2012

AquAdvantage is Not Real Advantage: European Biotechnology Regulations and the United States' September 2010 FDA Review of Genetically Modified Salmon

Katherine Wilinska

Note

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I. INTRODUCTION

Recent years have brought an increase in public concern over genetically modified (GM) organisms and their possible impact on the health and safety of consumers and the environment. GM food supporters revere the enhanced quality and taste, increased yield, lower production costs, heightened pest and drought resistance, and shorter production times of transgenic foods. However, opponents fear the yet unknown environmental, social, health, and ethical risks that these foods bring with them.[1] The divided views are, to different extents, reflected in the divergent regulation of GM foods in the United States and the European Union.[2]

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1. *See* MARK A. POLLACK & GREGORY C. SHAFFER, WHEN COOPERATION FAILS: THE INTERNATIONAL LAW AND POLITICS OF GENETICALLY MODIFIED FOODS 34–38 (2009) (listing such positives to GM organisms' development as the prevention of hunger in developing countries, the clean-up of toxic spills, and the elimination of toxic chemicals from crop production; whereas some negatives include the impairment of biodiversity, irreversible changes to the natural food chain, the triggering of allergenic reactions, and even a monopoly of modified products concentrated in a few corporate hands); Simonetta Zarilli, *International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks*, at 1–2, UNCTAD/ITCD/TAB/30, U.N. Sales No. E.04.II.D.41 (2005) (contrasting the benefits of GM foods in resolving issues such as the nutritional needs of the world's growing population and the efficient use of agrarian space with possible negative impacts on human health and the environment).

2. *See* POLLACK & SHAFFER, *supra* note 1, at 7 ("In both the US and the EU [the differences in the regulations] remain unchanged in their fundamental approaches.").

September 2010 brought a new wave of public debate when the U.S. Food and Drug Administration (FDA) held hearings on the possible approval of a genetically modified fish, AquAdvantage Salmon (AAS), for public consumption.[3] Aqua Bounty Technologies, Inc. (ABT) maintains that the product is safe for consumption and poses little environmental risk, but consumer and environmental groups disagree and point out the lack of effective risk assessment methods with respect to GM animals, as no other such animal has been approved for human consumption.[4] While the controversy centers around the review's precedential value,[5] the unknown health risks, and a serious environmental concern if AAS escape into the wild,[6] there is also a more complex impact on the U.S.-E.U. salmon trade and international laws because ABT intends to sell AAS eggs commercially to farmers.[7]

This Note will examine the possible consequences of FDA approval of AAS for mass consumption. Part II will discuss the ABT application packet (the Packet), the social perception and regulation of GM foods in both the United States and the European Union, and relevant international agreements. Part III will analyze AAS environmental assessment, the review's possible impact on international trade and international laws, and the sufficiency of ABT research. It will propose trade-friendly legislative solutions, uniform labeling within a new statutory regime, and stricter research requirements in the submission process. Overall, this Note argues that relevant congressional action is overdue, and the FDA should not approve AAS at this time. American GM foods' marketability in the international trade arena requires new laws consistent with the labeling, tracing, and monitoring requirements of other nations in order to protect the environment and maintain overall consumer trust.

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3. Lyndsey Layton, *FDA Hears Concerns over Approving Genetically Modified Salmon*, WASH. POST, Sept. 20, 2010, http://www.washingtonpost.com/wp-dyn/content/article/2010/09/20/AR2010092005967.html (reporting that Aqua Bounty Technologies, Inc., a company that spent the last fifteen years developing superior qualities in Atlantic salmon, is now seeking a green light to start massive production of the fish for sale to the public).

4. *See* Kim Geiger, *Genetically Modified Salmon Safe to Eat, FDA Report Says*, L.A. TIMES, Sept. 4, 2010, http://articles.latimes.com/2010/sep/04/nation/la-na-fda-salmon-20100904-15;

Susan Heavey, *Biotech Salmon Faces Scrutiny at FDA Panel*, REUTERS, Sept. 20, 2010, http://www.reuters.com/article/2010/09/20/us-fda-biotech-salmon-idUSTRE68J0EZ20100920 (discussing the rising public concern about GM salmon safety).

5. Other GM animals await similar approvals including environmentally friendly manure producing pigs and mad cow disease resistant cattle. If and when the FDA approves AAS, such companies will proceed with their approval petitions. ABT itself hopes to approve its own GM tilapia and trout in the future. *See* Heavey, *supra* note 4.

6. PETER COATES, SALMON 104 (2006) (explaining that wild salmon populations would be negatively affected by any genetically superior species).

7. *See* Heavey, *supra* note 4; Geiger, *supra* note 4.

II. BACKGROUND

GM organisms have been genetically altered[8] to obtain certain desirable traits, such as drought resistance in plants and virus resistance or accelerated growth in animals.[9] In the United States, the FDA, which has statutory and regulatory authority over genetically modified foods,[10] defines GM animals as animals altered by recombinant DNA (rDNA).[11] In addition, the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) provide oversight for GM crop planting and its impact on the environment and food safety.[12] The three agencies constitute the Coordinated Framework[13] responsible for regulation and oversight of GM plants and animals.

European legislation defines a genetically modified organism as "one in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."[14] In Europe, GM-related regulation is not effectuated by governmental agencies; instead, it arises from the interaction between E.U. government bodies such as the

8. *See* POLLACK & SHAFFER, *supra* note 1, at 9 (defining genetic engineering as a process in which genes from one organism are isolated, manipulated in a laboratory and injected into another organism).

9. *See What are Genetically Modified (GM) Foods?*, HUMAN GENOME PROJECT INFORMATION (last updated Nov. 5, 2008), http://www.ornl.gov/sci/techresources/Human_Genome/elsi/gmfood.shtml (listing other possible names for living organisms whose genetic traits have been modified to obtain desirable traits such as "genetically modified," "genetically engineered," or "transgenic").

10. *See* POLLACK & SHAFFER, *supra* note 1, at 10 (noting that agencies regulate GM plants in terms of the final products' characteristics—not in terms of the production process).

11. *See* CTR. FOR VETERINARY MED., FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY: REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS 3 (2009) [hereinafter REGULATION OF GENETICALLY ENGINEERED ANIMALS] *available at* http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf (defining genetically modified or engineered animals as those whose DNA has been injected with parts of DNA from another animal which possessed certain desirable traits like resistance to viruses or cold temperatures, thus producing a "recombinant DNA").

12. *See* POLLACK & SHAFFER, *supra* note 1, at 10.

13. *See generally* Margaret Rosso Grossman, *Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State measures, and Liability in Tort*, *in* THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES 299, 300 (Luc Bodiguel & Michael Cardwell eds., 2010); POLLACK & SHAFFER, *supra* note 1, at 46; Antonia Eliason, *Science versus Law in WTO Jurisprudence: The (Mis)Interpretation of the Scientific Process and the (In)Sufficiency of Scientific Evidence in* EC-Biotech, 41 N.Y.U. J. INT'L L. & POL. 341, 370 (2009); Valery Federici, Note, *Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws*, 35 BROOK. J. INT'L L. 515, 538 (2010); David E. Sella-Villa, *Gently Modified Operations: How Environmental Concerns Addressed Through Customs Procedures Can Successfully Resolve the US-EU GMO Dispute*, 33 WM. & MARY ENVTL L. & POL'Y REV. 971 (2009).

14. Council Directive 2001/18, art. 2(2), 2001 O.J. (L 160) 4 (EC).

European Commission, European Parliament, and relevant authorities in each of the member states.[15] Those bodies are collectively referred to as the Community Framework.[16]

AAS falls under both the U.S. and E.U. GM definitions. Its genetic code has been altered by injecting the Chinook salmon growth hormone, which promotes growth by stimulating the thyroid, and the ocean pout antifreeze protein, which enables the salmon to survive in near freezing temperatures.[17] The FDA is reviewing AAS under the Federal Food, Drug, and Cosmetic Act[18] (FFDCA) and its New Animal Drug Application[19] (NADA) as a "new animal drug" intended for use in animals[20] in accordance with its 2009 Guidance for Industry 187, created to streamline the GM animal application process.[21] NADA triggers environmental analysis under the Code of Federal Regulations Title 21,[22] the environmental impact statement (EIS),[23] and the FDA examination of environmental impacts of GM animals[24] including inadvertent release or escape.

A. ABT'S APPLICATION PACKET, ENVIRONMENTAL ASSESSMENT, AND WEBSITE

The Packet submitted for FDA review to the Center for Veterinary Medicine (CVM) contains publicly accessible information on the AAS health and environmental risk assessment.[25] The submission is a result of fourteen year research and sixty million dollar development efforts by ABT.[26] ABT plans to produce eggs in its facilities in Canada, to grow-out

15. *See* POLLACK & SHAFFER, *supra* note 1, at 10.

16. *Id.* at 60.

17. VETERINARY MEDICINE ADVISORY COMM., FOOD AND DRUG ADMIN. CTR. FOR VETERINARY MED., BRIEFING PACKET: AQUADVANTAGE SALMON 65 (2010) [hereinafter THE ABT BRIEFING PACKET], *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf.

18. Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301–399a (2006).

19. Id. § 512, 21 U.S.C. § 360b(a)(1).

20. Id. § 201, 21 U.S.C. § 321(v).

21. *See* REGULATION OF GENETICALLY ENGINEERED ANIMALS, *supra* note 11.

22. 21 C.F.R. § 25 (2011) (requiring an environmental impact statement (EIS) in extraordinary circumstances under § 25.21 when there is a potential for serious harm to the environment and the action adversely affects endangered species).

