

**GENETICALLY MODIFIED ORGANISMS IN AQUACULTURE:
FROM PRESENT TO FUTURE**



AMANDA NICHOLS
OCEAN AND COASTAL LAW FELLOW

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TABLE OF CONTENTS

I. Introduction	1
II. The Use of GMOs in Aquaculture	2
III. Current Regulation	4
IV. Third Party Labeling.....	5
V. National Bioengineered Food Disclosure Standard Final Rule	6
VI. The Future of GMOs in Aquaculture	8
VII. Conclusion	10

I. Introduction

The term “GMO” generally refers to a plant or animal that has been given new traits through modern genetic manipulation, in one of two ways: 1) genetic material from unrelated species are combined; or 2) heavily modified DNA is inserted into an organism’s genetic code.¹ Genetic modification (GM) has been utilized by humans throughout history. For example, selecting organisms with the most desired traits and breeding them is a form of genetic modification. Any offspring the breeding pair yields will possess a combination of their parents’ desirable traits to a certain degree. The birth of modern genetic modification, however, didn’t occur until the 1970s, when two scientists created the first successful genetically engineered (GE) organism by specifically cutting out a gene from one organism and pasting it into another. In 1980, the U.S. Supreme Court permitted ownership rights over GMOs, thus giving large companies the incentive to develop GM tools that would be both useful and profitable.² Since then, genetic engineering has been applied in multiple agricultural contexts, including the creation of GMO salmon for use in aquaculture.

With the advent of modern genetic engineering techniques, GMOs have swiftly become a topic of controversy and public debate. Proponents of GE food argue that the products have generally been proven safe, and genetic engineering of plants and animals helps bolster the world’s food supply. However, opponents allege that credible, independent feeding studies conducted long-term do not exist, and, thus, the true safety of GE food is unknown. Additionally, critics residing in the United States cite the current lack of mandatory, federal labeling laws that allow consumers to make informed choices regarding the influence of genetic modification in the products they choose to buy.³ Further negative arguments allege GE crops threaten farmer sovereignty due to biotechnology companies’ freedom to patent GE seeds and animals in the United States.

As genetic modification becomes more pervasive in terrestrial agriculture, the aquaculture industry has shown growing interest, hoping to utilize the technology to increase both the sustainability and productivity of commercial farms. From an environmental perspective, genetic modification can allow farmers to cultivate larger individuals more quickly, potentially reducing the aquaculture industry’s reliance on wild fish populations for feed. Economically, the technology could prove beneficial as well, drastically increasing the amount of fish farmers can cultivate and market within a specific time period. However, critics doubt the benefits that cultivation of GE fish and shellfish could yield, arguing that widespread use of the technology carries unknown human and environmental risks. Due to such criticism, as well as the complicated regulatory landscape aquaculturists wishing to market GE fish and shellfish must navigate, the future of genetically modified aquacultural products in the United States is uncertain. This report examines the current role of GMOs in aquaculture, outlines the regulations governing product labeling and sale, and analyzes the factors driving the future of GE fish and shellfish marketed domestically.

¹ *What are GMOs?*, GENETIC LITERACY PROJECT, <https://gmo.geneticliteracyproject.org/FAQ/what-are-gmos/>.

² *Diamond v. Chakrabarty*, 447 U.S. 303, 303, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (1980).

³ As discussed further in this report, while the United States has enacted a mandatory, federal labeling law, it has not yet become enforceable.

II. The Use of GMOs in Aquaculture

a. Cultivation

GMOs used in the context of aquaculture are most commonly discussed in relation to the cultivation of genetically modified species. Most genetic modification at this level aims to increase food production by modifying the expression of growth hormone. Over-production of growth hormone from a fish's pituitary gland increases growth rate mainly due to increased food consumption, but also because of improvement in feed conversion efficiency.⁴ Some GE fish are also induced to develop "double muscling," which utilizes genes that grow an extra muscle layer in order to increase meat production.

Perhaps the most noteworthy company utilizing genetic modification in aquaculture is AquaBounty Technologies. AquaBounty, a biotechnology company based in Massachusetts, first developed their GE AquAdvantage salmon with a goal of increasing the productivity of aquaculture. The hybrid Atlantic salmon incorporate a growth hormone-regulating gene from Pacific Chinook salmon, as well as a promoter⁵ sequence from ocean pout that acts as an antifreeze protein, thereby enabling the fish to grow year-round instead of only during the spring and summer. The resulting fish can reportedly grow to market size in 16 to 18 months rather than the three years that conventionally cultured salmon require. While these traits may appear quite favorable in farmed fish, AquaBounty has faced significant pushback from the United States in marketing its salmon.

