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## Bottomfeeding: How The USDA's Noodling With Catfish Regulations Violates the United States' WTO Obligations

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# Bottomfeeding: How The USDA's Noodling With Catfish Regulations Violates the United States' WTO Obligations

Chelsea Fernandez Gold\*

## ABSTRACT

In 2008, Congress passed the Farm Bill with an amendment to the Federal Meat Inspection Act, which shifted the authority to regulate catfish and catfish products from the United States Food and Drug Administration (FDA) to the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), an agency that had no history of overseeing the inspection of seafood. The USDA, as required by law, drafted a proposed rule detailing this regulatory shift and sent it to the Office of Management and Budget (OMB) on June 3, 2014; the rule was then finalized on November 25, 2015. While the domestic catfish industry and its supporters advocated for the speedy publication of the final USDA rule, foreign exporters of catfish to the United States considered it to be a thinly veiled attempt to prevent the entry of catfish from countries like Vietnam. Given that the rule has been finalized, this Article details the set of allegations that Vietnam, or any foreign exporter of catfish, could bring before a World Trade Organization (WTO) Panel in which it would assert a violation of the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures. Ultimately, this Article concludes that, if the United States seeks to avoid a WTO dispute settlement, the only recourse is to repeal the provisions contained within the 2008 and 2014 Farm Bills and allow the authority to inspect catfish and catfish products to revert to the FDA.

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INTRODUCTION

In the struggle for survival, the fittest win out at the expense of their rivals because they adapt best to their environment.<sup>1</sup> For roughly thirty years, the United States has been negotiating its way through the global market by tearing

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1. See CHARLES DARWIN, ON THE ORIGIN OF SPECIES 112 (6th ed. 2004) (“[I]n the struggle for life over other forms, there will be a constant tendency in the improved descendants of any one species to supplant and exterminate in each stage of descent their predecessors and their original parent.”).

down trade barriers through free trade agreements.<sup>2</sup> But the United States only believes in the free trade game until it starts losing; then, it accuses the other side of cheating or quits the game altogether.<sup>3</sup> At the very least, this is the message the United States sends the rest of the world when it seeks to engage in free trade agreements while enacting protectionist policies, such as the rule requiring the mandatory inspection of catfish and catfish products.<sup>4</sup>

The rule is the result of a provision tucked into the Food, Conservation, and Energy Act of 2008 (“2008 Farm Bill”), which authorizes the unique treatment and inspection of catfish.<sup>5</sup> Since its proposal, the rule has sparked an international controversy<sup>6</sup> because it delegates regulatory responsibility for the inspection of catfish to the Food Safety and Inspection Service (FSIS), an office housed within the United States Department of Agriculture (USDA).<sup>7</sup> This will differentiate catfish inspections from all other seafood inspections, which the Food and Drug Administration (FDA) handles.<sup>8</sup> This shift in regulatory oversight will subject catfish to more stringent, continuous, and mandatory inspections and will require nations that export catfish to the United States to establish inspection systems equivalent to those in place in the United States. Aside from the cost,<sup>9</sup> which is sure to be high, the new inspection regime is expected to ban foreign catfish producers from entering the United States market until they can meet the FSIS’s standard of equivalency, which can take years to achieve.<sup>10</sup>

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2. See Chris Matthews, *Why the Era of Global Free-Trade is Dwindling*, FORTUNE (July 24, 2014), <http://fortune.com/2014/07/24/free-trade/>.

3. Editorial, *The Looming Shrimp War*, N.Y. TIMES, Oct. 6, 2003, <http://www.nytimes.com/2003/10/06/opinion/the-looming-shrimp-war.html>.

4. See generally Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, 80 Fed. Reg. 75590 (Dec. 2, 2015) (to be codified at 9 C.F.R. pt. 300, 441, 530–34, 537, 539–54, 544, 548, 550, 552, 555, 557, and 559–61).

5. See Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, § 11016(b), 112 Stat. 1651 (June 18, 2008) (classifying catfish as an “amenable species,” thereby subjecting it to mandatory, continuous inspections).