23. *See* REGULATION OF GENETICALLY ENGINEERED ANIMALS, *supra* note 11, at 19, 25 (requiring an EIS until the FDA has more experience in processing applications for GM animals).

24. *Id.* at 12.

25. *See* THE ABT BRIEFING PACKET, *supra* note 17.

26. Geiger, *supra* note 4.

the fish in Panama,[27] and to license AAS eggs to fish farmers.[28] In assessing the risks, ABT used 144 market-sized salmon to measure their food safety.[29] The report states that AAS contains ocean pout antifreeze protein to increase resistance to freezing temperatures and Chinook salmon growth hormone to promote growth and increased levels of allergens.[30] AAS grows several times bigger than and twice as fast as wild salmon and the Packet claims that "adequate containment measures appear to be in place" to insure a "low probability of escape."[31] Nevertheless, the possibility of escape does exist because "no single containment measure can be assured to be 100% effective."[32] Furthermore, despite AAS's "extremely small" survival likelihood,[33] subsistence is possible because "up to 5%" of females are not sterile.[34] In light of data insufficiency, ABT "conservatively assumed that older life stages . . . would survive if they escape containment" but that "there are no likely consequences on the U.S., foreign nations not participating in the action, or on the global commons as a result of applicable reproductive and geographic/geophysical confinement."[35]

ABT submitted a separate Environmental Assessment (EA) to the CVM[36] pursuant to NADA's requirement of showing that the "new animal drug" is safe and effective for its intended use.[37] The EA states that the AAS trans-gene will not mutate into unknown forms,[38] even though wild salmon undergo genetic change in response to different environmental conditions.[39] Further, research shows that at an escape rate of 1%, traditional farm-raised salmon escapees interbreed with wild salmon, compete for food, and disrupt the ecosystem.[40] However, AAS will be farmed in land based facilities with redundant containment measures.[41]

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27. THE ABT BRIEFING PACKET, *supra* note 17, at 65.

28. *See* Heavey, *supra* note 4; Geiger, *supra* note 4; AQUA BOUNTY TECHNOLOGIES INC., ENVIRONMENTAL ASSESSMENT FOR *AQUADVANTAGE* SALMON 41 (Aug. 25, 2010), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224760.pdf.

29. THE ABT BRIEFING PACKET, *supra* note 17, at 86.

30. *Id.* at 65, 75.

31. *Id.* at 131.

32. *Id.* at 116.

33. *Id.* at 116, 130.

34. *Id.* at 115, 127.

35. THE ABT BRIEFING PACKET, *supra* note 17, at 130.

36. AQUA BOUNTY TECHNOLOGIES INC., *supra* note 28.

37. *See* REGULATION OF GENETICALLY ENGINEERED ANIMALS, *supra* note 11, at 13; *see also* AQUA BOUNTY TECHNOLOGIES INC., *supra* note 28, at 14 (informing that NADA approval triggers environmental assessment).

38. AQUA BOUNTY TECHNOLOGIES INC., *supra* note 28, at 19.

39. *Id.* at 21.

40. *Id.* at 30.

41. *Id.* at 43, 54.

These will be in areas where no natural disasters have occurred.[42] At the same time, relevant research on salmon shows that a mere 25% size advantage is enough to push smaller fish away from feeding and mating grounds.[43] Thus, one can presume that AAS, which has a significant size advantage over its natural cousin, could decimate the natural salmon population.

The ABT's website assures the public that AAS has no mating advantage, would not alter native salmon populations, is 100% sterile, and has undergone adequate environmental assessment.[44] Further, no antifreeze or growth hormones will be passed on to the consumers, adequate federal laws are in place, and the FDA has sufficient expertise to approve the transgenic fish.[45]

The FDA accepted public comments on the approval until November 22, 2010.[46] At the time of this publication, the FDA has not issued a conclusive decision, but Congress voted in June 2011 to prohibit the FDA from approving GM salmon.[47] The general concerns were a hasty approval process and insufficient review of impact on the health of American consumers and the environment.

B. GENETICALLY MODIFIED FOODS IN THE UNITED STATES

In the United States, genetically modified foods have enjoyed greater consumer tolerance, a more lenient regulatory framework, and easier approval process due to an assumption that the new genetic varieties are not harmful unless evidence indicates the contrary.

1. Consumer Tolerance of Genetic Modification

American consumers have historically been more tolerant of GM foods and have not demanded harsher laws regulating their proliferation

42. *Id.* at 53.

43. *Id*. at 35.

44. *See Frequently Asked Questions*, AQUABOUNTY.COM, http://www.aquabounty.com/technology/faq-297.aspx (last visited Oct. 4, 2011) ("Q. Can we be sure that AAS will really be sterile? A. Yes").

45. *Id.*

46. *FDA to Convene Public Hearing on the Labeling of Food Made from AquAdvantage Salmon*, FDA (Aug. 25, 2010), http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm222601.htm.

47. Press Release, Center for Food Safety, U.S. House of Representatives Passes Amendment to Prohibit Genetically Engineered Salmon Approval (June 16, 2011), *available at* http://www.centerforfoodsafety.org/2011/06/16/u-s-house-of-representatives-passes-amendment-to-prohibit-genetically-engineered-salmon-approval/ (providing that in the H.R. 2112, Agriculture, Rural, Food and Drug Administration, and Related Agencies Appropriations Act of 2012, the House of Representatives asserted its discretionary budget authority).

on the market,[48] although that position appears to be changing.[49] The United States began its biotechnological developments with caution. However, a more liberal approach has evolved regarding the use of genetic modifications for enhancement[50] with an active engagement in promotion since the 1970s. In 1999, upwards of 60% of grocery store foods were grown from genetically modified seeds, a fact of which only 33% of Americans were aware.[51] By 2007, approximately 89% of soybeans and 61% of corn grown in the United States had been genetically modified.[52] Yet, recent trends illustrate that when American consumers are asked directly if they would like to know whether their food is genetically modified, 94% say yes.[53] There is also growing pressure for change in the regulation of GM foods, which is manifested by commercial adaptation, political mobilization, and policy change.[54] Combining the ubiquity of genetic modification and the growing desire of public opinion that modified food be labeled before it can be sold; it is somewhat surprising that approval of new GM foods for production in the United States is relatively simple.

2. The Equivalence Principle: Safe until Proven Otherwise

The U.S. approval system operates in accordance with a risk-based outlook: the equivalence principle.[55] This principle allows approval of new

48. *See* Heavey, *supra* note 4; Luc Bodiguel & Michael Cardwell, *Genetically Modified Organisms and the Public: Participation, Preferences, and Protest*, *in* THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES, *supra* note 13, at 11, 23.

49. Bodiguel & Cardwell, *supra* note 48, at 23.

50. Diahanna Lynch & David Vogel, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, COUNCIL ON FOREIGN RELATIONS (Apr. 5, 2001), http://www.cfr.org/publication/8688/regulation_of_gmos_in_europe_and_the_united_states.html.

51. *Id.*; *see also* POLLACK & SHAFFER, *supra* note 1, at 266–67 (revealing that most recent polls indicate a number as low as 26%); Grossman, *supra* note 13, at 299.

52. POLLACK & SHAFFER, *supra* note 1, at 1 (listing other GM foods such as canola, potatoes, tomatoes, papaya, squash and sunflowers).

53. Federici attributes the desire for labels as a result of the popular fear of the unknown and points out that most consumers are "against eating GM food despite inadvertently having already made it part of their daily diets." Federici, *supra* note 13, at 522; *see also* Bodiguel & Cardwell, *supra* note 48, at 12 (revealing that a majority would appear unhappy with Government policy that consisted of not labeling GM products).

54. While commercial adaptation results from the voluntary compliance of the United States with E.U. regulations to gain access to E.U. markets, political mobilization results from consumer interest groups advocating for stronger regulations. Yet further policy change results from the United States protecting both the market and its consumers. *See* POLLACK & SHAFFER, *supra* note 1, at 25–26.

55. *See* Grossman, *supra* note 13, at 300; POLLACK & SHAFFER, *supra* note 1, at 50; Franz Xaver Perrez, *Risk Regulation, Precaution and Trade*, *in* GENETIC ENGINEERING AND THE WORLD TRADE SYSTEM: WORLD TRADE FORUM 246, 251 (Daniel Wüger & Thomas

products that are substantially equivalent to natural ones in the absence of significant adverse effects on production and consumption.[56] This approach is meant to ensure "easy and reliable access to foreign markets for their biotechnology exports."[57] In other words, the introduction of GM foods, which are considered equivalent to their natural counterparts, into the U.S. food industry, is governed by free market principles. In light of the equivalence concept, the U.S. legislature puts complete trust in scientific research and delegates approval tasks to government agencies that safeguard public health and the environment under the Coordinated Framework.[58] In spite of the presumed equivalence approach, and in response to growing consumer demands, the FDA has recently released guidelines on voluntary labeling of GM products.[59] Although AAS's EA mentions labeling for transport from Canada to Panama,[60] and the Packet mentions containment requirement labels,[61] there is no note of actual consumer product labeling once AAS reaches market shelves. However, the FDA could exercise its discretion to require such labels under the Guidance for Industry.[62]

3. Less Restrictive Laws

In general, the United States has less pronounced federal legislation on GM foods than the European Union[63] and does not require its regulatory

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Cottier eds., 2008); Eliason, *supra* note 13, at 349, 365; Federici, *supra* note 13, at 534–36; Melissa Ince & Meredith Mariani, *The EU, the United States, and the GMO Dispute: Ten Years and Counting*, AGRIC. MGMT. COMMITTEE NEWSL. (A.B.A. Section of Env't, Energy, and Res.), Apr. 2008, at 15, 16; Sella-Villa, *supra* note 13, at 971; Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the E.U. Ban of Genetically Modified Foods*, 45 AM. BUS. L.J. 775, 780, 784 (2008); Zarilli, *supra* note 1, at 4.