In November 2015, the FDA approved AquaBounty's application to sell AquAdvantage salmon to U.S. consumers, a decision marking the first time a GE animal had ever been approved to enter the U.S. food supply. However, a rider to the 2016 Omnibus Appropriations Act banned its import until the appropriate governmental agency could mandate labels for the product. Following the Omnibus Appropriation Act's passage, the FDA issued an Import Alert for the salmon, meaning that all future shipments of AquAdvantage salmon into the United States could be refused admission without physically examining the product in each shipment. This Alert severely imperiled AquaBounty's plans to market its salmon to U.S. consumers, although the company successfully made its first sale of 4.5 tons of the fish to Canadian customers in July 2017.

b. Feed

Genetic modification can also be utilized in growing crops that help feed commercially farmed fish. Traditionally, fishmeal and oil have been used to feed cultured species, requiring that an average of one to two pounds of fish be used as meal in order to produce one pound of farmed fish. A growing demand for farmed fish means that demand for fishmeal and oil grows as well, therefore putting strain on wild fisheries, from which the fish used in fishmeal are typically harvested. To help combat this strain and encourage sustainability of the industry, aquaculturists are increasingly looking to soy as a feed

⁴ "Feed conversion" here references the efficiency with which farmed fish convert feed into meat that can be consumed by humans.

⁵ In genetics, a promoter is a region of DNA that initiates transcription of a particular gene. Transcription is the first step of gene expression, in which a particular segment of DNA is copied into RNA by the enzyme RNA polymerase.

supplement. Soybeans are one of the world's best non-animal sources of omega-3 fatty acids, healthy proteins, and unsaturated fats, and soy protein can be fed to farmed fish and shellfish to support their growth and development. Doing so can replace anywhere from one-third to one-half of the fishmeal and oil in feeds for many farmed species, thus reducing the need for wild-caught fish. Soybean meal also costs significantly less than most animal meals, including fishmeal.

As of 2014, 94% of the soybeans farmed in America were genetically modified in some way, usually to increase the production of oil production and/or oleic acid.⁶ As a result, even when fish themselves are not genetically modified for cultivation purposes, they may have consumed some amount of GE food prior to harvest. Consequently, some have argued that those fish should bear labels disclosing the possible presence of GE material when marketed, while others argue that such a labeling requirement would go too far, as “there is no ‘evidence whatsoever of any harmful impacts of GE soy to fish, to humans or to marine ecosystems.’”⁷ The use of GE soy in fish feed also raises issues with the sale of aquacultural products in some international markets, as European consumers, for example, are generally reluctant to purchase and consume products from animals fed with GMOs.

III. Current Regulation

a. Federal Law

Until recently, GMOs in the United States were solely regulated under the Coordinated Framework for Regulation of Biotechnology (“Coordinated Framework”). The Coordinated Framework is a risk-based system that ensures new biotechnology products are safe for the environment as well as human and animal health. It is based on existing laws governing conventional (non-organic) products that are designed to protect public health and the environment, and is administered by several federal agencies, including: 1) the USDA’s Animal and Plant Health Inspection Service (APHIS); 2) the FDA; and 3) the EPA. Depending on its characteristics, a product may be subject to the jurisdiction of one or more of these agencies, and regulatory officials from the three agencies regularly communicate and exchange information to ensure that any safety or regulatory issues that may arise are appropriately resolved.

Under the Coordinated Framework, plant GMOs are regulated by APHIS under the Plant Protection Act, while GMOs present in food, drugs, and biological products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as well as the Public Health Service Act. GMO pesticides and microorganisms are regulated by the EPA pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act as well as the Toxic Substances Control Act.

The FDA, under its authority to regulate “new animal drugs” (NADs), regulates the use of GMO fish in aquaculture. Under the FFDCA, the FDA generally deems NADs to be unsafe unless the agency has first approved a New Animal Drug Application (NADA) for the particular use of the NAD. Except in cases

⁶ Soy, NON-GMO PROJECT, <https://www.nongmoproject.org/high-risk/soy/>.

