, all valid in the context in which they emerge and most often mutually exclusive, therefore controversial (Sarewitz 2004).

Moreover, open field technoscientific experiments, such as GMO’s for food production, imply high stakes, as they require considerable investments, they are designed to be carried out on a global scale and, in case of failure, cannot be reversed. Finally, as they are performed on socio-ecological systems, including the agents performing them, they entail the presence of emergent complexity and radical uncertainty (Funtowicz and Ravetz 1994). As a result, in the evaluation of their impact, facts and values are inextricably entangled, uncertain and disputed, a condition that can be defined as post-normal (Funtowicz and Ravetz 1993).

Based on these premises, in this paper we address the complex and controversial issue of the possible commercialization of a genetically engineered salmon for human consumption: the AquaAdvantage Salmon®, by one of the leading US aquaculture corporations, AquaBounty Technologies Inc (ABT). According to ABT, through the addition of a growth-hormone gene construct, the patented fish is designed to reach the market size in about 18 months, close to half of the average time-to-market of conventionally farmed salmon. Moreover, the total feed required to produce the same fish biomass is reduced by 25%, giving the producer a significant net overall economic gain. As the AquaBounty narrative goes, this saving would make economically viable to rear the fish in otherwise too costly, physically contained inland facilities, isolated from marine ecosystems, therefore less polluting and more environmentally sustainable (AquaBounty Technology 2010).

Over the past two decades, a number of different stakeholders, ranging from activists,

¹ The etymology of the term impact is to “press closely into something,”: from Latin *impactus*, past participle of *impingere* “to push into, dash against, thrust at”. Originally sense preserved in impacted teeth (1876). Sense of “strike forcefully against something” first recorded 1916. Figurative sense of “have a forceful effect on” is from 1935 (see online etymology dictionary www.etymonline.com).

to concerned citizens and scientists, traditional fisheries and the aquaculture industry have been contesting these promised economic advantages and ecological benefits. At the same time, the environmental risks of genetic pollution of the wild salmon population and the possible hazards for human health have been widely discussed, prompting the need for precaution in the adoption of this new technological product. The scientific and political controversy around the AquAdvantage Salmon® has dominated the debate about the extension of genetic engineering from plants to animals, stalling the regulatory process and discouraging the research and development of other cases (Pollack 2012a).

We consider here this exemplary case, in order to revisit and deepen our investigation on the notion of impact assessment, along two routes.

In the first part, we consider the issue of scientific uncertainties and the normative implications, the complexity and controversy implicit in the impact assessment procedure. Indeed, as we will explicitly review, the research, implementation and commercialization of transgenic salmon involves a number of uncertain facts and contrasting values, concerning the definition, detection, measurement and evaluation of both the possible risks and the declared benefits.

Moreover, the stakes are high; On the one hand the authorization for human consumption would constitute a precedent and open the doors to genetically engineered animals in food production systems, creating a whole new economy for industrial farming. On the other hand, the possible interactions of transgenic salmon with the wild species could induce irreversible damages to global marine ecosystems.

Finally, even though the genetically engineered salmon has been under the

attention and then the review of the US Food and Drug Administration (FDA) since 1995, the regulatory, decision-making process is embedded in a narrative of urgency. As we will explore, the global growing need for animal protein, the raising concerns about ocean degradation and depletion, the US seafood trade deficit and the possible competitive disadvantage with other countries eventually ahead in the market of transgenic animal food, are some of the main arguments in favor of a fast and effective approval of the AquAdvantage salmon in the US. Ultimately, and way more specifically, the financial survival of AquaBounty Technologies itself is at stake in the waiting.

This narrative of urgency will be explored in the second part of the paper, where we extend our analysis by concentrating on the logically former, fundamental premise of the whole framework of analysis, namely the strong and implicit normative stance according to which we identify impact evaluation with future developments.

This assumption is the grounding pillar of the modern principle of responsibility, according to which we need to predict the future in order to justify our action in the present (Jonas 1985). If we follow these premises, we are lead to paradoxical situation in which we need to know about the future consequences of our implementation in order to act, but we are prevented from knowing the future developments, as a consequence of the intrinsic nature of the very same implementation (Benessia et al., 2012). A way out of this inherent contradiction is to shift our attention back to the present and to divert our analytical and reflective capacity from prediction to diagnose and from responsibility under risk to commitment in times of change (Funtowicz and Strand 2011).

The idea is then to divert our focus from the possible targets and the consequences of the impact, to the impacting object itself,

considering the driving forces that bring it into being and determine its trajectory. In other words, we propose to suspend for a moment the scenario of the future developments, risks and promises, and ask in what kind of world this technoscientific product - a genetically engineered, fast-growing salmon - has a meaning that justifies the scientific and economic effort of actually fabricating it, proposing to sell it and being confident that someone will buy it. These issues have to do with how we collectively value the salmon at stake and therefore with its quality: as a living being embedded into a net of socio-ecological systems, as a technoscientific commodity, and as food.

As we will see, in this framework, the AquAdvantage salmon can be interpreted as a belonging to the path-dependent trajectory of technoscientific innovation and its main drivers of optimization and substitution (Benessia and Funtowicz 2015).

With these elements in mind, let's begin our investigation with the scientific uncertainty and disputed values embedded in the research and implementation of genetically engineered salmon.

2. GE salmon: scientific uncertainties and normative implications

As any other technoscientific product, GE salmon depend on scientific research in at least three ways: for its production, impact evaluation and regulation. Accordingly, different epistemic and normative cultures, modes of analysis and decision-making praxes can be applied to its implementation and regulation. More specifically, as we have extensively developed in our previous work (Benessia and Barbiero 2012), both the production and the regulation are driven by the epistemic culture of innovation², whereas

² Innovation science (Wynne quoted by Jasanoff, 2005) is typically carried out by private industries, not rarely granted with public funds (Goldenberg

the impact evaluation can and should be conducted by focusing on the so-called negative or liminal knowledge (Kastenhofer 2007, Knorr Cetina 1999) within the epistemic culture of precautionary science³, in order to deconstruct the main pillars of the innovation approach and leave room for a democratized, post-normal evaluation of biotechnology applied to aquaculture. In what follows, we will start by reviewing the main results emerging from the scientific literature regarding the research behind the production of the AquaBounty GE salmon. We will then move to the complexity and controversy inherent in its possible commercialization.

2011), with the explicit aim of developing and introducing new (bio)technological products in the market. The prevalent goal of this type of endeavor is to make things work. This, in turn, entails a methodology founded on laboratory trial-and-error iterative approximation to the desired result, through the design and management of linear cause-effect relationships between a limited or limitable number of variables (i.e. a specific gene for a specific property, according the central dogma ideal which we will discuss in the following section). The corresponding epistemic culture of innovation science is therefore essentially based on determinism, reductionism and mechanism, applied *in vitro*, to small and de-contextualized temporal and spatial horizons, and resulting in the production of so-called hard facts, namely new goods, characterized by a given set of properties, with the externalization of uncertainty.

³ Precautionary science (Ravetz, 2004) is normally undertaken within research institutions such as universities, and it involves the understanding and the management of the consequences of large-scale techno-scientific implementation. Its main focus is therefore the complexity of interaction between the organisms involved – conceived and treated as processes – and the environment. The correlated epistemic culture of this type of scientific research is based on observation *in situ*, through systemic approaches over large population systems and extended temporal and spatial horizons, involving highly non-linear causal links, such as retroaction mechanisms, dependence on initial conditions etc.