6. See, e.g., Ron Nixon, *Catfish Program Could Stymie Pacific Trade Pact, 10 Nations Say*, N.Y. TIMES, June 28, 2014, at A15 (highlighting that Vietnam’s success is garnering international support for assertion that the catfish inspection program violates international law); Zhenhu Bian, *America’s Fishy Trade Barriers*, WALL ST. J. ASIA, Aug. 29, 2013, <http://www.wsj.com/articles/SB10001424127887324009304579040741754600398> (stating that Chinese catfish producers “reserve the right to ask [their] government to use all the tools available to it as a WTO member to challenge this unfair obstacle”).

7. See Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, 80 Fed. Reg. at 75590.

8. See Mark Hemingway, *What Will it Take to Kill the Farm Bill’s Wasteful Catfish Subsidy?* THE WKLY. STANDARD (Jan. 28, 2014), [http://www.weeklystandard.com/blogs/what-will-it-take-kill-farm-bills-wasteful-catfish-subsidy\\_775862.html](http://www.weeklystandard.com/blogs/what-will-it-take-kill-farm-bills-wasteful-catfish-subsidy_775862.html).

9. Nixon, *supra* note 6 (explaining that Vietnam finds this shift to be an expensive, burdensome, and unnecessary regulation).

10. K. William Watson, *Crony Catfish*, CATO INST. (Aug. 13, 2014), <http://www.cato.org/blog/crony-catfish>.

While the domestic catfish industry supports the rule as necessary to ensure food safety and the economic security of their industry, foreign exporters find it to be arbitrary, subjective, and protectionist in nature.<sup>11</sup> Foreign catfish producers contend that the rule is in direct violation of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (“SPS Agreement”).<sup>12</sup>

The SPS Agreement is a set of binding rules and disciplines for all relevant laws, regulations, and procedures directly related to food safety in the Member countries.<sup>13</sup> It also provides Members with the ability to set the level of protection of human, animal, or plant health that they deem appropriate.<sup>14</sup> However, there is a difference between SPS measures that are appropriate and necessary for the protection of human, animal, and plant health and those that merely function as protectionist measures. In the case of the rule, this Article asserts that the United States’ shift in regulatory oversight to an office with more stringent and onerous regulations amounts to a protectionist measure because the increased level of oversight for the catfish industry in particular is not supported by sufficient scientific evidence<sup>15</sup> or based on a risk assessment.<sup>16</sup> The

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11. Compare Joey Lowery, Address at the Pub. Meeting Concerning the USDA Proposed Rule for Mandatory Inspection of Catfish and Catfish Products 65 (May 24, 2011), available at [http://www.fsis.usda.gov/wps/wcm/connect/eefd3e0d-ea69-4c75-b1ac-ea4df9d133e4/Transcripts\\_05242011\\_Catfish\\_meeting.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/eefd3e0d-ea69-4c75-b1ac-ea4df9d133e4/Transcripts_05242011_Catfish_meeting.pdf?MOD=AJPERES) (representing Catfish Farmers of America and claiming that, for the sake of consumer health and the well-being of an important, job-creating, domestic industry, it is critical that the FSIS begin inspecting catfish), with Thad Cochran’s *Crony Catfish: K. William Watson Comments*, CATO INST. (Aug. 12, 2014), <http://www.cato.org/multimedia/daily-podcast/thad-cochrans-crony-catfish> (finding the then-proposed rule to be a very obvious example of an attempt by a domestic industry to regulate its foreign competitors) and *A Fish By Any Other Name*, WALL ST. J. ASIA, May 20, 2009, <http://online.wsj.com/articles/SB124276314037135959> (finding the regulatory switch is “protectionism at its worst”).

12. Letter from Pham Binh Minh, Minister of Foreign Affairs, Socialist Republic of Vietnam and Vu Huy Hoang, Minister of Industry and Trade, Socialist Republic of Vietnam, to the Honorable John Kerry, Secretary of State, United States (Oct. 30, 2013), [http://thehill.com/sites/default/files/joint\\_ministers\\_letter\\_to\\_hon\\_john\\_kerry.pdf](http://thehill.com/sites/default/files/joint_ministers_letter_to_hon_john_kerry.pdf) (“[Vietnam’s] government is unwilling to sit by as this program is implemented . . . when the program so clearly violates America’s WTO obligations.”).