⁷ James Wright, *GMO labeling a sticky situation for seafood*, SEAFOODSOURCE (Sept. 1, 2013), <https://www.seafoodsource.com/news/environment-sustainability/gmo-labeling-a-sticky-situation-for-seafood>.

where the FDA exercises its discretion to decline to require compliance, or where a NAD is statutorily exempt, the FDA requires that a GE animal gain approval through a NADA based on a demonstration that it is safe and effective for its intended use. Such a NADA must include information regarding the animal's identification; chemistry; clinical purpose; labeling; components and composition; manufacturing methods, facilities, and controls; safety and effectiveness; and environmental impact, among other things.⁸

In addition to the Coordinated Framework, President Obama signed the National Bioengineered Food Disclosure Law ("Disclosure Law") into effect in 2016, which amends the Agricultural Marketing Act of 1946, and requires that the federal government establish rules governing the labeling of GMO products within two years of enactment. Specifically, the Disclosure Law charges the USDA's Agricultural Marketing Service (AMS) with establishing a standard for disclosing the presence of bioengineered ingredients in a rule entitled the National Bioengineered Food Disclosure Standard ("National Standard"). The USDA published its final rule on the National Standard on December 21, 2018,⁹ with enforcement anticipated to commence on January 1, 2020. The specifics of the final rule and its potential impact on GE aquacultural products are discussed later in this report.

b. State Law

State law matters little in the regulation of GMO labeling in the United States. The doctrine of "federal preemption" bars conflicting state regulations when Congress either expressly or impliedly intends for federal law to fully occupy a particular field. The Disclosure Law—promulgated in response to Vermont's efforts to regulate GMO labeling and disclosure requirements within its borders—expressly overturns all active state legislation related to GMO labeling and preempts any further state laws. However, the Disclosure Law does permit states to enact GMO disclosure laws that are identical to the National Standard. In preempting state GMO regulations through the Disclosure Law, the federal government avoids the possibility that a patchwork of labeling laws are enacted across the country, with varying requirements and stringency from state-to-state.

States do, however, have the ability to create laws that wholly prohibit GE animal species from being imported into their borders. In the context of aquaculture, these types of regulations are often created to prevent the harm that accidental introduction of GE fish or shellfish into native waterbodies could impose. Delaware, for example, has adopted such a regulation into its Administrative Code. The state first defines "non-native finfish species" to include genetically modified, native species of fish.¹⁰ It then defines "invasive finfish species" to include such non-native finfish species (as well as their eggs and other biological material) that are capable of spreading, reproducing, or propagating, and whose introduction or proliferation either causes or is likely to cause economic or environmental harm or harm to human

⁸ Luis Acosta, *Restrictions on Genetically Modified Organisms: United States*, LIBRARY OF CONGRESS (Mar. 2014), https://www.loc.gov/law/help/restrictions-on-gmos/usa.php#_ftn57.

⁹ 7 C.F.R. § 66 (2018).

¹⁰ DEL. CODE ANN. tit. 7, § 9.942(a)(2).

health or safety.¹¹ The State is permitted to authorize, regulate, prohibit, prescribe, or restrict anywhere in Delaware the acquisition, importation, introduction, possession, transportation, disposition, or release into public or private tidal waters any such invasive finfish species (including their eggs and other biological material).¹² In effect, this allows the state to prevent GE aquacultural products from entering the state, so long as they fall within the scope of the regulation's definitions. In another example, Florida requires certified aquaculturists to receive state authorization before culturing GE fish species, and authorization will only be considered if such culture will not pose a threat to the public health, safety, and welfare.¹³ Regulations such as these can limit the states in which GE aquacultural products can be propagated and perhaps even marketed.

IV. Third-Party Labeling

Producers not required to disclose the presence of GMOs in their foods under the Disclosure Law may wish to signify the absence of such through the use of third-party labels. Even those entities that must mandatorily disclose may choose to utilize additional, third-party labels on their products' packaging to denote satisfaction of different, perhaps more stringent standards. Third-party labeling certifications are created from private, voluntary standards, and can serve as informative markers for consumers. While third-party labelers set their own standards, they use unbiased, non-stakeholder entities to verify that such standards are being met. Furthermore, many third-party certifiers implement a public comment or consumer-driven consultation period to incorporate feedback and critique in shaping their standards. Such opportunities help build trust among manufacturers and consumers utilizing the labels.

Perhaps the most commonly utilized third-party certifier of non-GMO products is the Non-GMO Project. Its Project Product Verification Program is currently North America's only third-party labeling certification for non-GMO food and products.¹⁴ In order to become verified through the Program, manufacturers must work with an outside technical administration company that provides unbiased evaluations on a product's ingredients as well as the facility in which it is manufactured. After successful verification, the technical administration company issues a certificate of compliance, and the manufacturer can begin using Non-GMO Project labels on the packaging of any verified products. Consumers can easily access the Non-GMO Project's own standards online, thus increasing their confidence that a product bearing the third-party label meets certain criteria. Use of third-party labels can also increase revenue for producers as consumers continue to demand higher quality standards in the products they buy. Even upon federal enforcement of the National Standard, third-party labelers such as the Non-GMO Project can continue to serve an important role for consumers by enforcing different or more stringent labeling requirements that those imposed by the government.