Salmon are osteichthyes belonging to the taxonomic family Salmonidae and they are divided into two genera: *Oncorhynchus*, which includes 14 species of salmon and trout that live in the Pacific Ocean, and *Salmo*, which includes 29 species of salmon and trout that live in the Atlantic Ocean. The most widely studied genetically modified salmon is the transgenic Coho salmon (*Oncorhynchus kisutch*), into which the promoter region⁴ of a gene regulator controlling the expression of the growth hormone (GH) gene has been inserted. The promoter is directly inserted into fertilized eggs using a vector. Since the fertilization and development of fish eggs occurs externally, no process of internal re-implantation is necessary. Once the females have spawned, their eggs can be collected and subsequently fertilized without any apparent effects upon the development of the salmon fry (Fletcher and Davies 1991). GH stimulates cell division, muscular and skeletal growth, the hepatic production of insulin-like growth factor (IGF) and the immune system. The production of GH is, in turn, inhibited by the presence of glucocorticoids, which have an anti-inflammatory function, and by somatostatin, which inhibits the production of insulin. In addition to Coho salmon, other species of salmon have been engineered to overexpress GH, including the Cherry salmon (*Oncorhynchus masou*) and, as we will see, the Atlantic salmon (*Salmo salar*).

2.1 Physiopathology of GE salmon

An analysis of the literature offers a fragmented view of the physiology of genetically modified salmon: studies have been conducted on different Salmoninae subfamily species using different methodologies and with different research objectives. It is therefore difficult to delineate a coherent overall picture. Nevertheless, it appears clear that genetically modified salmon, independent of the originating

species, differ from corresponding non-transgenic on at least three levels: growth, deregulation of the GH axis, and reproduction.

2.1.1 Growth

The most studied species of salmon that has been genetically modified to continually produce GH is the Coho salmon (*Oncorhynchus kisutch*). This transgenic salmon grows at a faster rate than non-transgenic Coho salmon as a result of its greater consumption of food (Sundström et al. 2005). Six months post hatching, genetically modified Coho salmon reach the weight and degree of coloration that non-transgenic Coho salmon achieve after 24 months (Devlin et al. 2004). When fed identical quantities of food, genetically modified Coho salmon do not grow faster than their non-transgenic homologues (Stevens and Devlin 2005). Furthermore, if farmed with insufficient access to food, fitness levels in the transgenic Coho salmon are drastically reduced compared to those of non-transgenic Coho salmon farmed under the same conditions, which instead adapt better to conditions of food insufficiency (Devlin et al. 2004).

A more in depth study was performed on Atlantic salmon (*Salmo salar*) by Deitsch and colleagues (2006). As for Coho salmon, transgenic Atlantic salmon grow quicker than non-transgenic salmon of the same species: transgenic Atlantic salmon achieve a body mass index (BMI) that is 21-25% greater than that of the non-transgenic ones. However, as expected, oxygen consumption is unchanged in transgenic Atlantic salmon compared to the non-transgenic, as the gill surface area is not influenced by GH activity. Whatever the cause, transgenic Salmon grow to become much bigger fish, although much less efficient. Transgenic Atlantic salmon have a metabolic rate that is 18% lower and a critical swimming speed that is 9% slower than non-transgenic. On the other hand, transgenic Atlantic salmon possess a cardiac volume that

⁴ Originating from the Sockeye salmon, *Oncorhynchus nerka*.

is 29% larger, a cardiac output that is 18% greater and a post-stress blood hemoglobin concentration that is 14% higher than that of non-transgenic homologues. These physiological modifications, associated with significant anatomical aberrations in transgenic salmon, may represent adaptations resulting from the excessive strain placed upon the fish's metabolic system. This, in turn, might have a negative impact upon swimming performance (Hu et al. 2010).

Thyroid function plays a key role in growth. In a study conducted to investigate thyroid function in relation to salmon growth, Eales and colleagues (2004) considered three groups of Coho salmon: non-transgenic salmon fed to satiation (NTS), transgenic salmon fed to satiation (TS) and transgenic salmon fed the same ratio of food consumed by the non-transgenic salmon (TNT). As expected, the TS group grew twice as fast as NTS and TNT fish. Eales and colleagues then evaluated the plasma concentration of the thyroid hormones T3 and T4. While no differences were found in T4 concentrations between the three groups, greater plasma concentrations of T3 were found in the transgenic salmon (TS and TNT) with respect to non-transgenic. At the same time, the activity of T3 (and T4) in the liver was less in the transgenic salmon (TS and TNT). Thus it seems that the plasma concentrations of T3 and T4 and their hepatic activities depend directly on the expression of GH and not on the quantity of food available.

2.1.2 Biochemical alterations caused by deregulated GH expression

In order to understand the chronic effects of the deregulated expression of GH, it is necessary to analyze the complex cascades of intra- and intercellular biochemical reactions. Although non-exhaustive, some lines of experimental evidence provide important information. For example, a study conducted on the expression of hepatic genes in

transgenic Cherry salmon (*Oncorhynchus masou*) revealed that the mRNA expression levels of the following proteins are all increased in these fishes: the enzyme haeme oxygenase; leukocyte cell-derived chemotaxin (LECT2); α -trypsin inhibitors; proteins linked to iron metabolism; and proteins linked to the reproductive system. On the other hand, the expression of lectin, D-6-desaturase, apolipoprotein and pentraxin were reduced in transgenic Cherry salmon. Pentraxin is involved in a specific immune processes, which appear to be weakened in second (F2) and third (F3) generations of transgenic Cherry salmon (Mori et al. 2007). In another study conducted on transgenic Coho salmon fed to satiation, increases were detected in: tissue levels of glutathione – a tripeptide that performs important antioxidant functions; glutathione reductase activity – which catalyzes the formation of glutathione disulfide; and γ -glutamyltranspeptidase activity in the intestine – an enzyme critical for the catabolism of glutathione (Leggat, et al. 2007). However, all values lay within normal ranges if food ratio were restricted, demonstrating that the regulation of the antioxidant system is linked to accelerated growth and not to the direct activity of the transgene.

2.1.3 Reproduction

The reproductive behaviors of transgenic Coho salmon have been studied in relation to the ecological consequences of their interaction with wild Coho salmon in natural habitats. Bessey and colleagues (2004) observed that transgenic Coho salmon are able to mate with their non-transgenic homologues and give rise to fertile offspring. Transgenic Coho salmon reach sexual maturity at around 2-3 years of age – extremely early compared to non-transgenic Coho salmon that instead require 4-5 years. Female transgenic Coho salmon appear to be more fertile, even though they display less courtship behavior and produce fewer eggs of smaller dimensions compared to non-

transgenic females in the wild. Transgenic male Coho salmon do not differ from the non-transgenic males with regard to the production of gametes and courtship behavior in non-competitive conditions; but in competitive conditions, the transgenic males also display less courtship behavior.

2.2 Ecology

The second line of investigation is focused on the ecological impact of genetically modified salmon: i.e. the study of the relationships between the communities of genetically modified and wild (non-transgenic) salmon. Two issues constitute the heart of the debate: does the presence of the transgene change the reproductive fitness of transgenic salmon compared to that of wild salmon? And, what happens if a transgenic salmon mixes with a population of wild salmon? Three main areas of experimental investigation can thus be defined: (1) the potential competition between genetically modified and wild salmon populations; (2) the possible transfer of the transgene into the wild salmon population; and (3) the evaluation of the predatory behavior expressed by genetically modified salmon towards their non-transgenic homologues.