56. *See* POLLACK & SHAFFER, *supra* note 1, at 46 (explaining that substantially equivalent products are those which are "not inherently risky" and may be regulated under existing statutes); *see also* Bernd van der Meulen, *Regulating GM Food: Three Levels, Three Issues*, *in* THE REGULATORY CHALLENGE OF BIOTECHNOLOGY 139, 153 (Han Somsen ed., 2007) (revealing that the U.S. approach looks at the absence of risk and that European authorities weren't able to refute the evidence presented by the United States that there were no risks).

57. *See* Zarilli, *supra* note 1, at 45.

58. Bodiguel & Cardwell, *supra* note 48, at 17; Sella-Villa, *supra* note 13, at 972–73.

59. *See* POLLACK & SHAFFER, *supra* note 1, at 50, 268; Grossman, *supra* note 13, at 317 ("Because consumers may be interested in whether food has been genetically modified, the agency developed a guidance to help industry ensure that voluntary labeling is truthful and does not mislead consumers.").

60. *See* AQUA BOUNTY TECHNOLOGIES INC., *supra* note 28, at 48.

61. *See* THE ABT BRIEFING PACKET, *supra* note 17, at 47.

62. *See* REGULATION OF GENETICALLY ENGINEERED ANIMALS, *supra* note 11, at 7 ("[I]n certain circumstances . . . we intend to exercise enforcement discretion . . . ."); *id.* at 15 (recommending labeling for a new animal drug "throughout all stages of its lifecycle").

63. *See* POLLACK & SHAFFER, *supra* note 1, at 268 ("[I]n the absence of . . . any federal legislation specifically dedicated to the regulation of genetically engineered products, the

agencies to impose labeling restrictions or tracing requirements.[64] GM products are handled within the 1986 Coordinated Framework designed to ensure "safety of foods and food ingredients from new plant varieties."[65] The FDA is the body responsible for approvals of GM foods[66] and looks at the final consumer *product* for its equivalence properties, not the *process*[67] of producing the item.[68]

In approving GM foods, the FDA looks only at research information provided by the applicant and does not conduct its own independent research,[69] although it does invite public comments.[70] Each applicant must prepare an extensive briefing packet with a product description, consumption and environmental hazard assessment, and claim validations.[71] For example, the ABT application came in a 180 page packet with information required by Industry Guideline 187, under which labeling, tracing, or monitoring of GM products is not mandatory.[72] Critics worry that the FDA neglects the wider impact of the new technology.[73]

The FDA uses section 201(g), the new animal provision, of the Federal Food, Drug and Cosmetic Act (FFDCA) for approving GM animals.[74] This section defines drugs as "articles (other than food) intended to affect the structure or any function of the body of man or other

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FDA and the USDA conducted hearings . . . ."); Strauss, *supra* note 55, at 780–81 ("Since the development of GM foods, no federal legislation has been enacted, nor have regulatory agencies required any labeling or special approval of these substances in the United States.").

64. *See* Strauss, *supra* note 55, at 781 (acknowledging that regulatory agencies in the United States do not require any labeling or special approval of GM substances).

65. *See* Grossman, *supra* note 13, at 311.

66. *See* POLLACK & SHAFFER, *supra* note 1, at 10 (noting that the FDA makes approvals, while the EPA and USDA have oversight duties within the Coordinated Framework).

67. POLLACK & SHAFFER, *supra* note 1, at 277.

68. NAT'L RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 14 (1989) ("[T]he *product* of the genetic modification and selection should be the primary focus for making decisions about the environmental introduction of a plant or microorganism and not the *process* by which the products were obtained.") (original emphasis); Federici, *supra* note 13, at 537.

69. *See* Grossman, *supra* note 13, at 312–13; Sella-Villa, *supra* note 13, at 973.

70. Bodiguel & Cardwell, *supra* note 48, at 17.

71. *See generally* REGULATION OF GENETICALLY ENGINEERED ANIMALS, *supra* note 11.

72. *See generally* THE ABT BRIEFING PACKET, *supra* note 17.

73. Martin D. Smith et al., *Genetically Modified Salmon and Full Impact Assessment*, 330 SCI. 1052, 1052 (2010) ("Although comparing health information for GM and non-GM salmon is essential, quantifying risks in this manner implicitly (and implausibly) assumes that the new product will simply replace the old one in the market and that the new product leads to no changes in aggregate market prices and quantities.").

74. Federal Food, Drug, and Cosmetic Act (FFDCA) § 201, 21 U.S.C. § 321(g)(1)(C) (2006); POLLACK & SHAFFER, *supra* note 1, at 44.

animals."[75] The FDA justifies its authority to regulate GM animals under this statute because, "the rDNA construct in a G[M] animal that is intended to affect the structure or function of the body of the G[M] animal, regardless of the intended use of products that may be produced by the G[M] animal, meets the FFDCA drug definition."[76] In other words, it is the rDNA construct and not the whole animal that qualifies as the statutory drug. In its 2009 Guidance for Industry, the FDA reiterated its authority under the FFDCA and did not mention any other statute referring to GM animals. The absence of current federal statutes[77] on GM foods led to failed FFDCA amendment efforts by members of Congress who proposed mandatory labeling of genetically engineered material.[78] As of today, GM/GM-free labeling in the United States is still voluntary.

C. GENETICALLY MODIFIED FOODS IN THE EUROPEAN UNION

Europeans disfavor GM foods and E.U. legislation operates on the precautionary assumption that such foods are harmful unless evidence indicates to the contrary. This view constitutes an ideological and political basis for any trade conflict related to GM foods.

1. Consumer (In)Tolerance

Historically, genetic research and the development of GM foods has been the subject of hot debate and vehement resistance in Europe.[79] European consumers have relatively low tolerance for GM foods' presence in their lives,[80] and European public opinion is far more mobilized over GM foods than that of the United States.[81] Contrary to American consumers, European consumers express deep skepticism about the low environmental impact of GM foods and exhibit a lack of trust in their governments' food safety regulations.[82] Europeans also express more skeptical attitudes towards the "human health and safety issues associated with GM food products."[83] Although GM food opposition differs from

75. FFDCA § 201, 21 U.S.C. § 321(g)(1)(C).

76. REGULATION OF GENETICALLY ENGINEERED ANIMALS, *supra* note 11, at 6.

77. *See* POLLACK & SHAFFER, *supra* note 1, at 51 (explaining that although there is no per se federal statute regulating genetically modified organisms (GMOs) and GM foods, the practical result is the mix of "the definition of regulatory authority and the agencies' risk assessment of GM products.").

78. *See* POLLACK & SHAFFER, *supra* note 1, at 268, 272; Federici, *supra* note 13, at 535–36.

79. *See* Federici, *supra* note 13, at 516 (declaring that substances have been "hotly debated and strongly resisted in Europe").

80. *Id.*

81. *See* POLLACK & SHAFFER, *supra* note 1, at 70, 79. In addition, because GM agriculture was not embraced by E.U. farmers from the very beginning, it never became an important point for agricultural lobbyists who could fight for GM friendly laws. *See id.*

82. Sella-Villa, *supra* note 13, at 973.

83. *See* Strauss, *supra* note 55, at 780 (acknowledging that regulatory agencies in the

country to country, Europeans are generally skeptical of GM foods, perceiving them as not useful and more dangerous.[84]

2. The Precautionary Principle: Unsafe until Proven Otherwise

The European Union, contrary to the U.S.-endorsed risk-benefit equivalence principle, is influenced by the precautionary principle. This principle assumes that new technology is not safe until proven so by extensive scientific research; thus, the European Union guards its markets against the unknown and undesirable effects of GM plants, organisms, and foods.[85] The E.U. legislature "err[s] on the side of caution, even in the absence of any demonstrable risk," and excludes any potential benefits from its analysis.[86] A GM applicant must demonstrate the safety and lack of harm of each individual product before the European Union will consider allowing the products to be marketed within its borders.[87]

3. Stricter E.U. Laws

Under the Community Framework,[88] the E.U. government consent bodies impose strict requirements on parties seeking approval of genetically modified products.[89] Before a modified product can be approved, the relevant body looks not only at the research and risk assessment information in the petitioner's application packet, but, unlike the U.S. agencies, also requires an *independent* research assessment by a separate designated agency.[90] In addition, as a prerequisite for placing a

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United States do not require any labeling or special approval of GM substances).

84. *See* Federici, *supra* note 13, at 542.

85. *See* Sella-Villa, *supra* note 13, at 976. One of the known negative impacts of GMOs on the environment is that GM plants, once comingled with natural species, undermine the natural plants' genetic integrity. *See id.* Due to their increased resilience to drought, viruses, and other destructive elements, they tend to completely and irreversibly replace the natural species and reduce biodiversity. *See id.*

86. Federici, *supra* note 13, at 536.

87. *See, e.g.*, Zarilli, *supra* note 1, at 10.

88. *See* POLLACK & SHAFFER, *supra* note 1, at 60 (stating that the Community Framework is counterpart to the Coordinated Framework in the United States).

89. For an overview of E.U. regulation of the GM-matter, see DAMIEN PLAN & GUY VAN DEN EEDE, THE E.U. LEGISLATION ON GMOS: AN OVERVIEW (2010), *available at* http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/14655/1/reqno_jrc57223_2010-08-12_eu_gmo_legislation_report_final.pdf%5B1%5D.pdf.