¹¹ *Id.* at § 9.942(a)(1).

¹² *Id.* at § 9.942(b).

¹³ Florida Department of Agriculture and Consumer Services, Aquaculture Best Management Practices Manual 30 (2016).

¹⁴ *About, NON-GMO PROJECT*, <https://www.nongmoproject.org/about/>.

V. National Bioengineered Food Disclosure Standard Final Rule

The USDA's National Bioengineered Food Disclosure Standard (NBFDS) final rule requires food manufacturers, importers of food labeled for retail sale in the United States, and some domestic retailers to disclose foods and ingredients produced from food that are or may be genetically modified. The rule contains multiple provisions that both directly and indirectly impact the aquaculture industry, including those related to definitions, listed foods, disclosure methods, exemptions from disclosure, and enforcement. Understanding the content of these provisions can help in assessing the marketable future of GE aquacultural products in the United States.

a. Definitions

The NBFDS final rule sets forth many definitions of significance, one of which outlines what foods are subject to the rule's disclosure requirements. Under the NBFDS final rule, "food," as defined by the FFDCa, is generally required to possess labeling disclosing the presence of GMOs only if it is intended for human consumption. Animal feed, for example, would not be required to bear such disclosure labeling. The preamble to the final rule goes on to note that both raw agricultural commodities as well as processed items qualify as "food." Furthermore, dietary supplements, processing aids, and enzymes fall within the scope of the definition.

Additionally, the final rule replaces the popularized term "genetically modified organism" and its abbreviation "GMO" with the term "bioengineered food" and its abbreviation "BE." "Bioengineered food" is defined as food that contains genetic material that has been modified through *in vitro* rDNA techniques and for which the modification could not be otherwise obtained through conventional breeding or found in nature.¹⁵ This definition narrows the general definition of GMO somewhat, making it clear that the National Standard will require disclosure only when foods contain genetic material introduced through bioengineering. As a result, the final rule does not apply to pure oils, starches, and sugars because they do not contain genetic material even when produced from bioengineered crops.¹⁶

Additionally, the definition specifically excludes foods where modified genetic material is not detectable. To demonstrate this undetectability, an entity must maintain records that either: 1) verify that the food is sourced from a non-BE crop or source; 2) verify that the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable; or 3) certify that testing or other analysis appropriate to the specific food has been conducted that confirms the absence of modified genetic material.¹⁷

¹⁵ 7 C.F.R. § 66.1.

¹⁶ Jacqui Fatka, *USDA releases final bioengineered food disclosure standard*, FEEDSTUFFS (Dec. 20, 2018), <https://www.feedstuffs.com/news/usda-releases-final-bioengineered-food-disclosure-standard>.

¹⁷ 7 C.F.R. § 66.9(a) (2018).

b. Listed Foods

The NBFDS final rule next promulgates a single “List of Bioengineered Foods” meant to identify the crops or foods that are both: 1) authorized for commercial production; and 2) reported to be in legal commercial production for human consumption somewhere in the world. The List also helps determine whether a food must bear a BE disclosure. If an entity utilizes a listed food or ingredient on its own, or if a product is sourced from a listed food or product, that entity must maintain records regarding the food or ingredient that help drive the disclosure determination. If a food or food ingredient is present on the List and the entity’s records show that the specific food they have utilized is BE, the food must bear a BE disclosure if no exemptions otherwise apply. In the context of aquaculture, the list specifically includes AquaBounty’s AquAdvantage salmon, meaning that foods containing the fish either in whole or in part must disclose the presence of BE technology through one of the final rule’s listed methods.