As the evaluation of reproductive fitness in natural environments is difficult to evaluate experimentally, several theoretical models have been developed. One of the most interesting model is the one proposed by Muir and Howard (1999) who coined the concept of the "Trojan Gene Effect". The two scientists from Purdue University posit that when a transgene confers a survival disadvantage while at the same time a mating advantage, the mating advantage would drive the transgene into a natural population while the survival disadvantage would cause population numbers to gradually spiral downward and eventually result in local extinction of the wild population. In another theoretical model, the increase in the frequency of the transgenic genotype

corresponds with a reduction in the reproductive fitness of the wild population (Hendrick, 2001). Together, these models highlight the fact that the simple introduction of a genetically modified salmon into a natural environment, independent of its relative reproductive fitness that may be greater or less than that of the wild homologue, increases the risk of extinction of the wild species.

It is also interesting to note the observations of Devlin and colleagues (2004): according to these authors, when transgenic Coho salmon are farmed in the same tank as their non-transgenic homologues with an abundance of food available, the fish develop without interfering with each other. However, when farmed under conditions of limited food resources, the transgenic Coho salmon adopt more aggressive behaviors, expressing dominance over the non-transgenic and interfering with the latter's growth to the extent that the GM fish may start to hunt and feed upon the smaller non-transgenic salmon; thus leading both populations towards extinction. Under the same food shortage conditions, the non-transgenic salmon farmed alone would have survived without any particular problem. Although it is difficult to establish conditions of food "shortage" or "abundance" in a natural environment, concerns remain relative to the danger represented by the accidental introduction of transgenic Coho salmon into a population of wild Coho salmon.

Overall, these studies seem to highlight a recurrent theme within the realm of ecology: even minimal variations in baseline conditions can result in very different results, making studies difficult to compare. It is therefore difficult to evaluate experimentally the risk associated with the introduction of GM salmon into aquatic ecosystems.

2.3. Towards the commercialization of GE salmon

When leaving the realm of research and stepping into the actual industrial production of a patented GE salmon for a possible commercial use, the reductionist framework of innovation and regulatory science clashes inevitably against the precautionary approach of ecology and physiology. The issues that we have explored so far become then inevitably controversial, facts and values entangled. Let's see how.

As we have mentioned, AquAdvantage Salmon is the trade name of the genetically modified Atlantic salmon created by AquaBounty Technologies Inc. (ABT). AquAdvantage Salmon contains a genetic construct made by the promoter and the terminal region of an antifreeze gene extracted from the Ocean Pout (*Zoarces americanus*) genome and the growth hormone (GH) regulating gene from Chinook salmon (*Oncorhynchus tshawytscha*). In non-transgenic salmon, the gene promoter that regulates the production of GH is only expressed in response to specific environmental stimuli, including temperature and the duration of daytime light (Bjornsson 1997), while the promoter in genetically modified salmon is constantly active (Devlin et al. 1995). As gene expression systems are regulated by negative feedback, it is clear that the choice of a promoter obtained from a species that does not belong to Salmonidae was aimed at preventing the action of the growth regulators in Atlantic salmon; thus isolating the system that produces GM from the salmon's own physiology⁵. GH in Atlantic salmon is very similar to that of Chinook salmon, although not identical. The mRNA nucleotide sequences of the two GH genes possess 90% homology (1013/1126

⁵ On the other hand, the choice of an *Oncorhynchus* is not necessary from the biological point of view, but it becomes essential to provide the transgenic fish with a more reassuring identity as a "natural" fish.

nucleotides). A comparison of the protein sequences found that 198/210 of the amino acids were identical, 7/210 of the amino acids were similar, but 5/210 amino acids were effectively different (Bodnar 2010)⁶. The process of integrating the genetic construct – called EO-1 α – resulted in the rearrangement of the promoter that reduced its potential expression. This transgenic salmon was then crossed with a non-transgenic Atlantic salmon and the EO-1 α genetic construct was found to be stable in second (F2) and fourth (F4) generations (Yaskowiak 2006).

Female AquAdvantage Salmon homozygous for the EO-1 α genetic construct are induced to transform into males (neomales) by treatment with 17-methyltestosterone. The male gametes produced (which do not contain male chromosomes, however, being derived from female chromosomes) are used to fertilize the eggs produced by non-transgenic salmon. In this way, all new-born are female and possess a copy of the EO-1 α gene (Bodnar 2010).

The data made available by ABT indicate that AquAdvantage Salmon grow in body weight approximately 2 times faster than non-transgenic Atlantic salmon and its feed conversion rate is about 10% lower than conventional salmon (AquaBounty Technology 2010). The idea is then to develop a fish product that is substantially equivalent to its wild type counterpart, but it is functionally different, namely more efficient, as it requires less time to grow and be ready for the market.

2.3.1. Growth rate and the standard Atlantic salmon

The official picture of the AquAdvantage salmon portrays two fish swimming in crystal clear waters over artificially blue pebbles,

⁶ This sex-reversal technique is a common practice in trout farming, as female grow faster and with has higher quality flesh (Dunham 2011).

side by side. They both look alike except the one is double the size of the other⁷. The image, first publicized by ABT itself and then filtered through all scientific and popular media, is meant to represent the difference in size – and size only – of two salmon of the same age, about 10 to 12 months old. In other words, it represents a growth rate and not the end state of development. The intrinsic ambiguity of the picture evokes ABT constant need to reassure the public of the fact the actual size of its trademarked salmon is not out of proportion when maturing and entering into the market. An overall larger size would indeed foster the stigma of abnormality associated with the GE fish and, even more importantly, raise ecological concerns about a possible mating advantage of the transgenic salmon over smaller non-transgenic populations⁸.

If the identity of the bigger fish – the GE salmon – is unequivocal, the other – the non-transgenic, standard comparator – is highly controversial. The technical-scientific counterpart of this photograph is the ABT growth diagram presented in the regulatory submission to the FDA, where weight is measured as a function of time (Aquabounty Technology 2010). There, we see the AquAdvantage growth curve comfortably above an unspecified “Standard Salmon” size development. The issue is to define what a “standard” farmed Atlantic salmon actually is. Indeed, different strains of salmon do not grow alike, and the traditional breeding technology has made enormous progress in optimizing growth-rates. In 2011, Norwegian grower Salmonbreed issued a press release showing that its own (non-transgenic) salmon grow as fast or faster than ABT salmon. In the document, within the same kind of diagram, the Salmonbreed growth curves are comparable or higher than the

AquAdvantage salmon (Salmonbreed 2011). More recently, a governmental Canadian risk assessment draft review casted further doubts about the accelerated growth rates of the GE salmon (Colwell 2015, Department of Fisheries and Oceans Canada 2013).

What is presented as an objective and certain scientific assertion becomes inevitably questionable - and it is questioned - when the stakes associated with the assertion begin to grow. In this case the European salmon farmers and breeders, particularly the Norwegian who dominate the aquaculture industry, a sector that globally amounts to a business of \$107 billion-a-year, obviously look at the possible emergence of a US GE salmon into the international market with careful and competitive attention (Gibbs 2011).