90. *See id*. at 6 (identifying the European Food Safety Authority (EFSA) as an independent body of scientists which conducts the evaluation of potential consequences and adverse effects, determines overall risks, and applies management strategies for risks); *see also* REECE WALTERS, ECO CRIME AND GENETICALLY MODIFIED FOOD 100 (2011) (explaining that, in the UK, safety assessments are done by the independent Advisory Committee on Novel Foods and Processes (ACNFP)). A successful petitioner is then burdened with periodic monitoring of risks and assessments and subject to a possible revocation of approval if risks and dangers are uncovered that were not known at approval. *See id.* These burdensome procedures effectively discourage GM developers from licensing. *See id.*

product on the market, the laws require mandatory labeling and traceability, post-market monitoring measures, and mandatory public disclosure including public registers.[91] Furthermore, exports of GM foods from the European Union require the recipient's consent, states must implement coexistence measures to avoid unintended presence of GM crops, any deliberate release and import into the European Union occurs upon strict review, and the producers must clearly label all GM products and trace their GM content.[92] Under this framework, GM food is approved separately by each Member State, and the deliberate release authorization is valid for no more than ten years subject to renewal.[93] Moreover, the "safeguard clause" allows an individual Member State to restrict or prohibit GM plants or foods within its territory, provided the restriction is based on a "justifiable reason" that an approved product poses a risk to human health or the environment.[94] Lastly, some E.U. states petitioned for an additional "opt-out" provision from all "economic legislation and agreements that would require all 27 E.U. countries to trade in GM foodstuffs."[95]

D. INTERNATIONAL AGREEMENTS

While the United States and the European Union operate on such diverse principles with regards to GM regulation, they interact in the

91. *See* Directive 2001/18, of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, 2001 O.J. (L 106) 1, 8–9 (permitting each member state the use of a "safeguard" to prevent unwanted GM product entry into its territory).

92. *See* Regulation 1946/2003, of the European Parliament and of the Council of 15 July 2003 on Transboundary Movements of Genetically Modified Organisms, 2003 O.J. (L 287) 1, 3–4 (stating that exports of GM foods require the E.U. recipient's consent); Regulation No. 1830/2003, of the European Parliament and of the Council of 22 September 2003 Concerning the Traceability and Labelling [sic] of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC, 2003 O.J. (L 268) 24, 24 (traceability and labeling); Directive 2001/18, of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, 2001 O.J. (L 106) 1, 5–6 (deliberate release and import into the European Union); Council Directive 2000/29, of 8 May 2000 on Protective Measures Against the Introduction into the Community of Organisms Harmful to Plants or Plant Products and Against Their Spread Within the Community, 2000 O.J. (L 169) 1, 7 (revealing special authorization measures to avoid unintended presence of GM organisms).

93. Directive 2001/18, of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, 2001 O.J. (L 106) 1, 10.

94. *Id.* at 13; *see also* POLLACK & SHAFFER, *supra* note 1, at 62; Jonathan Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Safety Protocol*, 35 TEXAS INT'L L.J. 173, 185 (2000).

95. WALTERS, *supra* note 90, at 55 (citation omitted).

international trade arena and are subject to international agreements. This has led to several trade conflicts that could emerge again if AAS is sold in the European Union.

1. WTO's Free Trade Approach to GM Foods

Although both the United States and the E.U. member states are members of the World Trade Organization (WTO), their approaches to GM foods and organisms differ because the European Union has additional obligations under the Cartagena Biosafety Protocol (CBP), wherein the main objective is preservation of biodiversity by limiting GM plant and animal presence.[96] However, the free-trade-friendly and WTO-compatible U.S. approach does not aspire to limit movement of GM foods, but rather seeks trade-friendly solutions in proscribing rules on how to produce, classify, transport, and market them.[97] For example, one agreement ensures that product requirements and procedures that are used to assess compliance with those requirements do not create unnecessary obstacles to trade.[98] In spite of its focus on promotion of free trade, the WTO framework does permit measures "necessary for the protection of the environment and the human health," provided the measures are not arbitrary or discriminatory.[99]

2. CBP's Pro-Biodiversity Approach

The United Nations (UN) initiated the CBP,[100] which comports with the E.U. precautionary principle,[101] by tolerating free trade only when no threats to biodiversity exist.[102] In fact, CBP will only promote international trade if transporting of genetically modified matter employs adequate biodiversity protections.[103] This is achieved by establishing rules and procedures for the safe transfer, handling, and use of GM plants and

96. SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, CARTAGENA PROTOCOL ON BIOSAFETY RATIFICATION LIST 2 (Sept. 12, 2011), *available at* http://www.cbd.int/doc/lists/cpb-ratifications.pdf (listing the European Union as party to the CBP, exemplifying their obligation to ensure safe transportation of GE animals to protect biodiversity).

97. *See* Agreement on Technical Barriers to Trade art. 2, ¶ 1, *adopted on* Jan. 1, 1980, 31 U.S.T. 405, 1186 U.N.T.S. 276 ("[Members] shall likewise ensure that neither technical regulations nor standards themselves nor their application have the effect of creating unnecessary obstacles to international trade.").

98. *Id*.

99. Perrez, *supra* note 55, at 267.

100. Sella-Villa, *supra* note 13, at 978–79 (stating that the UN-initiated CBP focuses on establishing stricter transport, transfer, and handling procedures that will significantly limit free movement of GMOs to protect biodiversity existing within the states' territories).

101. *See id*. at 972.

102. *See id*. at 979.

103. *See* Zarilli, *supra* note 1, at 29–30.

animals, with a specific focus on trans-boundary movements.[104] The CBP also considers possible risks to human health.[105] CBP members have access to a web-based information system to assess their GM-related risks.[106] The E.U. obligations under the CBP require limiting GM-matters' movement across its borders and allow such drastic measures as complete prevention of entry onto its territory.[107] Panama, where AAS is to be grown-out, is a party to the CBP and thus amenable to its obligations.[108]

The CBP provides a significant counterbalance to the WTO's free trade rules but does not stand in direct opposition to its provisions.[109] While the United States is not a party to the CBP,[110] the CBP provisions implicitly impact interpretations of the WTO rules.[111] Most of the E.U. members (and for purposes of this Note, Panama) have signed and ratified agreements protecting biological diversity, while the United States and Canada have not signed any of such agreements.[112]

3. The WTO Crop Dispute Stalemate

The differing principles and approaches of the United States and the European Union regarding GM foods, grounded in diverging cultural and institutional aspects of risk assessment and management,[113] came to light in the 2003 seeds crisis. The crisis arose when the European Union failed to process approvals for U.S. export of GM seeds into its territory for

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104. *See id.*

105. *See id.* at 24 (noting the CBP having a specific effect on trade policy).

106. *See* Laurence Boisson de Chazournes & Makane Moïse Mbengue, *Trade, Environment and Biotechnology: On Coexistence and Coherence*, *in* GENETIC ENGINEERING AND THE WORLD TRADE SYSTEM: WORLD TRADE FORUM, *supra* note 55, at 205, 209 (discussing the internet-based information system called "Biosafety Clearing-House" which enables countries to make informed decisions before agreeing to importation of GM matters).

107. *See* WALTERS, *supra* note 90, at 64 (Cartagena Parties are permitted to reject GM food); Sella-Villa, *supra* note 13, at 979. In fact, the European Union was a driving force behind the CBP and most of its members signed it.

108. *See* SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, *supra* note 96, at 3 (listing Panama as party to the CBP).

109. *See* POLLACK & SHAFFER, *supra* note 1, at 176. WTO and CBP are not mutually exclusive; even though the United States is not a CBP member, WTO panelists can implicitly invoke its provisions when solving trade conflicts between the United States and the European Union. *Id.*

110. *Id.* at 155.

111. *Id.* at 176 ("The existence of the Protocol can affect the interpretation of WTO legal provision . . . .").

112. *See* SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, *supra* note 96 (revealing that the United States and Canada are not obligated internationally to protect biological diversity); *see also* WALTERS, *supra* note 90, at 90 (discussing that Argentina, Australia, Canada, Chile, Uruguay and the United States, the so-called 'Miami Group,' strongly oppose Cartagena environmental protection objectives and see them as harmful to trade).

113. *See* POLLACK & SHAFFER, *supra* note 1, at 33–34.

several years. This allegedly caused massive financial damage to U.S. farmers.[114] As a result, the United States filed a suit with the WTO for violation of international agreements.[115] In the document filed with the WTO, the United States reserved the right to retaliate against the European Union to compensate for the annual value of lost U.S. exports, royalties, and licensing fees to the European Union from biotech crops.[116] These losses resulted from various E.U. member states' use of the safeguard clause[117] to block GM crops from their territories.[118] The United States argued that the resulting ban on GM imports was a violation of global trade rules.[119] The WTO ultimately decided not to rule on the issue of GM crop safety but agreed that the European Union's undue delay in approvals of U.S. GM crop imports caused trade disruption.[120] The European Union was encouraged to process the approvals, but the WTO ultimately failed to rule on the safety of GM crops.[121] The United States walked away from

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114. *See* POLLACK & SHAFFER, *supra* note 1, at 183 (declaring that the United States could lose $4 billion in exports).

115. *See* POLLACK & SHAFFER, *supra* note 1, at 14 (stating that the suit took place in 2003 and alleged that E.U. regulations, which allow member states to block the access of GM seeds to their markets, caused a de facto moratorium on E.U. approvals of those products).

116. Jonathan Lynn, *U.S. Seeks to Retaliate against EU in GMO Case*, REUTERS (Jan. 30, 2008, 11:03 AM), http://www.reuters.com/article/idUSL3043174920080130.