The List is not exhaustive, and AMS acknowledges that it may not be complete. Therefore, the agency has stated it will consider revisions to the List annually, soliciting recommendations regarding updates and taking into account supporting information and input from other federal agencies. Following an internal review, AMS will then determine whether to initiate rulemaking to amend the List, and if the List is revised, regulated entities will have 18 months to make updates to their labels as needed.

c. Disclosure Methods

For those entities subject to mandatory disclosure, such disclosures must appear prominently and conspicuously on a product’s label, and must also be easily read and understood by consumers. The rule provides four different methods for companies to disclose the presence of GE products in food when modified genetic material is detectable. Companies may either: 1) include clearly written disclosure text on their product’s nutrition information panel; 2) place the USDA’s new symbol for bioengineered food on the packaging; 3) include a QR code on the packaging that consumers can scan with their smartphones; or 4) include a text message disclosure on the packaging, such as “Text [word] to [phone number] for bioengineered food information.” The rule also provides additional disclosure options for small food manufacturers as well as modified disclosure options for small and very small packages.

In addition to mandatory disclosures, the final rule also provides for those entities that wish to voluntarily disclose the presence of BE foods in their products. Entities may choose to do so if either: 1) they are otherwise excepted from the requirements of the NBFDS, but wish to disclose the presence of a food included on the List of Bioengineered Foods;¹⁸ or 2) a food does not meet the definition of “bioengineered food” but is derived from listed BE crops or food.¹⁹ In the latter “derived from” scenario, food cannot act as an incidental additive nor can it be otherwise exempt under 7 C.F.R. § 66.5 in order to qualify for voluntary disclosure.

¹⁸ An exception from mandatory disclosure could arise either due to the undetectability of BE material in a food product or because of a product or entity’s qualification under one of the final rule’s five listed exemptions.

¹⁹ 7 C.F.R. § 66.116.

d. Exemptions from Disclosure

In 7 C.F.R. § 66.5, the NBFDS final rule outlines five exemptions that excuse certain entities from the rule's otherwise mandatory disclosure requirements. First, food served in a restaurant or similar retail establishment (including food trucks and transportation carriers) is exempt. AMS also notes that salads, soups, and other ready-to-eat items prepared by grocery stores are additionally exempt. Second, the final rule exempts very small food manufacturers with annual receipts of less than \$2.5 million. Third, the rule sets a threshold for the inadvertent or technically unavoidable presence of bioengineered substances. If a BE substance is included in a food in amounts up to 5% for each ingredient, it is exempt from disclosure requirements. Fourth, food derived from an animal is prohibited from being considered a BE food solely because the animal consumed feed produced from, containing, or consisting of a BE substance. Finally, food certified under AMS' National Organic Program (NOP) is exempt. This exemption covers all NOP-certified label categories. As use of genetic engineering is prohibited in products bearing a USDA Organic seal, this exemption stands to reason. Any products bearing the seal will have already undergone certification that they are free of BE substances before being retailed.

e. Enforcement

The final provisions of the NBFDS final rule discuss enforcement. The rule makes it a prohibited act for an entity to fail to make a mandatory BE food disclosure. Those found to have done so will be subject to further investigation by AMS, a record audit, and potential agency-imposed penalties. If an entity subjected to a record audit requests a hearing on the results of that audit, the final rule also includes procedures for how the hearing can be requested as well as AMS' role in reviewing and potentially revising its findings. Ultimately, the summary of the results of an audit or the summary of the final results of an investigation at the conclusion of the hearing will be made public.

The rule's voluntary compliance period for regulated entities other than small food manufacturers²⁰ begins on January 1, 2020. The compliance period for small food manufacturers begins on January 1, 2021. During this period, regulated entities may use labels that meet the requirements of preempted state labeling regulations for GE food. Stickers or ink stamps may be applied to existing labels to provide appropriate BE food disclosures provided that they do not obscure other required label information. The voluntary compliance period ends on December 31, 2021, and January 1, 2022 marks the beginning of mandatory compliance. By that date, all regulated entities must comply with the requirements of the NBFDS.

VI. The Future of GMOs in Aquaculture

AMS's promulgation of the NBFDS final rule could mean a great deal for the future of cultivated GE salmon in the United States—AquaBounty's AquaAdvantage salmon, in particular. With the inclusion of AquaAdvantage salmon on the rule's List of Bioengineered Foods, it would seem that the time is drawing near when the FDA may lift the Import Alert and allow the GE fish to enter the U.S. market.

²⁰ "Small food manufacturers" are those with annual receipts of at least \$2.5 million, but less than \$10 million.