2.3.2 *Physiopathological problems and the data controversy*

In a report addressed to the Center for Veterinary Medicine of the U.S. Food and Drug Administration (CVM-FDA), ABT acknowledges that the first generations of AquAdvantage Salmon exhibited a high rate of malformations, although they then underline that after ten years of crosses “the health and well-being” of AquAdvantage Salmon does not differ from that of non-transgenic Atlantic salmon (AquaBounty Technology 2010). However, no scientific explanation of this phenomenon is supplied. The Veterinary Medicine Advisory Committee (VMAC) seemed to be surprised, above all because “the decrease in irregularities was not as notable in non-GE comparators”, but they then concluded that “it may be a function of the underlying genetics of the brood stock families used in the breeding crosses, or possibly, other factors” (VMAC 2010, p. 29). It would be interesting to know what these “other factors” are, as the data arising from only five years of investigation were

⁷ See <http://aquabounty.com>.

⁸ Published studies report that, in some cases, transgenic fish do not only grow faster, but also reach a larger size (de la Fuente *et al.* 1999).

considered and, above all, the trend in the values of malformations seems to be random: for example, in the final year of analysis, the percentage of non-transgenic salmon, used as controls, presenting malformations was equal to 71.5% (Table 4, p. 28), a surprisingly high value.

In addition, a more complete understanding of animal physiopathological issues is problematic, as a consequence of the standard culling practice for selectively improving the brood stock and optimize the use of available space, the AquaBounty data about physiopathological problems were inherently biased (FDA-VMAC 2010 p.26). This issue has been acknowledged by the VMAC and the FDA suggested implementing “post-approval safety surveillance” measures, applying a controversial post-market regulatory approach (FDA-VMAC 2010 p.60, Development Fund 2013).

Finally, until ABT releases the experimental protocols about the growth of the AquaAdvantage salmon, the only possibility for independent researchers is to extract inferential data from similarly engineered species. And, as we have seen, the available data indicate: 1) serious skeletal and muscular malformations that can compromise the swimming performance of the fish (Lee et. al. 2003) 2) un-synchronic growth of the skeleton-muscular apparatus with respect to the cardio-breathing apparatus, which can even kill the fish for suffocation (Deitch et al. 2006) 3) hormonal dysfunctions, in particular regarding the thyroid gland, which regulates the overall metabolism of the organism (Eales et al. 2004).

2.3.3. Ecological problems and the narrative of control

Currently, ABT produces GE salmon eggs in its facility in Saint Prince Island, Canada and then fly them to another facility in Boquete, Panama where the salmon are grown to

market size. The plan is then to ship the final fish product to the United States for consumption. This quite impractical geographical and logistic configuration has a specific history.

In 1995, when E/F Protein – the early name of today AquaBounty - first applied to the U.S. Food and Drug Administration to regulate its product, the AquaAdvantage salmon was meant to occupy a (possibly advantageous) place into the conventional open-water net-pen marine aquaculture industry (Bratsbies 2008). The life of this business plan was meant to be short.

As transgenic salmon can mate and give rise to fertile offspring, in the late nineties, raising concerns about the environmental risks of GE escapees into open waters prompted the North Atlantic Salmon Conservation Organization (NASCO) to issue specific guidelines directing that aquaculture of transgenic salmon occurred only in self-contained, land-based facilities (NASCO 1997) and enacted an agreement to adopt a precautionary approach to the possible implementation of GE salmon aquaculture (NASCO 1998). In 2002, the National Research Council also called for caution in experimentation and commercialization of transgenic fish (NRC 2002). The open questions of gene transfer and possible genetic invasion of the transgenic species, fostered by the formulation of the Trojan-Gene Effect by Muir and Howard in 1999, fuelled vigorous objections to the possible commercialization of GE salmon by a number of NGOs and other representative of the civil society, such as the Union of Concerned Scientists, calling for more information and research given the many unknowns of this open field experimentation (UCS 2001). In 2003, this overall climate lead NASCO to issue a resolution terming transgenic salmon as “high risk” and proposing a set of guidelines to direct member states to “take all possible actions to ensure that the use of transgenic salmon, in any part of the NASCO Convention

Area, is confined to secure, self-contained, land-based facilities” (NASCO 2003).

Given the broad and raising agreement about the potential risks of GE salmon joining the vast crowds of escapees from conventional open water net-pen aquaculture (Gausen and Moen 1991, McKinnell et al. 1997 and Crozier 1998), and the consequent lowering probability of approval from the FDA, AquaBounty modified its business plan, abandoning the idea of conventional open sea facilities and moving towards the idea of self-contained, land-based aquaculture. From then on, with a quite brilliant marketing shift, the GE salmon became the only solution to make this highly expensive and less polluting fish farming technique economically feasible.

A new facility was established in 2007 in the remote Panamanian location of Boquete, on the banks of the Calderas river in the western highlands of Chiriqui province. The choice of the place was never commented by ABT, if not on the grounds of being a highly hostile environment for possible escaped salmon. Indeed the water temperature of the nearby canals is high enough to jeopardize the survival of a GE salmon, and the closest sea is the Pacific ocean, where AquaAdvantage Atlantic salmon would have no chance to reproduce, given that Atlantic and Pacific salmon don't interbreed⁹ (Bodnar 2010).

Established in 1996, the hatchery in Saint Prince Island is also self-contained. Although the fresh watercourses in Eastern Canada have been historically one of the natural habitats of Atlantic salmon, their current degradation due to acid rain and the installation of physical barriers make them an

unfriendly environment to salmon escapees (Bodnar 2010).

Following a narrative of control (Benessia and Barbiero 2012), in addition to these environmental barriers, ABT implemented a number of containment strategies within its facilities. The first barrier is biological, consisting on farming only sterile female salmon. Sterility occurs due to the fact that these salmon are made triploid, i.e they contain three copies of each chromosome, instead of the usual two copies (diploid). Crucially in this context, triploid fish do not produce gametes. The most common method used to create triploid fish is to expose the eggs to a pressure shock treatment. This causes the retention of the second polar body and the eggs thereby retain their chromosome complement (Benfey et al. 1988). However, triploid fish develop more slowly (Devlin et al. 2004) and exhibit a higher probability of manifesting aberrant phenotypes (VMAC 2010), but this seems to be the price that the industry is willing to pay in order to guarantee the sterility of farmed salmon.

Moreover, and quite significantly in this scenario, sterility is never complete (Devlin 2010). This procedure has a success rate equal to 98.9% in the ABT laboratories, with 1.1% of eggs remaining diploid. An open concern about this issue emerges in the report by ABT: “the acceptance criterion is such that the likelihood of releasing a batch of eyed-eggs that are not at least 95% triploid is less than 0.05. Individual upwelling chambers that fail to meet test criteria will be re-tested and destroyed upon confirmed failure” (AquaBounty Technology 2010, p. 61). Confirming the lack of reliability of the proposed sterilization procedure, in 2011, the US Department of Agriculture granted the company a controversial funding of about half a million dollars to improve ABT biological containment technologies (USDA 2011).

⁹ Commentators suggest that ABT moved to Panama for its less regulated approach to biotechnology. Indeed, if the GE salmon they are grown outside of the United States, AquaBounty does not have to complete a full Environmental Impact Statement as required by the Environmental Protection Agency (Greenberg 2010).

Finally, the physical containment consists on an elaborate series of measures, leading the ABT CEO Roy Scottish to define its facilities as “aquatic Forth Knox” (Henry 2014). Indeed, ABT isolates its structures through the use of security enclosures, the use of 24-hour surveillance guards assisted by security cameras, the implementation of a series of filters, nets and other containment systems, and the sterilization of the egg production plant drainage areas using chlorine to kill eggs that escape filters (Bodnar 2010).