13. Dale E. McNiel, *The First Case Under the WTO’s Sanitary and Phytosanitary Agreement: The European Union’s Hormone Ban*, 39 VA. J. INT’L L. 89, 90 (1998); see Agreement on the Application of Sanitary and Phytosanitary Measures, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instruments—Results of the Uruguay Round, Apr. 15, 1994, 1867 U.N.T.S. 493, 496–97 [hereinafter SPS Agreement].

14. See SPS Agreement, *supra* note 13.

15. See *id.* art. 2.2.

16. See *id.* art. 5.1.

transition from the FDA to the USDA functions as a disguised barrier to international trade.<sup>17</sup>

Part II provides a framework to understand and evaluate the alleged violation of the SPS Agreement by tracing the legislative history of catfish food safety policy. In particular, Part II emphasizes the impact of the rule by highlighting the significant differences between the FDA and the USDA's inspection programs, as these differences will result in a costly and burdensome process for foreign catfish producers.

This historical background informs Part III, which analyzes a hypothetical case brought before a WTO Panel by Vietnam alleging that the rule amounts to a violation of the WTO SPS Agreement. Part III first establishes how the rule is neither founded on sufficient scientific evidence nor based on a risk assessment, thus violating articles 2.2 and 5.1 of the SPS Agreement. The Article then asserts that the rule is a "disguised restriction on international trade" in violation of article 5.5 of the SPS Agreement.

In Part IV, this Article recommends that Congress repeal section 11016 of the 2008 Farm Bill, either through the introduction of new legislation or through the passage of a congressional resolution of disapproval. Though there are alternative paths, such as reallocating funding to the FDA for increased catfish inspections or requiring a lengthy transitional period in which the FDA-compliant countries remain unaffected, they do not safeguard against a WTO complaint. Repeal is the only guaranteed safeguard against a potential WTO complaint against the United States.

## I.

### THE HISTORY OF FISHY CATFISH FOOD SAFETY POLICY IN THE UNITED STATES

The cultivation of the domestically raised catfish species *Ictaluridae* is the leading aquaculture industry in the United States.<sup>18</sup> Many of the early pioneers entered into the farm-raised catfish industry looking for crop diversification or profitable alternatives to growing cotton on marginally productive lands.<sup>19</sup> But the industry soon became much more than a mere alternative to cotton, growing to generate billions of dollars,<sup>20</sup> and becoming a primary source of economic

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17. See *id.* art. 5.5.

18. See FSIS, USDA, EXECUTIVE ORDER 12866—PRELIMINARY REGULATORY IMPACT ANALYSIS 23 (2011) [hereinafter FSIS IMPACT ANALYSIS] ("Commercial *Ictaluridae* catfish production generates over [forty-six] percent of the value of aquaculture production in the [United States].").

19. Terrill R. Hanson, *Catfish Farming in Mississippi*, MISS. HIST. NOW, Apr. 2006, <http://mshistorynow.mdah.state.ms.us/articles/217/catfish-farming-in-mississippi>.

20. See Bartholomew Sullivan, *Federal Report Claims Vietnam Dumped Catfish on U.S. Market*, COM. APPEAL, Sept. 5, 2013, <http://www.commercialappeal.com/business/federal-report-claims-vietnam-dumped-catfish-on> (stating that catfish sales surpass \$4 billion annually).

activity and employment in many southern states.<sup>21</sup> However, the catfish industry today is not what it used to be.