However, the FDA must still provide labeling guidance on the fish before it can lift the Alert. While AquaBounty is hopeful that this will happen shortly, it has noted that there are no assurances such guidance will be issued in close proximity to the final rule's promulgation.²¹ In the meantime, the company's CEO is having discussions with potential partners outside of North America, including those in China and the Middle East, in order to sell AquaAdvantage salmon in other, perhaps more favorable, markets.²² As the company's current sales to Canada are expected to remain "modest and infrequent," expanding to other markets could be critical for the company, which has not turned a profit in its two-decade history.²³

However, even if companies culturing GE fish and/or shellfish like AquaBounty are permitted to sell their products in the U.S. market, consumer perceptions may limit the success of such sales. Generally, consumer knowledge of GMOs is low in the United States, according to studies based on direct consumer surveys.²⁴ A 2013 survey conducted by the School of Environmental and Biological Sciences at Rutgers University found that U.S. consumers as a whole were fairly unknowledgeable about GMOs, with just 43% knowing that GE products were available in supermarkets and only 26% believing that they had most likely consumed a GE product in their lifetime.²⁵ However, those that did report having familiarity with GMOs tended to prefer non-GE products and show a higher willingness to pay for such products.²⁶ As the topic of GMOs becomes more commonly discussed in the general media and mandatory labeling laws go into effect, increasing familiarity with genetic modification could drive some consumers away from purchasing products created using the technology. Certain private retailers may be reluctant to stock GE products as well. Producers will have to find a way to overcome such negative perceptions surrounding genetic modification if they wish to find true success in marketing GE aquacultural products.

The implications of using GE feed in commercial aquaculture are now clearer since the promulgation of the NBFDS final rule. As noted above, there exists a question of whether fish at least partially fed GE crops would be required to bear disclosure labeling when packaged for sale. The final rule clears this up somewhat by prohibiting food derived from an animal from being considered BE solely because the animal consumed feed produced from, containing, or consisting of a BE substance. However, the inclusion of the word "solely," indicates that feeding non-GE animals GE crops could play some part in determining whether an animal product must bear a BE disclosure. It remains to be seen whether this would actually be the case in practice, and, if so, exactly what such a determination would look like.

²¹ Christine Blank, *New labeling rule paves way for GM salmon to enter US market* (Dec. 21, 2018), <https://www.seafoodsource.com/news/supply-trade/new-labeling-rule-paves-way-for-gm-salmon-to-enter-us-market>.

²² Jason Smith, *With new CEO, AquaBounty looks beyond US for markets, partner*, UNDERCURRENT NEWS (Jan. 16, 2019), https://www.undercurrentnews.com/2019/01/16/with-new-ceo-aquabounty-looks-beyond-us-for-markets-partner/?utm_source=Undercurrent+News+Alerts&utm_campaign=72054c9e5b-Americas_briefing_Jan_16_2019&utm_medium=email&utm_term=0_feb55e2e23-72054c9e5b-92659481.

²³ *Id.*

²⁴ Shahla Wunderlich & Kelsey A. Gatto, *Consumer Perception of Genetically Modified Organisms and Sources of Information*, 6 ADVANCES IN NUTRITION 842 (2015), available at <https://academic.oup.com/advances/article/6/6/842/4555145>.

²⁵ WILLIAM K. HALLMAN ET AL., RUTGERS SCHOOL OF ENVIRONMENTAL AND BIOLOGICAL SCIENCES, PUBLIC PERCEPTIONS OF LABELING GENETICALLY MODIFIED FOODS 4 (2013), available at http://humeco.rutgers.edu/documents_PDF/news/GMlabelingperceptions.pdf.

²⁶ *Id.* at 5.

VII. Conclusion

There are still many questions that must be answered before GE aquacultural products can succeed in the U.S. market. It is unclear if the marketing of such products will be met with more political backlash, and it is also uncertain how American consumers will respond. The first companies to successfully market their products domestically—AquaBounty in particular—will yield great insight into how the U.S. views GE fish and shellfish as a whole. It also remains to be seen exactly what impact new policies such as the NBFDS final rule will have on the aquacultural GMOs. Proponents of the rule are hopeful that it will provide necessary transparency for consumers by allowing them to make informed decisions while protecting the innovation that is critical to the sustainability of agriculture. However, critics argue that the way the USDA has written the rule will erode consumer confidence by providing unwarranted exemptions and utilizing unfamiliar terms such as “bioengineered.” Whatever the result, aquaculturists wishing to utilize genetic modification should familiarize themselves with relevant federal and state regulations as well as the requirements of third-party certification programs in order to best prepare for the future.

²⁷ Phillip Brasher & Spencer Chase, *USDA issues GMO disclosure rules*, AGRI-PULSE (Dec. 20, 2010, 10:00 AM), <https://www.agri-pulse.com/articles/11754-usda-issues-gmo-disclosure-rules>.

²⁸ *Id.*