The risk of harm from GE animals is defined in the regulatory framework as the product of (a) harm, given exposure to the hazard (i.e. the GE animal) and (b) the probability of exposure. By focusing on the reduction of the probability of exposure, with its redundancy of biological, environmental and physical security measures, ABT has obtained a favorable environmental assessment from the FDA in 2013, with a “finding of no significant impact” (FDA 2013).

William R. Muir, one of the authors of the well-known work on the “Trojan gene effect”, presented his own favorable scientific-based opinion in a VMAC public meeting, hosted by the FDA in September 2010 (Muir 2013). In his talk, he explained why the AquAdvantage salmon would not be a plausible carrier of a Trojan gene, thus presenting “little or no environmental risk” of genetic spread, quoting among others, the work of Moreau and colleagues. In this paper, published in 2011, the authors conclude that: “Although transgenic males displayed reduced breeding performance relative to non transgenic ones, both male reproductive phenotypes demonstrated the ability to participate in natural spawning events and thus have the potential to contribute genes to subsequent generation” (Moreau et al. 2011). The search for liminal knowledge that characterizes the epistemic culture of precautionary science is measured up against the more pragmatic need for certainty of regulatory science: what constitutes a little – essentially not

measurable – risk of genetic spread, becomes not significant in the hands of a scientific advisor called to regulate a product of technoscientific innovation¹⁰.

In the second part of its report, Muir presented “theory and data concluding that conventional farming of salmon in net pens is potentially more harmful than GE salmon due to competition and genetic load issues” (Muir 2013). His rationale for comparing the two distinct cases is justified by the fact that, in his words, “there is no such thing as zero risks and all risks are relative to an alternative” (Muir 2013). In analogy with the purported benefits of AquAdvantage salmon – namely its growth rate – the objectivity inherent in the choice of the relative risk comparator is questionable. More specifically, the idea that the two options are mutually exclusive and they are the only available possibilities is the result of a specific implicit framing of the issue at stake. As we will see, the more likely scenario in case of approval is that both products (GE salmon produced inland and non-GE salmon produced in open waters) are available and competing on the market.

Moreover, in this approach to risk assessment, the kind of farmed fish (i.e. the

¹⁰ In addition to the concerns related to the impact on the genetic makeup of wild salmon populations of a Trojan Gene, escaping GE populations might also adversely affect other native fish, invading their niches. In a recent article, scientists from Canada have found that transgenic Atlantic salmon can cross-breed with the brown trout, a closely related species (Oke et al. 2013). Even sterile GE fish may pose problems to wild populations, as escaped transgenic fish would still engage in courtship and spawning behaviour that could disrupt breeding in wild populations and decrease overall reproductive success. Also, even without exhibiting any reproductive behaviour at all, escaped sterile fish could still create ecological interference by simply competing with wild fish. In this overall scenario, the presence of radical uncertainty and unknown unknowns cannot be ruled out (Kapucinsky in Palca 2011).

harm factor) and the facilities in which they are raised (i.e. the probability of exposure) are intertwined: when compared to the highly vulnerable conventional aquaculture net-pens, in direct contact with open waters and prone to the attack of predators and extreme weather events, the ABT actual aquatic Fort Knox-types facilities are predictably less exposed to a risk of breakdown. On the other hand, the risk of escaped non-transgenic salmon compromising the wild populations relative to the one of escaped GE salmon is essentially skewed towards the latter: this is the reason why, as we have seen, conventional aquaculture of GE salmon has been classified as “high risk” by NASCO in 2003¹¹. Clearly, then, the safest way to farm GE salmon is inland, but the optimal solution in terms of relative risks would be to raise non-GE salmon under the same conditions, requiring less security measures. When combined with the dispute about the actual growth rate of non-transgenic salmon, the debate about relative risk and benefits becomes inevitably complex and controversial.

Finally, in terms of absolute, cumulative risk, when the pre-market scenario is scaled up to the extensive commercial operations, all measures of containment and risk mitigation become questionable. Indeed, in the event of a final approval, AquaBounty plans on selling the GE sterilized eggs to ad hoc contained, inland facilities in the US territory and Canada, supposedly equipped with the same complex, expensive system of barriers. Given the significant numbers of fish raised in such a large-scale industrial production system,

¹¹ The FDA did examine the likelihood of GE salmon escaping (i.e. probability of exposure), but did not extensively analyze the environmental consequences if salmon did escape (i.e. harm, given the exposure to the hazard). The quality of the expertise of the US Agency has been highly contested, together with the failure to adequately consult with other US government agencies with the required expertise (US Senate Subcommittee on Ocean, Atmosphere, Fisheries and Coast Guard Oversight 2011).

even a very low but non zero probability of accident, inherent in any system of barriers (Guarnieri et al. 2008), would end up amounting to a significant risk of GE salmon escape, drastically raising up the probability of exposure.

2.3.4 Human health implications and material equivalence

As we have mentioned, the AquAdvantage Salmon is the first genetically modified animal designed for human consumption. The issue of its health implication is thus absolutely new and, for this reason, independent, systematic studies about food safety do not yet exist. The matters of concern are two-fold: (1) allergenicity, and (2) the undesired modification of the biochemical composition of the edible tissues due to the alteration of metabolic processes.

The Atlantic salmon in itself is a known allergenic food, thus it is probable that the AquAdvantage Salmon is also as such. ABT claims to have conducted studies on its allergenicity, but they were considered as unsatisfactory by the CVM-FDA. The CVM-FDA have since conducted their own studies on the allergenic potential of triploid salmon expressing the EO-1 α gene, which did not result as being different from that of controls (VMAC 2010).

ABT declares to have carried out analyses on the principal biochemical components of the edible tissues of the salmon (carbohydrates, proteins, total fats, vitamins and minerals) without finding any significant variations, with the only exception of a slight increase in the concentration of vitamin B6 in the AquAdvantage Salmon (0.77 mg/g of tissue), which anyway remains lower than that found in other edible fish, such as tuna (0.8 mg/g). However, the most important problem could be the increased hormone content of the edible tissues of the AquAdvantage Salmon. In particular, the higher concentration of insulin-like growth factor-1 (IGF-1) gives rise

to concern: 10.26 ng/g in AquaAdvantage Salmon compared to 7.34 ng/g in wild Atlantic salmon. IGF-1 in salmon, though being relatively different to the human version (35/141 amino acids are different), could conserve significant biological activity. IGF is a strong stimulator of cell proliferation and its production by specific types of hepatocyte depends directly on the activity of GH (Giovannucci et al. 2003). According to Bodnar (2010), salmon IGF-1 is 2-3 times less effective at binding human IGF-1 receptors compared to mammal IGF-1. But these are very approximate data. The conditions of these evaluations are not indicated and the receptor-hormone affinities in very different species is not explored. As IGF-1 represents a critical issue, it is unsettling that the FDA hasn't conducted a complete analysis in order to evaluate on the one hand the actual concentration of IGF-1 in edible tissues of the AquaAdvantage salmon, on the other the binding affinity with the human IGF-1 receptor (McEvilly 2013).

In addition, as we have seen regarding the biochemical alterations caused by deregulated GH expression, the study of the possible health implications cannot be limited to the analysis of the direct effect of the transgene action (VMAC 2010), nor to the study of allergens (Van Eenemann and Muir 2011) but has to be extended to the direct and indirect effects on the entire cell metabolic network.