#### A. *The 2002 and 2008 Farm Bills*

Beginning in 2002, United States imports of foreign catfish grew exponentially.<sup>22</sup> This influx of low-priced catfish<sup>23</sup> put significant pressure on the United States catfish industry by driving down the market price of catfish and reducing the domestic industry's market share.<sup>24</sup> Rather than compete with the foreign catfish imports, the domestic catfish industry called on Congress, which responded by enacting section 10806 of the Farm Security and Rural Investment Act of 2002 ("2002 Farm Bill").<sup>25</sup> Section 10806 mandated that only fish from the same taxonomical family as United States-grown catfish, *Ictaluridae*, could legally be labeled as "catfish."<sup>26</sup> In doing so, Congress prevented all foreign species of catfish, such as the Vietnamese *Pangasius*, from being marketed as "catfish."<sup>27</sup>

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21. See FSIS IMPACT ANALYSIS, *supra* note 18, at 23 (estimating that there are 1,300 catfish farms in at least sixteen states and that ninety-four percent of catfish are farmed in Alabama, Arkansas, Louisiana, and Mississippi).

22. See Kara Petteway, *Free Trade vs. Protectionism: The Case of Catfish in Context*, 30 N.C. J. INT'L L. & COM. REG. 475, 475 (2004) (finding a main cause of this growth to have been the Vietnam-U.S. Bilateral Agreement in 2001, after which Vietnamese imports fared "surprisingly well," capturing as much as twenty percent of the United States frozen catfish fillet market and dramatically increasing its exports to the United States).

23. See Ted Carter, *Catfish Farming: Future Fading on a 'A Great American Story'*, MISS. BUS. J. BLOG, Feb. 22, 2013, <http://msbusiness.com/blog/2013/02/22/catfish-farming-future-fading-on-a-great-american-story/> (stating that *Pangasius* exporters sell at \$2.50 a pound lower than the U.S. product).

24. See *Appropriations for Fiscal Year 2002: Hearings Before the Subcomm. on Agric., Rural Dev., and Related Agencies of the S. Comm. on Appropriations*, 107th Cong. 269 (2001) (statement of Sen. Thad Cochran, Chairman, S. Subcomm. on Agric., Rural Dev., and Related Agencies) (stating that data suggests that catfish imports displaced significant volumes of U.S. produced catfish and suppressed producers' prices).

25. See Opinion, *Harvesting Poverty: The Great Catfish War*, N.Y. TIMES, July 22, 2003, <http://www.nytimes.com/2003/07/22/opinion/harvesting-poverty-the-great-catfish-war.html> (explaining how U.S. catfish farmers persuaded Congress to disregard science in the 2002 Farm Bill).

26. See Farm Sec. and Rural Inv. Act of 2002, § 10806(a)(1); see also FDA GUIDANCE FOR INDUSTRY: IMPLEMENTATION OF SECTION 403(T) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (21 U.S.C. 343(T)) REGARDING THE USE OF THE TERM "CATFISH" 1 (2002) ("[I]mporters, domestic distributors, and sellers of fish from families other than *Ictaluridae*, who previously used the term 'catfish' . . . may no longer use that term, either when the fish are offered for import into the United States or distributed or sold in interstate commerce within the United States. Other names must be used.").

27. See Farm Sec. and Rural Inv. Act of 2002, § 10806(a)(1) (requiring that the term "catfish" only be used for fish classified within the family *Ictaluridae*).

The 2002 Farm Bill was only the first step in protecting the United States catfish industry. It was followed by an aggressive and offensive publicity campaign aimed at American catfish buyers, which characterized foreign catfish as “dirty, even toxic, and definitely un-American.”<sup>28</sup> Despite these efforts, foreign catfish producers continued to successfully develop and cultivate a significant and growing presence in the United States by marketing and selling their products as “basa,” “tra,” and “swai.”<sup>29</sup>

Because the impact of foreign catfish on the United States market remained strong,<sup>30</sup> many in the industry believed that the first attempt at regulation had failed.<sup>31</sup> Consequently, catfish farmers and their supporters again turned to Congress expressing concerns over the safety of imported catfish<sup>32</sup> and articulating a need for more stringent inspection procedures.<sup>33</sup> This amounted to an attempt to artificially prop up the failing domestic catfish industry,<sup>34</sup> and in