117. *See* POLLACK & SHAFFER, *supra* note 1, at 63 (explaining that the safeguard provision allows individual member states to restrict or suspend GM seeds or GM animals from entering into their state).

118. *EU Wants to Put GMO Dispute to an End*, EURACTIV.COM (July 12, 2010), http://www.euractiv.com/en/cap/%20EU-wants-GMO-dispute-to-end-news-496059 ("The plans would allow large-scale commercial planting in pro-GM countries such as Spain, the Netherlands and the Czech Republic, opening up new markets for major biotech companies, while at the same time legally endorsing existing GM bans in countries like Italy, Austria and Hungary.").

119. *U.S., Canada and Argentina Ask for WTO Dispute Settlement over EU's GMO Policy*, FOOD AND DRINK WEEKLY (Aug. 23, 2003), http://www.allbusiness.com/government/business-regulations/629606-1.html ("Austria, France, Greece, and Italy, have prohibited the importation and marketing of GM products, even though those products have already been approved for sale in the EU.").

120. *See* Strauss, *supra* note 55, at 786. The Panel focused on the delay rather than the validity of GM regulations. *Id.* The European Union itself later made a statement that its regulatory provisions are not affected by the WTO judgment. *Id.* It is another question whether the WTO has the authority to impose legislation changes on it members. *Id*. *See also* POLLACK & SHAFFER, *supra* note 1, at 21 (detailing the judgment of the WTO).

121. *See, e.g.*, Ince & Mariani, *supra* note 55, at 17–18 (noting that the WTO did not discuss whether GM foods were safe, whether the European Union had the right to set their own standards as to U.S. imports, or whether the approval requirements of the European Union violated E.U. obligations under the WTO); *see* POLLACK & SHAFFER, *supra* note 1, at 21 ("[T]he panel avoided determining whether the European Union had based a decision on a risk assessment or whether the assessments showed actual risks or greater risks than for conventional plant varieties . . . ."); *id.* at 7 ("[T]he WTO has empowered domestic political actors . . . with an interest in complying with WTO law, and as a result, has encouraged regulators on both sides of the Atlantic to operate more transparently, taking into greater

the 2003 seeds crisis with faster processing of its GM crop import applications to E.U. member states but no long-term guarantee of a merit-based ruling in the form of changed E.U. laws that would ease future tensions, like those that may arise from AAS imports into the European Union.[122] While this stark contrast of viewpoints continues to divide the United States and the European Union,[123] the FDA's approval of AAS for public consumption in the United States would further exacerbate the international tensions.[124] Salmon is an international commodity and a "natural resource of the high seas or common heritage of mankind"[125] and is governed by special international instruments such as the Convention for the Conservation of Salmon in the North Atlantic Ocean, of which the United States, Canada, and the European Union are members.[126]

E. U.S.-E.U. SALMON TRADE STATISTICS AND IMPACT ON WILD POPULATIONS

There are two important statistical considerations with regard to AAS approval. First, the United States currently exports 23% of its total $536 million salmon production to the European Union;[127] in turn, ABT would have difficulty selling AAS in the European Union due to their strict GM-related regulations. Second, wild salmon move freely in oceanic waters,[128] and if AAS ever escaped or were maliciously or accidentally released into the wild, AAS could destroy endangered wild salmon populations.[129]

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account the effects of their actions on third parties.").

122. *See* POLLACK & SHAFFER, *supra* note 1, at 252–53; *see also* Strauss, *supra* note 55, at 804 (stating that the WTO did not rule decisively on any issue significantly affecting the suit brought by the United States).

123. *See generally* Ince & Mariani, *supra* note 55 (speculating that even the WTO dispute resolution entity will not be able to reconcile the two contrasting approaches without significant conceptual and philosophical changes).

124. *See* Layton, *supra* note 3.

125. *See* Wen-Chen Shih, *Conflicting Jurisdictions over Disputes Arising from the Application of Trade-Regulated Environmental Measures*, 8 RICH. J. GLOBAL L. & BUS. 351, 365 (2009) (inferring that migratory fish need regulation by international tribunals that will have the power to implement effective measures of protection and only common international efforts can prevent further eradication of endangered fish species).

126. KEITH CIALINO, OFFICE OF INT'L AFFAIRS, INTERNATIONAL AGREEMENTS CONCERNING LIVING MARINE RESOURCES OF INTEREST TO NOAA FISHERIES 24 (2010) (stating that the Convention for the Conservation of Salmon in the North Atlantic Ocean obligates the parties to cooperate in using a precautionary approach to "introductions and transfers including aquaculture impacts and possible use of transgenic salmon.").

127. Alaska Sea Food Marketing Institute, *Salmon Export Timing - The Big Picture*, SALMON MKT. BULLETIN, Jan.–Feb. 2004, at 1, 1, *available at* http://www.alaskaseafood.org/fishingprocessing/0204smb.pdf.

128. *See The Atlantic Salmon*, N. ATLANTIC SALMON CONSERVATION ORG. (last updated Nov. 14, 2011), www.nasco.int/atlanticsalmon.html.

129. *See* POLLACK & SHAFFER, *supra* note 1, at 38 (warning that the escaped and integrated salmon could eventually eliminate the wild salmon populations and degrade larger ecosystems); *see also* COATES, *supra* note 6, at 104; *Frequently Asked Questions*,

Research shows that just "60 [GM] fish among 60,000 wild fish would bring [a] species [to] extinction within 40 generations."[130] Further, studies show that the estimated escape rate of salmon from sea cages [farmed salmon] is about 1%.[131] While ABT ensures that its production method minimizes the risks of escape by using inland tanks, its intent to sell the eggs commercially poses far greater risks.[132] The Packet does not mention who will monitor the independent farmers to ensure that they indeed use inland tanks, located far away from reservoirs, as opposed to the far cheaper sea cages.

III. ANALYSIS

ABT should not be granted approval at this time because of the FDA's lack of environmental expertise on GM animals, the insufficiency of the legal framework, and the possible disruption of the international salmon trade. The high impact on international laws, exceptional environmental risk, and unparalleled precedential value also preclude such approval. Instead, to prepare for future GM animal approvals and to minimize chances of WTO involvement, along with precluding environmental damage, Congress should enact stricter Coordinated Framework review of labeling laws to facilitate GM animal entry into local and foreign export markets.

A. FDA'S LACK OF ENVIRONMENTAL EXPERTISE ON GM ANIMALS, STATUTORY INSUFFICIENCY, AND THE NEED FOR FULL IMPACT ASSESSMENT LAWS

Until the FDA has more experience in approving GM animals, AAS should be reviewed by environmental protection bodies that specialize in the environment. ABT does not guarantee that AAS will not escape,[133] but

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WILD SALMON CTR. (2004), http://www.wildsalmoncenter.org/about/faq.php (last visited Nov. 14, 2011) (explaining that farm-bred escapee fish such as salmon or tilapia migrate thousands of miles and may "colonize and crowd out the native wild populations."). *See generally* Lars P. Hansen & Malcolm L. Windsor, *Interactions Between Aquaculture and Wild Stocks of Atlantic Salmon and Other Diadromous Fish Species: Science and Management, Challenges and Solutions*, 63 ICES J. MARINE SCI. 1159, 1160 (2006) ("Escaped fish disperse quickly from site of release . . . .").

130. COATES, *supra* note 6, at 104.

131. AQUA BOUNTY TECHNOLOGIES INC., *supra* note 28, at 54; *see also* L.P. Hansen et al., *The Incidence of Escaped Farmed Atlantic Salmon,* Salmo salar *L., in the Faroese Fishery and Estimates of Catches of Wild Salmon*, 56 ICES J. MARINE SCI. 200, 201 (1999) ("[L]arge numbers of escaped farmed Atlantic salmon were present in oceanic waters . . . ."); *id.* at 203 ("[In some catches] more than 40% of the fish sampled were estimated to be of farmed origin.").

132. AQUA BOUNTY TECHNOLOGIES INC., *supra* note 28, at 41 (stating that AAS eggs will be produced for "commercial release"); *see also* Heavey, *supra* note 4 ("[ABT's CEO] said [ABT] plans to sell the eggs to inland fish farmers.").

133. THE ABT BRIEFING PACKET, *supra* note 17, at 131 ("[A]dequate containment measures *appear to be* in place . . . to insure *a very low probability* of escape for all life

claims that AAS are designed to be sterile and will not be able to survive and reproduce if they escape into the wild.[134] Despite this design precaution, up to 5% of AAS are not sterile; this raises environmental concerns. Studies on wild salmon migration show their free movement within oceanic waters.[135] AAS, if released in Panama or Prince Edward Island, could pose a serious threat to the already endangered wild salmon populations due to its superiority. AAS grow in half the time of wild salmon,[136] are several times their size, resistant to cold,[137] and have a greater survival ability than that of wild salmon.[138] Thus, ABT's assessment that there are no likely environmental consequences on foreign nations and global commons is false, and at minimum, merits independent assessment and verification.[139] The FDA review system regime[140] is flawed and insufficient because it does not require independent environmental assessment and research. Furthermore, the FDA relies exclusively on the data provided by ABT to approve AAS indefinitely.[141] A heavily invested company is the only provider of assessment and reports without any re-assessment mechanism. Because of precedential value, the FDA's lack of expertise in assessing the environmental impact of GM animals and an absence of independent research precludes federal approval at this time. Although AAS's probability of escape is low, the magnitude of impact if an escape occurs is overwhelming, thus making FDA review alone insufficient.[142]

Further, AAS should not be approved under current law because the FFDCA statute may, as some critics point out, be outdated and inadequate.[143] First, the statute is designed for drug approval, not approval

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stages of salmon present.") (emphasis added).