In conclusion, from what we have explored so far, the assessment of environment and health implications is fragmented and incomplete within the regulatory framing of the FDA. However, even more radically, it is also inherently limited by the choice the framing. The health risks are quantified by FDA by comparing the nutritional profile of a GE salmon to a non-GE salmon and screening for toxins and allergens, in order to evaluate if the transgenic fish is "materially equivalent" to the non-transgenic one. This quite restrictive approach, which doesn't

consider the environmental issues per se, derives from the fact that the transgenic animals are regulated as veterinary drugs and not as food. Indeed, according to US regulatory processes¹², the transfer of genetic information can be viewed as a way to deliver a drug (hormone, protein, etc.) to the tissue of the animal. In the case of the AquaBounty's transgenic fish, the ocean pout promoter gene is considered as a drug delivering growth hormones to the tissues of the fish. Moreover, only an abstract pre-market scenario is analyzed, leaving aside the considerable possible larger-scale, irreversible implications of the actual GE salmon commercialization (Bratspies 2008, Smith 2010).

Overall, in this highly reductionist framework, the complexity of the interaction between the transgenic fish and the network of ecological, economical, social and cultural systems it depends upon, is not acknowledged.

3. GE salmon and the narrative of innovation: optimization and substitution

With this overall picture in mind, let's now shift our attention to the driving forces that have brought into existence the AquaAdvantage salmon, and the current legal, scientific and regulatory controversy around it¹³.

¹² The United States has decided to regulate transgenic animals under the Food and Drug Act's New Animal Drug Act (NADA) authority (CEQ/OSTP 2000).

¹³ A full account of the controversy around the commercialization of AquaAdvantage salmon is beyond the scope of this work. We provide here an overview by listing the main stakeholders involved and referring to a few articles in journals and mass media for some details: 1) ABT, trying to financially survive and move forward its business plan (Pollack 2012b); 2) FDA, slowly progressing in the regulation

As we have mentioned, the motives behind the research, production and possible commercialization of the transgenic fish can be regarded as belonging to a grand narrative of technoscientific innovation, defined as the engine of economic, social and environmental wealth, and a way out of our contemporary systemic crisis (European Commission 2010 and 2011).

3.1. The narrative of innovation and the commoditization of food

The dominant discourse about innovation is invoked as a solution for sustaining our accelerating increase of global resource consumption within a single planet, i.e. a complex, closed and finite system, with limited stocks and bio-geo-chemical resilience (Rockström et al. 2009). The way out of this paradoxical dynamic is to rely on the (unlimited) human creativity, in order to decouple growth from scarcity, optimizing the use of natural resources and ultimately substituting them altogether, with substantially equivalent, technological optimized artifacts. At the same time, in the narrative of innovation, the human power to enhance socio-ecological systems has to be applied to treat the possible negative outcomes as they arise, taming complexity, uncertainty and the risks of failures through

process (Pollack 2010) 3) the government of Canada and Panama addressing regulatory and economic issues (Goldenberg 2013, Colwell 2015); 3) US Senate and Congress, Obama administration (United States Senate 2013, Congress of Representatives 2013, Goldenberg 2013, Entine 2011); 4) US aquaculture industry (Joy 2010); 5) other nations expressing the interests of their aquaculture industry (Development Fund 2013); 6) the animal biotechnologists and the biotech industry (Prakash *et al.* 2012, Muir 2013 and Roberts *et al.* 2014); 6) food related NGOs (<http://www.centerforfoodsafety.org> <http://www.foodandwaterwatch.org> see for example Larsen 2014) 7) the US retailers and consumers (Burros 2002). For a general overview of the recent chronology see:

http://www.thestar.com/projects/genetically_modified_food_should_we_fear_this_fish.html

the implementation of effective ad hoc technoscientific silver bullets.

Moreover, innovation is taken as the mainstream solution in order to keep sustaining growth in a hyper-saturated market, by opening up new pathways of competitiveness and consumption, to be filled with new, constantly upgraded and more seductive products and services.

Finally, in order for the whole narrative to be functional, a fundamental condition has to be met: citizens of developing, developed and declining economies have to value and ultimately buy - both metaphorically and literally - the processes and products of technoscientific innovation. This means that the societal expectations about the goods have to be encouraged and the concerns about the bads deflected (EC 2013).

In terms of food production, this narrative was first at work in the 60s, with the wonders of the "Green Revolution": the prospect to intensify and optimize the process of agriculture and farming through the use of chemical and mechanical technologies, all based on fossil fuels. With the industrialization of the production system and the ability to accumulate a significant surplus, the commodification of food became possible. As a result of this process, food began to be considered for its exchange-value first, and its use-value only second (Araghi 2003). The ideal of technological power as a way to provide food security and at the same time economic growth was then established. Production efficiency had to be indefinitely increased in order for industries to continue growing and rising return of investments: the combination of selective breeding, fertilizers and pesticides became essential for the whole system to be functional. This focus on optimization necessarily externalized environmental degradation and ecosystems disruption, and fostered the idea that natural resources could be substituted with technologically enhanced products.

In early nineties, with the globalization of food markets, this transition was deepened by a number of factors, including the decoupling of animal farming from land (Naylor et al. 2005) and the onset of genetic engineering into the agri-food industry (Jasanoff 2005). With the so-called “Gene Revolution”, biotechnology monopolized the scene of technoscientific innovation for food production, with the promise of boosting yields and reducing production costs and environmental impacts, thus ensuring – again – both higher profits and food security for a growing population. This further move towards the commodification of food consisted on the possibility to transform the conventional practice of selective breeding into an invention – through direct genetic manipulation – that could be patented, just like any other technological breakthrough. In the late nineties, this further technoscientific move encountered the opposition of citizens and governments, especially within the European Union, for a combination of environmental, health and economic concerns (Jasanoff 2005). In a quite unanticipated scenario, the biotech industry had to develop a whole new set of positive narratives, in order to balance the resistance of both investors and consumers (Benessia and Barbiero 2012): once again, the urgent need to feed a fast growing global population, then the necessity to adapt to and even mitigate climate change, and finally the possibility of limiting the use of chemical and pesticides. These were developed then as main arguments in favor of a transition to a genetically engineered agriculture system.

Around the same time and within the same context, the farming of aquatic organisms in controlled environments became a global industry, supplementing the declining supply of fisheries and increasing the global fish market. In perfect analogy with industrial agriculture and farming, the ideal of the “Blue Revolution” is to use technology to maximize productivity by reducing unpredictability – in this case of harvesting fish – and boosting the

efficiency of animal growth and feed-to-biomass ratio through selective breeding.

A new “food regime” was then in place, where animal proteins produced with feed from a variety of nations were channeled into consolidated food chains to supply privileged consumers with fresh meat and fish (McMichael 2009).

As we have seen, in the same years, a US aquaculture industry named E/F Protein developed and patented a fast-growing fish called AquAdvantage salmon. The US Food and Drug Administration was then appointed to regulate its possible commercialization for human consumption.

3.2 The salmon industry: optimization and substitution

Today, approximately half of all fish consumed by humans is raised on farms and modern industrial salmon aquaculture is among the most relevant and profitable form of fish farming (FAO 2014). The recent history of the relationship between human beings and salmon follows a common pattern of over-exploitation and environmental degradation, leading to a major decline in the wild fish populations, both in the Atlantic and the Pacific rivers and oceans (Greenberg 2010). Like with other natural resources, we are facing the paradox of a required production growth within a regime of increasing scarcity. The majority of the world’s fisheries are either fully exploited, overexploited, or depleted. It is estimated “that the global ocean has lost more than 90% of large predatory fishes” since the pre-industrial level (Meyers and Worm 2003).