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28. Seth Mydans, *Americans and Vietnamese Fighting Over Catfish*, N.Y. TIMES, Nov. 5, 2002, <http://www.nytimes.com/2002/11/05/world/americans-and-vietnamese-fighting-over-catfish.html>; see, e.g., Opinion, *Harvesting Poverty: The Great Catfish War*, N.Y. TIMES, July 22, 2003, <http://www.nytimes.com/2003/07/22/opinion/harvesting-poverty-the-great-catfish-war.html> (“Congressman Marion Berry . . . suggest[ed] that [foreign] fish were not good enough for American diners because they came from a place contaminated by so much Agent Orange[, and the] Catfish Farmers of America . . . ran advertisements warning of a ‘slippery catfish wannabe,’ saying such fish were ‘probably not even sporting real whiskers’ and ‘float around in Third World rivers nibbling on who knows what.’”).

29. See Carter, *supra* note 23 (affirming that the United States market preferred *Pangasius*); Congressman Bennie Thompson, Address at the Pub. Meeting Concerning the USDA Proposed Rule for Mandatory Inspection of Catfish and Catfish Prods. 60 (May 24, 2011) (transcript available at [http://www.fsis.usda.gov/wps/wcm/connect/eefd3e0d-ea69-4c75-b1ac-ea4df9d133e4/Transcripts\\_05242011\\_Catfish\\_meeting.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/eefd3e0d-ea69-4c75-b1ac-ea4df9d133e4/Transcripts_05242011_Catfish_meeting.pdf?MOD=AJPERES)) (showing that foreign catfish producers continued to have an impact because acreage has fallen forty percent, production numbers have decreased, and the number of people working in the catfish industry is down to less than 10,000 employees in recent years).

30. See, e.g., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO 12-411, SEAFOOD SAFETY: RESPONSIBILITY FOR INSPECTING CATFISH SHOULD NOT BE ASSIGNED TO USDA 7 (2012) [hereinafter GAO REPORT] (providing data that indicates the volume of imported catfish entering the U.S. market has continued to increase, while the volume of domestic catfish entering the market has declined). The percentage of imported catfish in the U.S. market was estimated at 2 percent in 2002, 12 percent in 2006, and 23 percent in 2010.

31. See, e.g., Cindy Hyde-Smith, Address at the Pub. Meeting Concerning the USDA Proposed Rule for Mandatory Inspection of Catfish and Catfish Prods. 25 (May 26, 2011) (transcript available at [http://www.fsis.usda.gov/wps/wcm/connect/eefd3e0d-ea69-4c75-b1ac-ea4df9d133e4/Transcripts\\_05242011\\_Catfish\\_meeting.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/eefd3e0d-ea69-4c75-b1ac-ea4df9d133e4/Transcripts_05242011_Catfish_meeting.pdf?MOD=AJPERES)) (stating that the attempts to redefine catfish in the 2002 Farm Bill were unsuccessful as “catfish stubbornly remained catfish in the eyes of the consumers, regulators, and retailers.”).

32. See, e.g., Comments of Michael Hansen, Consumers Union, on Proposed Rule for Mandatory Inspection of Catfish and Catfish Prods. 4 (June 24, 2011) (on file with the FSIS) (emphasizing worries about foreign catfish producers’ use of drugs unapproved for use in aquaculture in the United States, which could affect consumers’ health or contribute to antibiotic resistance).

33. See *id.* (“FSIS is better suited than the [FDA] to ensure the safety of domestic and imported catfish, as FSIS does a more comprehensive review of food safety systems.”).