134. *Id*. at 130 ("[I]t is concluded that the likelihood is extremely small that [AAS] will establish and reproduce if they escape . . . .").

135. *See* POLLACK & SHAFFER, *supra* note 1, at 38; *see also* Jamie Doward, *GM Food Battle Moves to Fish as Super-Salmon Nears US Approval*, THE GUARDIAN (Sept. 25, 2010), http://www.guardian.co.uk/environment/2010/sep/26/gm-food-battle-salmon.

136. *See* Heavey, *supra* note 4 ("[ABT's] salmon has a gene to make it grow twice as fast as natural Atlantic salmon.").

137. THE ABT BRIEFING PACKET, *supra* note 17, at 65–66, 75.

138. AQUA BOUNTY TECHNOLOGIES INC., *supra* note 28, at 34–35 (noting that AAS are likely to avoid predation better than wild salmon due to their ability to adjust faster to the saline environment and swim faster).

139. THE ABT BRIEFING PACKET, *supra* note 17, at 131.

140. *See* PLAN & VAN DEN EEDE, *supra* note 89.

141. The E.U. system, on the other hand, grants GM approvals for periods of only ten years subject to subsequent extensions.

142. *See* Geiger, *supra* note 4 (stating that although there is a small risk of escape and co-mingling, it should not render the GM salmon safe for human consumption and the environment because the small probability of harm is outweighed by the magnitude of impact on the environment).

143. *See* TADLOCK COWAN & GEOFFREY S. BECKER, AGRICULTURAL BIOTECHNOLOGY: BACKGROUND AND RECENT ISSUES 9 (2010), *available at*

of animals intended for human consumption.[144] The plain language of section 201(g)(1)(C) refers to drugs by defining them as "articles (other than food) intended to affect the structure or any function of the body of man or other animals . . . ."[145] Second, the definition within the FFDCA statute cannot possibly refer to whole living animals intended for human consumption because the plain meaning of the "other than food" provision indicates the contrary.[146] It appears that the rDNA that AAS contains is a "drug" because it is intended to affect the structure or function of AAS by causing AAS to grow faster.[147] Would the definition apply to a human who consumes AAS flesh and the rDNA with it? The Packet does not report that the consumption of AAS affects the structure or any function of humans.[148] Thus, if rDNA is considered a "drug," does it stop being a drug before ingestion by consumers? The statute lacks transparency, introduces ambiguity, and has never before been used to approve a GM animal intended for human consumption.

Even if the statute was adequate section 201(v)(2) requires that a new animal drug must be determined safe "as a result of investigations."[149] Opposing consumer and environmental groups point out, however, that research is lacking on GM animals to determine safety and warrant their large scale production and consumption. Indeed, several U.S. senators have criticized the FDA approval process of GM foods for lack of adequate review of health and environmental risks[150] necessary under the risk-benefit equivalence principle governing the U.S. approval scheme.[151] The senators expressed concerns that "[s]uch a limited review of the first GE animal for human consumption is wholly inadequate to review potential public safety concerns associated and recklessly and needlessly endangers

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http://infousa.state.gov/economy/industry/docs/73949.pdf ("Critics . . . [have raised] questions about whether the current laws themselves remain adequate to protect human health and the environment, particularly as . . . GE applications [have begun to emerge].").

144. See *This Week In FDA History - June 20, 1963*, FDA, http://www.fda.gov/AboutFDA/WhatWeDo/History/ThisWeek/ucm117831.htm (last updated May 20, 2009) (noting the legislative history of the FFDCA which included the Kefauver-Harris Amendments that allowed the FDA to more strictly govern the "manufacture, effectiveness and promotion of drugs.").

145. Federal Food, Drug, and Cosmetic Act (FFDCA) § 201, 21 U.S.C. § 321(g)(1)(C) (2006).

146. *Id*.

147. *See* Heavey, *supra* note 4.

148. THE ABT BRIEFING PACKET, *supra* note 17, at 131.

149. FFDCA § 201, 21 U.S.C. § 321(v)(2).

150. Christian Nordqvist, *Lawmakers Make Move to Stop Genetically Modified Salmon Approval*, MEDICAL NEWS TODAY (Sept. 29, 2010), http://www.medicalnewstoday.com/articles/202932.php (noting the letter was signed by eleven Senators and supported by fifty-two environmental groups, consumer groups, retailers, food businesses, and commercial and recreational fisheries associations).

151. *See generally* sources cited *supra* note 55 (regarding how the United States analyzes the risks and benefits for GM food).

consumer health."[152]

The recent FDA Guideline for Industry 187 for approval of GM animals does not mention any updated or alternative statute under which AAS could possibly be approved. However, it does list groups of animals currently being developed to which the ABT product might apply.[153] A careful reading of animal groups listed in the Guidance could theoretically justify regulation of AAS under group (1) "food quality traits," because AAS grows twice as fast as farmed salmon, or group (6) "consumer product." The Packet, however, does not mention these provisions as a basis for approval but instead uses the new animal drug statute for AAS review.[154]

Even if the existing statutes were adequate, Congress must still enact full impact assessment laws and impose statutory monitoring and traceability requirements modeled on the E.U. framework if the United States wants to be an active competitor in the international GM food trade. Compatibility with E.U. laws would enable AAS and other GM foods to be sold overseas. If ABT was obligated to periodically report to the FDA (or some other agency) and label the product appropriately to ensure traceability in the AAS derivatives, U.S. and non-U.S. consumers, along with interest groups, would likely embrace AAS. A new GM animal-specific statute would facilitate trade relations and boost consumer confidence in both the United States and the European Union.[155]

In the meantime, AAS could still be introduced to the national and international consumer markets based on ad-hoc event-specific and product-specific agreements with the European Union and other nations.[156]

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152. Thomas Corriher, *The F.D.A. is Using a Unique G.M.O. Salmon Approval Process to Bypass U.S. Regulations*, THE HEALTH WYZE REP. (Sept. 30, 2010), http://healthwyze.org/index.php/component/content/article/499-the-fda-is-using-a-unique-gmo-salmon-approval-process-to-bypass-us-regulations.html.

153. *See* REGULATION OF GENETICALLY ENGINEERED ANIMALS, *supra* note 11, at 4 ("GE animals currently being developed can be divided into six broad classes based on the intended purpose of the genetic modification: (1) to enhance production or food quality traits (e.g., pigs with less environmentally deleterious wastes, faster growing fish); (2) to improve animal health (e.g., disease resistance); (3) to produce products intended for human therapeutic use (e.g., pharmaceutical products or tissues for transplantation; these GE animals are sometimes referred to as 'biopharm' animals); (4) to enrich or enhance the animals' interactions with humans (e.g., hypo-allergenic pets); (5) to develop animal models for human diseases (e.g., pigs as models for cardiovascular diseases); and (6) to produce industrial or consumer products (e.g., fibers for multiple uses).").

154. *See* THE ABT BRIEFING PACKET, *supra* note 17, at 1 (acknowledging that the only statute the Packet discusses is the "drug" statute). Accordingly, if the FDA concludes that its statutory authority is insufficient, it should take proactive steps and issue a guidance request to related agencies of Congress. *Id.*

155. Since there are no monitoring or traceability requirements in the United States, this could be an initial step to bring the GM framework for approval closer to the E.U. framework for approval. Further, because no animal has ever been approved for human consumption, this change appears to be appropriate.

156. *See* Thomas Cottier, *Genetic Engineering, Trade and Human Rights*, *in* GENETIC

Perhaps the biotechnology revolution may no longer be stopped,[157] and the only reasonable step is to revamp existing laws by adding GM-favorable amendments to existing international agreements such as the CBP or to initiate a new coalition of pro-GM communities and negotiate with the GM-averse communities such as the European Union.

B. UNIFICATION OF THE SALMON TRADE TO PREVENT WTO INVOLVEMENT AND FACILITATE CBP COMPLIANCE: LABELING

AAS approval under current laws will perpetuate the history of international trade disagreements between the United States and the European Union.[158] Additionally, AAS approval under the existing legal framework will widen the prominent and vast legislative and conceptual fissure already apparent in the international arena and visible in the U.S.-E.U. crop dispute.[159] The gap will widen[160] because it is reasonable to anticipate that the European Union will ban any imports of AAS into its territory, thus depriving the United States of a portion of its exports.[161] Reminiscent of the GM crop crisis,[162] this could lead to a temporary and possibly permanent trade freeze and a stalemate, which could bring about another U.S.-E.U., GM-related dispute under the WTO.

The existing discrepancy is vast because currently in the European Union, AAS-type applications would have to undergo independent agency assessment such as the one conducted by the European Food Standards Agency (EFSA).[163] Further, they would need to comply with labeling and tracing requirements, post-market monitoring measures, full public disclosure, and separate approval by each E.U. state with an active

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ENGINEERING AND THE WORLD TRADE SYSTEM: WORLD TRADE FORUM, *supra* note 55, at 17, 47–48 (proposing that biotechnology could be addressed in entirely new international agreements).

157. *See* Michael Cardwell, *Introduction* to THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES, *supra* note 13, at 1, 2.

158. *See* POLLACK & SHAFFER, *supra* note 1, at 276–77 (providing that the United States and the European Union have, historically, not agreed on numerous issues relating to export-import international trade). For example, when the European Union essentially froze approvals on the U.S. soybean and maize seed entry into its territory by imposing strict monitoring, approval and traceability requirements, the United States brought a lawsuit with the WTO. The United States is in stark contrast to the European Union because U.S. laws do not require labeling, segregating or monitoring of the crops. *Id.*; *see also* Federici, *supra* note 13, at 516; Cardwell, *supra* note 157, at 6.