In the framing of innovation, the growing demand of seafood is driven by consumption needs, caused population growth and a legitimate call for healthier sources of animal proteins, leading to the necessity of producing more fish for the global market. On the other hand, scarcity of salmon resources

is due to overfishing and habitat depletion. The solution to this conundrum consists on a number of technological fixes, enacted both as conservation measures and production boosts. These innovations are founded on two fundamental principles: optimization and substitution. The first is the ideal that the efficiency of production can be increased more or less indefinitely, through a progressive reduction of the matter, energy and time involved in the process. This is only possible if a second assumption is considered, i.e. that natural resources can be substituted with technologically enhanced artifacts. In our case, the ecological and biological characteristics of salmon can and have to be altered so that they no longer require free-flowing clean rivers for spawning and reproduction, and entire seasons in the ocean for predated and maturing.

In their recent studies on fisheries and aquaculture, US environmental sociologists Clausen, Longo and Clark (2012, 2014 and 2015) provide a compelling historical and socio-economic analysis of these technoscientific fixes on wild salmon, essentially structured in three phases: hatchery enhancement, conventional fish farming and genetic engineered inland aquaculture. In our context, each phase corresponds to the substitution of a component of salmon lifecycle, in order to keep optimizing the production process and increasing its output, in spite of environmental degradation and ocean depletion.

The first hatchery-enhancement policies, introduced in the late nineteenth century in Basin Columbia, aimed at supplementing wild population to increase the number of salmon that could be sold on the market, while mitigating the effect of salmon habitat degradation. At that time, the migratory rivers were progressively covered with dams to supply with hydroelectric power the raising industries and irrigation-intensive farms, and the clean, oxygenated watersheds

were polluted by agricultural run-off and industrial waste (Lichatowicz 1999). Salmon could no longer reach their natural spawning grounds and the technical solution was to substitute natural with artificial spawning: fish managers could extract the eggs and milt from salmon brook stock, mix their genetic material and raise the fertilized eggs in closed containers. Once the salmon grew enough in the hatchery, they would be released into selected streams and allowed to reach the oceans. This technological fix introduced the issue of genetic pollution: the genetic traits selected to optimize the salmon's early life in the hatchery environment decreased their fitness in natural environment. As they were interbreeding with wild salmon, they ended up weakening the overall population and paradoxically contributing to its further decline. In other words, the substitution had a cost.

The next stage in the process of optimization was the introduction of salmon farming, which expanded in the global market in the early 1980s. In this case, the entire migration process is eliminated and salmon remain in captivity for their whole lifecycle. The young smolts¹⁴ are transferred from the hatchery where they were born to net pens or cages suspended in coastal marine waters, where they are artificially fed and allowed to grow until right before sexual maturity. At that time, they are harvested and sold.

By compensating and ideally substituting traditional fishery in the global market, this innovation is meant to eliminate the need to regulate harvest and protect or restore salmon habitat. Moreover, this optimization process allows producing fresh salmon all year around, of uniform size and features. In analogy with industrial agriculture and farming, conformity and predictability substitute variety and seasonality. Moreover, as the industrialization process is complete,

¹⁴ The young salmon are called smolts when they are ready to live in saltwater.

the energy, matter and time required to produce one salmon can and have to be optimized: through selective breeding, photoperiod and water temperature manipulation, mechanized and high performance feeding. The costs of this substitution, namely the physiological, environmental and ecological drawbacks – such as infectious salmon anemia (ISA) outbreaks, sea lice infestations, water and genetic pollution – are supposedly controlled and treated through more fixes and containment measures, or simply externalized (Lymbery 2002). Moreover, as the natural ratio between big predators - such as salmon - and the small fish they eat is broken, a new resource scarcity issue has to be solved. Small fisheries and the fish oil derived from them, fundamental for intensive aquaculture feed, are rapidly declining.

In this framework, salmon is conceived and valued as a commodity for global markets, requiring constant growth and returns on investments, rather than as a nutritional food source and a component in an ecosystem. Interestingly though, in order for the whole system to be functional, as we have mentioned, people have to value farmed salmon in order to buy them, and they are certainly more inclined to do it if they identify them as a source of healthy and environmentally friendly food, than as an industrially optimized commodity. Hence the inherent ambivalence of the whole narrative of innovation: For investors, salmon farming is the best solution for optimizing the production process and boosting productivity and profits. For consumers, salmon farming is meant to fix the issue of wild fish population decline, while feeding a growing human population with a healthy and cheap source of animal proteins. This is the ideal and controversial win-win scenario of sustainable growth (Benessia and Funtowicz 2015): one interesting open question in this regard is if the actual demand of seafood is driven by production (i.e. need for economic growth) or consumption (i.e. actual need for food). From

what we have seen, in the current “third food regime”, the former is a far more likely candidate for an answer than the latter.

In this overall context, the idea of producing a genetically modified, fast-growing salmon for human consumption becomes perfectly understandable and not novel at all, as belonging to the same path-dependent trajectory of innovation. The narrative associated with the product of AquaBounty follows the lines of the previous technologies: For the consumers, it is meant to address the issue of global hunger and provide healthy and cheap animal proteins (Smith et al. 2010), while tackling the problem of fishery depletion (the first level of environmental cost of the industrialization process). Moreover, it promises to fix the ecological consequences of the technology it is supposed to replace, namely the environmental pressure of conventional aquaculture (the second level of environmental costs). For the investors, transgenic salmon aquaculture is meant to further lower the budget of production, by improving productivity and profit shares¹⁵.

All this is proposed at the price of a new kind of substitution, within the salmon’s own physiology. The idea is to push the optimization process one step further by enhancing the fish metabolism so that it requires even less time, space and matter to grow to market size. What was originally a wild fish is substituted with a technoscientific, patented invention¹⁶. As we have explored in the first part of our work, once again, this substitution has an inherent cost, represented by the higher stakes in

¹⁵ This aspect is controversial, as it depends on the amount of licensing fees for the patented eggs and the cost of the environmental conditions and the containment measures required for deployment (Kelso 2003).

¹⁶ The AquAdvantage salmon was defined as one of ten best inventions of 2010 by Times magazine (Walsh 2010).

terms of public and private investments, health and environmental risks.

Finally, given the resistance of both potential consumers and investors (Kelso 2003), a new set of arguments is added to the narrative, mainly directed to regulators and based on the political economy of food, namely the global competition for market shares. First, as a major innovation in the homeland industry of fish farming, the production of transgenic salmon is aimed at bridging the gap of the US seafood trade deficit (Forristall 2014). Second, a refusal or even a delay in the approval of the new technology could create a possible competitive disadvantage with other countries eventually ahead in the business of transgenic animal food (Maxmen 2012, Van Eenennaam in Watson 2013).

The AquAdvantage salmon can then be interpreted as the tip of the iceberg of a global, fully commodified food production system whose dynamic is constrained within the path-dependent trajectory of innovation. However, as the stalling FDA regulatory status manifests, the emergent complexity and radical uncertainty of this open-field experimentation challenge its inevitability and open up a democratic space of discussion.

We devote our concluding remarks to explore how.