34. See John McCain, *The Fishy Deal on Catfish*, POLITICO, June 7, 2013,



2008, Congress complied. Without a single committee hearing, mark-up, floor debate, or scientific finding of any kind—in either the House or the Senate—Congress passed section 11016 of the 2008 Farm Bill.<sup>35</sup> Section 11016 amended the Federal Meat Inspection Act<sup>36</sup> (FMIA) to designate catfish, as defined by the Secretary of Agriculture, an “amenable species.”<sup>37</sup> This rebranding had the effect of shifting regulatory oversight of catfish (a term that had not yet been defined) from the FDA’s seafood Hazard Analysis and Critical Control Point (HACCP) program to the FSIS’s program of mandatory and continuous inspection.<sup>38</sup>

### B. *A Bait and Switch in Inspection Programs*

Since 1995, the FDA has used the HACCP program as its main food safety management tool to control pathogens and prevent product contamination in seafood.<sup>39</sup> The program is a risk-targeted approach to food safety in which processors are responsible for the safety of the seafood they process.<sup>40</sup> Such responsibilities include: identifying the likely hazards of a specific product, recognizing critical control points in a specific production process where a failure could result in a hazard being created or allowed to persist, implementing control techniques to prevent or mitigate these hazards, and monitoring the critical control points.<sup>41</sup>

For example, under the FDA’s HACCP program, a processing establishment that handles peeled, undeveined shrimp must draft a plan detailing the steps taken between the receipt of the raw shrimp and their shipment, including their quality check, rinsing, peeling, washing, chilling, packing, and

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<http://www.politico.com/story/2013/06/the-fishy-deal-on-catfish-92415.html> (“Rather than compete, southern catfish farmers asked their powerful friends . . . to support a law . . . that forces Americans to buy domestic catfish.”).

35. See Comments of John P. Connelly, President, The Nat’l Fisheries Inst., on Proposed Rule for Mandatory Inspection of Catfish and Catfish Prods. 4 (June 24, 2011) (on file with the FSIS).

36. Federal Meat Inspection Act, 21 U.S.C. § 601(w)(2) (1907).

37. Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, § 11016(b)(2), 112 Stat. 1651 (June 18, 2008).

38. See Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, 80 Fed. Reg. at 75592.

39. Andrew Kaplan, *Is Something Fishy Goin’ On?: H.A.C.C.P. Regulations and the Seafood Industry*, 23 RUTGERS L. REC. 4 (1999).

40. See Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65096, 65100 (Dec. 18, 1995) (codified in 21 C.F.R. pts. 123 and 1240) (defining the FDA’s HACCP program as a preventative system of hazard control that can be used by processors to ensure the safety of their products to consumers).

41. See Kaplan, *supra* note 39, at 4.

freezing phases.<sup>42</sup> From there, the establishment must identify the potential hazards associated with the shrimp, such as parasites, pathogens, and chemical contaminants, as well as the measures that can be applied to minimize and mitigate the significant hazards.<sup>43</sup> These measures range from monitoring and maintaining low temperatures to fly proofing the shrimp and using sanitized gloves.<sup>44</sup> With the passage of the amendment to the FMIA in the 2008 Farm Bill and the subsequent shift in regulatory oversight from the FDA to the FSIS,<sup>45</sup> catfish will become the first and only seafood product to be subject to the FSIS's system of mandatory and continuous inspection under the USDA.<sup>46</sup>

The FSIS's inspection program, on the other hand, involves mandatory and continuous oversight of every official establishment relating to processing, facility sanitation, hazard mitigation, and product transportation.<sup>47</sup> Specifically, the FSIS has an inspector at every domestic facility to monitor all aspects of processing.<sup>48</sup> The FSIS also requires foreign facilities exporting meat, poultry, egg, and now catfish products to the United States to establish and maintain inspection systems that are in line with the FSIS's regulations.<sup>49</sup> While there is no set timeline for equivalency determinations, imports from foreign catfish producers will be banned until an equivalent inspection system is established.<sup>50</sup> Even when a foreign exporter's processing plant has been deemed equivalent, all incoming shipments must be re-inspected by an FSIS import inspector at the port of entry into the United States to ensure that foreign countries have maintained their equivalent inspection systems.<sup>51</sup> Moreover, unlike the FDA's

42. See KANPA INTERNATIONAL SALES, HACCP MANUAL: KANPA INTERNATIONAL SALES 10, available at <http://www.kanpa.com/HACCP.pdf>.