159. *See* POLLACK & SHAFFER, *supra* note 1, at 181–82.

160. *See* Strauss, *supra* note 55, at 780, 807 (providing that U.S. regulations with regard to GM produce are much less rigorous as compared to the European Union's regulation on GM produce).

161. Alaska Sea Food Marketing Institute, *supra* note 127, at 1 (stating that the United States exports 23% of its salmon to the European Union).

162. *See* POLLACK & SHAFFER, *supra* note 1, at 182.

163. *See* WALTERS, *supra* note 90, at 100 (explaining that the EFSA is an independent agency that reviews GM applications to ensure food safety consumer protection).

"safeguard provision."[164] In contrast, in the United States, the FDA would only require a *unilateral* risk assessment from ABT[165] without any labeling,[166] mandatory monitoring measures, or safeguard withdrawal provisions. Furthermore, once the FDA allows it on the market, AAS can be sold in each state regardless of the state's residents' opinion of GM foods.

While it is unreasonable to expect that the United States and the European Union will reconcile their GM-related laws any time soon, one viable solution seems to exist which would facilitate GM food and crop trade and, possibly, AAS imports into the European Union. A compatible labeling system would increase consumer confidence and the flow of information and approval transparency. The FDA has already issued guidance on voluntary labeling which could be used as a model for mandatory labeling laws.[167] Moreover, there is growing pressure to impose GM-related labeling laws from members of Congress and various public organizations. Furthermore, individuals,[168] and a majority of Americans would prefer labeling.[169]

Labeling would also help achieve the WTO's free trade objectives to ensure unobstructed trans-boundary movement of GM plants and animals.[170] Because all WTO member countries are obligated to regulate, produce, classify, transport, and market GM plants and foods in a trade-friendly way,[171] mandatory labeling would necessitate that all recipients of AAS operate under the same labeling principle.

Not pursuing the labeling objective could lead to another WTO dispute and likely result in a repeat of the 2006 WTO crop crisis. Would the European Union, with its strict laws that would likely prevent AAS entry into its territory, be responsible for international trade disruption, or would the United States' lenient GM-related approval laws which essentially prevent the European Union from allowing the entry of AAS in the first place, be to blame? Regardless of the answer, ambiguity still exists. Since the WTO's authority does not reach so far as to *impose* regulations on its members, it may only recommend actions for conflicted

164. *See supra* notes 88–93 and accompanying text (providing that the safeguard provision was effectively used by the European Union in the crops crisis).

165. *See generally* THE ABT BRIEFING PACKET, *supra* note 17, at 112–14.

166. *See generally* Strauss, *supra* note 55, at 780, 784.

167. *See* Grossman, *supra* note 13, at 317 (stating that the guidance was issued in 2001); *see also* REGULATION OF GENETICALLY ENGINEERED ANIMALS, *supra* note 11, at 2.

168. *See* Center for Food Safety, *supra* note 47.

169. *See* ROBERT PAARLBERG, STARVED FOR SCIENCE: HOW BIOTECHNOLOGY IS BEING KEPT OUT OF AFRICA 23 (2008) *cited in* Federici, *supra* note 13, at 530 (noting that 94% of Americans polled prefer that their food be labeled for its GM content).

170. *See generally* Sella-Villa, *supra* note 13, (discussing labeling as part of a common customs classification system that would speed up E.U. GMO imports).

171. *Id.* at 978.

parties that are designed to help them resolve their dispute.[172] While the WTO arbitration body in the GM crop dispute was able to achieve faster approvals of U.S. GM crop applications, the European Union retained its GM-relevant laws.[173] It is reasonable to expect that any AAS-related lawsuit would not result in the WTO imposing mandatory approval of AAS in Europe. However, proper labeling of AAS, as a precondition of FDA approval, could minimize the risk of trade disruption and prevent a lawsuit in the first place. In turn, the fate of AAS on the European market would be determined by free market principles of customer demand, instead of administrative reasons of blocked entry.

Even the CBP community, of which the United States is not a member, would benefit from labeling requirements universally imposed on AAS, because Panama could avoid violating its Cartagena obligations to "avoid or minimize . . . potential adverse effects"[174] of handling GM food and animals, when AAS is accepted there for grow-out. Panama, an intended home for AAS's grow-out facility,[175] would then likely comply with CBP's requirements of safer transport and handling of GM products because each transport batch would presumably be labeled as containing GM matter. Without the labeling, it remains an open question whether Panama's acceptance of transgenic eggs would amount to violations of the CBP.

Indeed, the benefits of AAS labeling are significant in facilitating international trade under binding international contracts, especially because both the WTO and the CBP promote trans-boundary movement of articles and products.[176] The objectives of both the WTO (free trade) and CBP (preservation of biodiversity) would meet on at least this point.

C. INSUFFICIENCIES OF THE ABT PACKET AND THE EA PRECLUDE APPROVAL

Even if the FDA possessed environmental expertise and the GM-relevant statute was adequate, the Packet and the EA still do not merit approval of AAS. The Packet, containing 180 pages of reports,

172. *Id.* at 974.

173. *See* Strauss, *supra* note 55, at 786.

174. Simonetta Zarilli, *Biotechnology in the Energy Sector: Some Implications for Developing Countries*, *in* GENETIC ENGINEERING AND THE WORLD TRADE SYSTEM, *supra* note 1, at 151, 167.

175. *See* THE ABT BRIEFING PACKET, *supra* note 17, at 23. The Packet reports that the AAS eggs will be produced at the Prince Edward Island, Canada facility, while the fish will be grown out in Panama facilities. *Id.*

176. *See* Sella-Villa, *supra* note 13, at 978. The WTO and the Protocol are not in direct opposition: both the WTO and the Protocol promote trans-boundary movements of articles, including GMO products; however, the Protocol imposes heightened safeguards to protect biological diversity. The Protocol member countries have thus increased responsibility to safeguard health and environment. *Id.*

assessments, and conclusions, does not warrant FDA approval at this time. First, although the Packet lists numerous containment measures,[177] it does not provide a guarantee that AAS is adequately contained to prevent escape from ABT facilities.[178] Moreover, ABT intends to license AAS eggs to third party farmers[179] but has not demonstrated any enforcement or monitoring measures to control their operations. Second, the Packet does not rule out a possibility that AAS is capable of reproduction in the wild.[180] Third, the Packet admits there is no scientific data to preclude AAS's capability of surviving in the wild.[181] In addition, although the corporation spent sixty million dollars on research, it used only 144 market-sized salmon to conduct its assessments.[182] Further, the Packet contains only one sentence concluding that international consequences are not likely.[183] While the Packet discloses that AAS has been modified with the Chinook salmon growth hormone and the ocean pout antifreeze protein, and that they contain higher level of allergens, there is no mention of any comparable research.[184] Instead, ABT concludes that there are no observed negative health consequences and that the heightened allergenicity levels are not of public concern because consumers already allergic to salmon will stay away from AAS as well.[185]

Further, the EA does not warrant approval as escapees will have high impact on wild salmon if they interbreed. First, salmon are known to alter genetically when they change environments.[186] Second, AAS would out-compete wild salmon for food[187] since 25% size advantage is enough to gain superiority,[188] and AAS is several times as large as wild salmon. Finally, AAS sterility is not guaranteed—up to 5% may not be sterile.[189]

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177. *See* AQUA BOUNTY TECHNOLOGIES INC., *supra* note 28, at 63.

178. *See* THE ABT BRIEFING PACKET, *supra* note 17, at 131 ("[A]dequate containment measures *appear to be* in place . . . to insure *a very low probability* of escape for all life stages of salmon present.") (emphasis added).

179. *See* AQUA BOUNTY TECHNOLOGIES INC., *supra* note 28, at 41; Heavey, *supra* note 4; Geiger, *supra* note 4.

180. *See* THE ABT BRIEFING PACKET, *supra* note 17, at 130 ("[I]t is concluded that the likelihood is extremely small that AquAdvantage Salmon will establish and reproduce if they escape . . . .").

181. *Id*. at 129 ("There are no specific study data addressing [the issue of AAS survival in nature] . . . .").

182. *Id.* at 78–79 ("A total of 144 market-sized . . . Atlantic salmon were included in the study . . . . [T]issue samples from a total of 73 salmon were analyzed . . . .").

183. *See id.* at 131 ("[T]here are no likely consequences . . . on the US, any foreign nations not participating in the action, or the global commons [as a result of applicable reproductive and geographic/geophysical confinement].").

184. *Id.* at 65.

185. *Id.* at 75.

186. *See* AQUA BOUNTY TECHNOLOGIES INC., *supra* note 28, at 21.

187. *See id.* at 35.

188. *Id.*

189. THE ABT BRIEFING PACKET, *supra* note 17, at 115 (noting that this could pose a

Although survival likelihood is "extremely small,"[190] it is still possible. This data does not prove that AAS is not a threat to the wild salmon population.

Thus, the conclusions presented in both reports do not qualify AAS for FDA approval, even under the more lenient U.S. risk-benefit equivalence scheme.[191] Although there would be a benefit in faster growth presumably lowering the price of salmon, the risks do not outweigh the costs. The lack of conclusive research on the health impact of AAS, the high allergenicity, and the catastrophic and irreversible environmental consequences in case of escape or malicious release, preclude approval by the FDA. Yet, this does not mean that AAS could never be approved. The FDA should demand research on a larger sample of AAS and more conclusive research on the growth hormone consumption impact on humans, require placement of emergency measures in case the containment measures fail,[192] and require a better than 5% sterility ratio. The FDA could also set up its own independent research body to evaluate the scientific conclusions submitted in the application.[193] Further, because AAS is a case of first instance, the FDA could require a "disabling" mutation to preclude survival in nature.[194] In the long run, the FDA should issue a formal request to Congress for legislative reform that would provide a more detailed framework for future approvals of GM animals in general.[195]

D. POTENTIAL INTERNATIONAL LAW VIOLATIONS: PANAMA

AAS approval by the FDA, in the United States, may indirectly lead

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risk of reproduction with the wild salmon if the GM salmon ever became integrated into the wild).