4. Concluding remarks: evaluating the quality of (GE) salmon

As we have mentioned, the whole narrative of innovation can only be functional if the citizens and potential consumers value and ultimately buy the products of the emergent technologies. This means that the societal expectations about the goods have to be encouraged and the concerns about the bads deflected. The set of arguments that we have reviewed so far have precisely this function. However, the ultimate fate of a new technology fundamentally depends on identifying what the goods and the bads

actually are and for whom, at any given time. This recognition has to do with how the product of technoscientific innovation is valued, therefore with its quality.

Failing to acknowledge the quality criteria of potential consumers and investors can be lethal, and it is at the heart of the so-called “Concorde syndrome” (Giampietro 2009). The Concorde syndrome occurs when the framing of the problem to be solved and therefore the technoscientific tools provided to address it, are obsolete with respect to the actual social perception of what the needs to be fulfilled are. In the case of the legendary airplane, the problem to be solved was to build a supersonic commercial aircraft that could fly much faster than all its competitors – as a matter of fact twice as fast – so as to become the preferred carrier for both investors and customers. However, the Concorde was permanently dismantled in 2003, and not because it was more risky or environmentally harmful, but because the actual flying time did not prove to be a critical factor for choosing it, and the global aviation industry ended up privileging slower, time flexible and cost effective flight systems.

In our case, the application of genetic engineering to commercial aquaculture in order to further optimize production rates and profits might end up being a failure, independently of the outcome of the regulation process, for two orders of reasons.

The first is more pragmatic: the overall limited potential economic gain of transgenic aquaculture (still to be demonstrated) might not justify switching to a new costly, risky and highly secured technology from conventional aquaculture practices. Moreover, the selectively bred salmon industry might boycotting it, fearing that the public perception of transgenic fish as environmentally risky would increase the social controversy and conflict surrounding its practice in the US and Canada, making the industry expansion more difficult.

The second order of reasons is more radical: it might well be that this ultimate technoscientific substitution process stretches excessively the definition of what a salmon is, possibly tearing apart the very texture of the space in which the trajectory of innovation moves along. The framing of food as a commodity entails the application of the principle of substantial equivalence, at the foundation of FDA's impact assessment procedure. This means that independently from their taste, texture, smell, cultural traditions and above all, independently of the process by which they are produced, food products with essentially the same nutritional components are assigned to the same category, and have all the same quality. In this framing, wild Atlantic salmon is equivalent to farmed Atlantic salmon, and the latter is in turn equivalent to the transgenic AquAdvantage salmon. It might well be that this equivalence breaks down on the shelf of grocery stores and on the tables of US consumers¹⁷, and not necessarily only for (more or less scientifically-based) health or environmental fears, but also because they simply don't identify the farmed (GE) salmon as valuable food¹⁸.

¹⁷ In September 2010, a US public survey commissioned by the Center for Food Safety showed that 91% of Americans opposed the commercialization of genetically engineered fish and meat into the market place, 83% of which strongly so (Lake Research 2010). Around the same time, more than 60% of readers of the conservative Wall Street Journal declared that they wouldn't eat the transgenic salmon (Wall Street Journal 2010). In 2013, the FDA public hearing period after the release of the GE salmon environmental assessment ended with 1,8 million of comments against the approval. Meanwhile, since 2002 some of the main US retailers such as Trader Joes, Whole Foods, Alti and Marsh, joined by a number of US chefs and grocers publicly declared that in case of approval they would not sell the GE salmon (Burros 2002).

¹⁸ The issue of the labeling of GE salmon is still unresolved, although an overwhelmingly 93% of US consumers are in favor (Thomson Reuters 2010). The

Indeed, the public's health and environmental concerns are shaped only in part by the scientific/technical information developed within regulatory impact assessments. More fundamentally, they emerge from inherently political issues about what risks are acceptable under what circumstances, and about how to evaluate the food they eat. If we unlock the framing of innovation at its roots, we may find a collective democratic space for discussing different quality criteria, based for example on the use-value of food, the inherent socio-ecological value of a species and of the entire landscape it depends upon. More generally, the question becomes: how many categories are needed to describe our food and who decides about the definitions to be adopted for the various categories?

This reflective awareness triggers the possibility of exploring alternative trajectories for our food production system and redefining the quality assessment criteria for its evaluation. Robust and resilient innovations can only emerge from opening up the collective space of options for both the framing of the problems to be solved and the tools proposed to solve them.

In our case, even if we keep the framing of the problem proposed by ABT, namely the growing population and demand of salmon, the decline of the wild population and the environmental and health drawbacks of open-water net-pen aquaculture, then transgenic salmon are not the only available option. A plurality of strategies and tools can be considered. The Arctic char, a close relative of the Atlantic salmon, is already being grown nearly exclusively in closed containment facilities and requires no genetic modification. Its taste is comparable to the one of farmed salmon and, given its size and texture, it performs all the culinary functions

resistance from ABT and in general from the biotech industry indicates the relevance of the consumers' quality assessment criteria.

of its comparator¹⁹ (Greenberg 2010a). Furthermore, a closed-containment-grown Coho salmon that is not genetically modified is now in production and has been evaluated as "best choice" by the Monterey Bay Aquarium's Seafood Watch²⁰ (Greenberg 2010b). Finally, a promising experiment of closed-containment, ecologically friendly, non transgenic, fast growing Atlantic salmon aquaculture is undertaken in the Northeast corner of Canada's Vancouver Island, by the 'Namgis First Nation, under the name of Kunterra project (Sittls 2014).

If, on the other hand, we question the framing itself, then we can argue that the actual demand for salmon could be reduced and balanced by incorporating into our food habits a variety of seafood products, including smaller fish, and an even larger diversity of animal and vegetal proteins, depending on our culturally, historically and geographically based food tradition. Moreover, the very old, artificial separation between the problem of the wild salmon decline and the preservation of its socio-ecological habitat could be removed.

A project like the Pebble copper, gold and molybdenum mine proposed for Bristol Bay in Alaska, could wipe out the most abundant and productive sockeye salmon grounds in the world—an annual run of 40 million fish²¹. If we fully embrace the dominant narrative of innovation and the principle of substantial equivalence, then this sanctuary of wild salmon and traditional fishery practice could be substituted by a number of aquaculture (transgenic or non-transgenic) farms, conveniently dislocated in areas where they don't conflict with the mining operations. The

win-win scenario would then be having the same or larger amount of salmon per year and foster the economic growth of both the mining and the aquaculture industry. On the other hand, if we question the dominant narrative of innovation and we apply different quality assessment criteria based on community and ecological needs, then the whole idea of destructing one of the few preserved habitats for wild salmon and for all the socio-ecological systems involved, becomes untenable²².

In conclusion, opening up a democratic space for evaluating the quality of innovation means being able, with time and imagination, to explore the controversies and conflicts emerging within its dominant trajectory, questioning not only the technologies involved, with their future risks and promises, but also and most importantly, the driving forces that might bring them – or not – into the world today.

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¹⁹ See for example <http://www.icywaters.com>

²⁰ See <http://www.seafoodwatch.org/consumers/seafood-and-your-health>

²¹ For more details, see <http://www.savebristolbay.org/about-the-bay/about-pebble-mine>

²² A legal, political and scientific controversy, fully analogous to the one we have explored in the first part of our work, is currently unfolding in the US regulatory system, through the authority of the Environmental Protection Agency (Reynolds 2015).

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