43. See *id.* at 12–14.

44. See *id.*

45. See Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, 80 Fed. Reg. at 75593–98.

46. See Press Release, John McCain, Floor Statement by Senator John McCain on the Agriculture Reform, Food, and Jobs Act of 2012 (the Farm Bill) (June 14, 2012), available at <http://www.mccain.senate.gov/public/index.cfm/2012/6/post-eb68cca1-0e3e-bf76-260d-cf86e079c5fb> (explaining that the USDA is creating a whole new government office just to inspect catfish even though catfish and all other seafood products are already inspected by the FDA).

47. See Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, 80 Fed. Reg. at 75619.

48. Federal Meat Inspection Act, 21 U.S.C. § 606(a) (1907) (stating that an inspector shall conduct examinations and inspections of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and shall have access at all times to every part of the establishment).

49. See *FSIS Import Procedures for Meat, Poultry & Egg Products*, FSIS, <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/fsis-import-procedures-for-meat-poultry-and-egg-products/fsis-import-procedures> (last visited July 22, 2014) (explaining the process of establishing equivalence).

50. See Melissa Harris, *Costly Switch? Farm Bill Moves Catfish Inspections from FDA to USDA*, CHI. TRIB., Mar. 2, 2014, [http://articles.chicagotribune.com/2014-03-02/business/ct-confidential-fortune-fish-0302-biz-20140302\\_1\\_catfish-industry-fish-exports-fish-tacos](http://articles.chicagotribune.com/2014-03-02/business/ct-confidential-fortune-fish-0302-biz-20140302_1_catfish-industry-fish-exports-fish-tacos).

51. See *id.*

HACCP program, which inspects facilities approximately every one-to-three years based on prioritization and risk, the FSIS system of mandatory and continuous inspection will result in inspection of *all* catfish produced by eligible countries.<sup>52</sup> Given the considerable difference between these two inspection approaches,<sup>53</sup> and the financial burden and overall difficulty associated with achieving equivalency in other countries,<sup>54</sup> this shift will have important consequences for international trade now that commercial catfish production will come under the jurisdiction of the FSIS.<sup>55</sup>

### C. *The Risk Assessment*

According to the 2008 Farm Bill, the regulatory shift would not apply until the FSIS issued implementing regulations.<sup>56</sup> In February 2011, the FSIS began drafting the proposal for these regulations, applying processes previously only used for meat, poultry, and egg products to catfish and catfish products.<sup>57</sup> However, due to its expected economic impact, the proposed rule was designated as a “major regulation” under the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994.<sup>58</sup> This designation

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52. See FSIS IMPACT ANALYSIS, *supra* note 18, at 21–22.

53. See, e.g., Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, 80 Fed. Reg. at 75592–93, 75597–98 (stating that a country seeking eligibility to import its product into the United States would have to have its processing systems deemed “equivalent,” as compared to the FDA’s HACCP program, which does not presuppose a regulatory finding by the FDA of equivalence, nor does the FDA conduct continuous re-inspection of imported products as a condition of their entry).

54. See Sesto Vecchi & Gage Raley, *Catfish Driving a Wedge Between U.S. and Its Trade Partners*, WORLD FISHING & AQUACULTURE (Oct. 2, 2014), <http://www.worldfishing.net/news101/industry-news/catfish-driving-a-wedge-between-us-and-its-trade-partners> (explaining that putting in place a USDA-equivalent system will require major overhauls, which would shut down catfish export operations for years until the process is complete, as lawmakers will have to debate and pass legislation, draft regulations, allocate funding, and implement the new system. In the meantime, many catfish farmers, who are already struggling, will go out of business); see also Megan Engle, *China’s Poultry Slaughter System not Equivalent to United States’ System*, LEXOLOGY (Nov. 21, 2013), <http://www.lexology.com/library/detail.aspx?g=6f4cc464-4a4e-41f1-b4ba-684955444c7e> (showcasing an example of the historical difficulty associated with achieving equivalence).