190. *Id.* at 130.

191. *See generally* Sella-Villa, *supra* note 13, (comparing U.S. and E.U. approaches to risks regarding GMOs).

192. *See generally* THE ABT BRIEFING PACKET, *supra* note 17, at 116. Aqua Bounty reports that "The U.S. Department of Agriculture's Agricultural Biotechnology Research Advisory Committee . . . has prepared performance standards for safely conducting research with genetically modified fish" and that those standards do not "require, or even recommend, specific . . . containment measures." *Id.*

193. EFSA, an independent body in the European Union, works exceptionally well: assessment results are comparable against one another, the risk of manipulation by applicants becomes minimal and the public has no reason to believe that research is biased or otherwise inadequate. *See* Council Regulation 178/2002, 2002 O.J. (L 31) (establishing EFSA). The creation of a similar body under the U.S. framework would be a revolutionary step.

194. *See* WALTERS, *supra* note 90, at 11 (noting that science permits injecting genes with "disabling mutations [that prevent] grow[ing] outside of the controlled environment of a laboratory test tube").

195. *See* POLLACK & SHAFFER, *supra* note 1, at 274 (explaining that recent biotechnology events might "call into question the adequacy of the Coordinated Framework to deal with new and emerging technologies").

to international law violations by Panama. As ABT plans to produce AAS eggs in Canada and grow the fish out in Panama,[196] transport between these facilities raises international law concerns given Panama's membership in the CBP.[197] Given that ABT does not guarantee 100% confinement of the AAS,[198] any release or escape during transport in Panama's territory that injures or contaminates the biodiversity of another country could involve the United States in a potential liability dispute as an indirect cause of contamination.[199] The United States is not bound by the CBP,[200] but ABT's plans to grow AAS in Panama are adverse to Panama's obligation to protect biodiversity within its territory. Thus, in the event that containment fails, the FDA approval will have an international impact on natural salmon resources in the Atlantic. AAS's free movement in oceanic waters could cause a domino effect in other nations by destroying their already dwindling wild salmon populations.

E. WILD SALMON PRESERVATION, WILD SALMON TRADE, AND GENERAL PRECEDENTIAL IMPACT OF THE APPROVAL

AAS could eradicate wild salmon populations because ABT's less than 100% effective containment measures combined with AAS's imperfect sterility rate[201] could cause AAS integration into wild populations[202] that move freely within oceanic waters.[203] Escaped or released AAS could impact both wild salmon trade worldwide and environmental preservation efforts that protect wild salmon. Under WTO agreements,[204] the United States is obligated not to cause unnecessary

196. THE ABT BRIEFING PACKET, *supra* note 17, at 65.

197. *See* SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, *supra* note 96*; see also* POLLACK & SHAFFER, *supra* note 1, at 155.

198. THE ABT BRIEFING PACKET, *supra* note 17, at 120–32.

199. *See* POLLACK & SHAFFER, *supra* note 1, at 154 (explaining that the United States never ratified the CBP and is therefore not bound by its provisions, although it might be liable under some other international agreements).

200. *See* SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, *supra* note 96.

201. *See* THE ABT BRIEFING PACKET, *supra* note 17, at 115, 127.

202. *See id.* at 116 (acknowledging that their containment measures are not 100% effective and do not preclude either the possibility of salmon escaping from its breeding grounds or "survival and possibly establishment" of the fish in the adjacent natural waters). Further, ABT reports that "there are no specific study data" addressing the issue of survival but that it "conservatively assumed that older life stages . . . would survive if they escaped containment in [Prince Edward Island, Canada]." *Id.* at 129–30.

203. *See Frequently Asked Questions*, *supra* note 129; s*ee also* COATES, *supra* note 6, at 104 ("[J]ust 60 genetically engineered fish among 60,000 wild fish would bring species extinction within 40 generations."); POLLACK & SHAFFER, *supra* note 1, at 274; Doward, *supra* note 135.

204. Agreement on Technical Barriers to Trade, Apr. 15, 1994, WTO Agreement, Annex 1A, Legal Instruments—Results of the Uruguay Round, vol. 27 (1994), http://www.wto.org/english/docs e/legal e/17-tbt.pdf; Agreement on Trade-Related Aspects

obstacles to trade, and AAS comingling with wild salmon could effectively eradicate non-GM salmon trade altogether, as well as trigger international litigation. A dispute over genetic contamination of wild salmon caught and internationally traded would likely be brought before the WTO Dispute Settlement Unit. This would be similar to the 2003 GM seeds case which was resolved in favor of the United States.[205] However, because the AAS dispute would stem from losses to a multitude of fishing industries, it is impossible to speculate that the resolution would in any way resemble the GM seed case or cause any changes to the E.U. GM-related approval system.[206] In the crop dispute, the WTO Panel did not rule against the E.U. endorsed "precautionary principle,"[207] but only focused on undue delays. It is reasonable to speculate that a possible AAS dispute would bring similarly inconclusive results. It is outside the scope of this Note to discuss any possible damage claims that the wronged states and communities would then bring.

In addition, E.U. GM-related laws,[208] designed to maintain control over which GM organisms enter the environment, would be redundant as soon as AAS would become part of the natural ecosystem, and all salmon caught in E.U. water territory would have to be presumed GM-tainted. Although each European state may independently ban import of GM products into its territory,[209] countries such as Ireland,[210] where wild salmon are still fished, would immediately be deprived of their refusal right to have GM salmon as part of their diets as the AAS could simply migrate into Ireland's waters.

Finally, there is no other genetically modified animal that has

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of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 1869 U.N.T.S. 299, http://www.wto.org/english/docse/legal e/27-trips.pdf; General Agreement on Tariffs and Trade, October 30, 1947, T.I.A.S. No. 1700, 55 U.N.T.S. 194.

205. *See* POLLACK & SHAFFER, *supra* note 1, at 187.

206. *See id.* (explaining that the WTO Panel's opinion ruled the E.U. delays in GMO crop seed approvals as 'not inconsistent' with the relevant treaties, criticized E.U. delays in approvals rather than the approval system, and did not rule on whether biotech products are safe in general or whether the E.U. regulations are adequate).

207. *See, e.g.*, Zarilli, *supra* note 1, at 7 ("For countries like the EU, that have adopted a 'no-risk' approach, the main preoccupation is to establish strict import measures that would guarantee that the chosen high level of health and environmental protection is indeed achieved.").

208. *See* Directive 2001/18/EC, *supra* note 92, (imposing mandatory tracing and monitoring requirements for deliberate releases of GMOs and mandatory public information disclosures).

209. The "safeguard provision" permits restricting or prohibiting a GM organism when new or additional scientific knowledge raises concern as to that GMO's safety for human health and environment. *Id.* at art. 23.

210. *See European Commission Orders Ireland to Protect Wild Atlantic Salmon*, FINFACTS (July 3, 2006), http://www.finfacts.com/irelandbusinessnews/publish/article_10006443.shtml.

previously been approved for public consumption,[211] and the FDA's approval of AAS would be a worldwide breakthrough paving the way for other corporations to apply for other GM animal-related FDA licensing.[212] The approval would initiate a new era in animal production. The GM plant market started slowly but became so prevalent that it achieved a point of no return as GM plants are now ubiquitously present and integral to almost all agricultural markets.[213] Just as the first GM plant was first approved in the United States for public consumption in 1996 leading to, in 2004, an estimated "global GM crop area [of] 81 million hectares, cultivated by 8.25 million farmers in 17 countries,"[214] the FDA approval of AAS will trigger developments that are inestimable and dangerous. While GM proponents argue that the FDA had already approved GM animals when it reviewed GloFish, the decorative fish,[215] this precedent should not be used for approving an animal that has an impact on the health of millions and on ecosystems across the world.

IV. CONCLUSION

The revolutionary nature and historic proportions of the FDA AAS review is a perfect opportunity for reassessment of the U.S. GM-related laws and for considering a possible change to the U.S. GM-related legislative regime. The FDA should not approve AAS at this time because the approval would exacerbate the historic GM trade conflict between the United States and the European Union, interfere with international biodiversity agreements, and endanger wild salmon populations.

Instead, the controversy should trigger new comprehensive legislation with respect to GM animal approvals in the United States as well as verifiable assessment, monitoring procedures, and labeling requirements. In light of prevalent and persistent consumer and environmental group protests, the FDA should seek resolutions with Congress as the new GM animal or GM food product issue is likely to become more prevalent in the future and may emerge in the context of international trade relations with other countries.

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211. *See* Layton, *supra* note 3 ("Scientists at the University of Guelph in Ontario, Canada, have asked the FDA to approve their 'Enviropig,' a hog genetically altered to produce environmentally friendly manure. Hematech of Sioux Falls, S.D., is developing genetically modified cows that are resistant to mad cow disease.").

212. Heavey, *supra* note 4 (noting that ABT itself announced it will seek approval for using the same GM technology for trout and tilapia to market the eggs to fish farmers).

213. *See id.*

214. Zarilli, *supra* note 1, at 3.

215. *See FDA Statement Regarding GloFish*, FDA (Dec. 9, 2003), http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm161437.htm (explaining that the FDA will not regulate the GloFish since they are not used for food and pose no threat to the environment).