55. See, e.g., Harris, *supra* note 50 (finding that catfish is a vital industry to Vietnam, accounting for more than \$380.7 million of the country’s more than \$1.5 billion in fish exports to the United States in 2013, which will be negatively impacted by the imposition of the proposed rule); Vecchi, *supra* note 54 (stating that the catfish trade is an important issue for Vietnam because its aquaculture sector has invested heavily in catfish farming to meet United States demand).

56. See Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, 80 Fed. Reg. at 75592.

57. See GAO REPORT, *supra* note 30, at 1–2.

58. See Fed. Crop Insurance Reform and Dep’t of Agric. Reorganization Act of 1994, Pub. L. No. 103-354 § 304(c), 108 Stat. 3178 (Oct. 13, 1994) (defining rules with a likely annual impact of

required the proposed rule to be supported by a risk assessment promulgated by the FSIS.<sup>59</sup>

In assessing the potential risks posed by catfish for its required risk assessment, the FSIS looked for vulnerabilities related to microbial pathogens, bacterial contaminants, heavy metals, unapproved antimicrobials, and pesticides, drawing on data from the FDA, the Center for Disease Control (CDC), state public health agencies, and the World Health Organization (WHO).<sup>60</sup> Despite this extensive research into various vulnerabilities, the FSIS's risk assessment ultimately focused on the potential risks associated with *Salmonella*, identifying the need to protect catfish consumers from this target pathogen as the primary scientific justification for the rule.<sup>61</sup> Yet the risk assessment was plagued with uncertainty,<sup>62</sup> and considering that Congress had yet to define catfish, it was unclear how far the proposed rule's effects would spread.

#### D. A Definitional Change of the Meaning of Catfish

Despite the many attempts to eliminate the catfish inspection program,<sup>63</sup> Congress clarified the definition of catfish when it passed the Agricultural Act

\$100 million or more in 1994 dollars as "major regulations").

59. See *id.* § 304(b)(1)(A) (requiring an analysis of the health risks, costs, and benefits for "major" proposed regulations that regulate human health, human safety, or the environment).

60. Mandatory Inspection of Catfish and Catfish Products, (proposed Feb. 24, 2011) 76 Fed. Reg. 10433, 10438–40 (to be codified at 9 C.F.R. pt. 300, 441, 530–34, 537, 539–54, 544, 548, 550, 552, 555, 557, and 559–61).

61. See *id.* at 10440; see also RISK ASSESSMENT DIV., FSIS, USDA, ASSESSMENT OF THE POTENTIAL CHANGE IN HUMAN HEALTH RISK ASSOCIATED WITH APPLYING INSPECTION TO FISH OF THE ORDER SILURIFORMES 10 (2015) [hereinafter 2015 FSIS RISK ASSESSMENT] (stating that the FSIS focused on *Salmonella* contamination because the presence of this pathogen in the United States remains a concern and there is evidence that at least one outbreak of salmonellosis may have been related to catfish consumption); RISK ASSESSMENT DIV., FSIS, USDA, RISK ASSESSMENT OF THE POTENTIAL HUMAN HEALTH EFFECT OF APPLYING CONTINUOUS INSPECTION TO CATFISH 9 (2012) [hereinafter 2012 FSIS RISK ASSESSMENT]; RISK ASSESSMENT DIV., FSIS, USDA, PEER REVIEW COMMENTS AND RESPONSES TO AN UPDATED RISK ASSESSMENT OF THE EFFECT OF AN FSIS CATFISH INSPECTION PROGRAM 9–11 (2011) [hereinafter RISK ASSESSMENT PEER REVIEW COMMENTS] (stating that while the FSIS evaluated data regarding many contaminants, they are no longer relevant as the risk assessment only focuses on the potential adverse effects of *Salmonella*).

62. See 2015 FSIS RISK ASSESSMENT, *supra* note 61, at 9 (explaining that the FSIS's lack of experience in implementing such an inspection program in the context of aquaculture makes estimating the impact of such a program difficult); 2012 FSIS RISK ASSESSMENT, *supra* note 61, at 9 (stating that specific information regarding the presence of *Salmonella* and the impact on mandatory and continuous inspection is unavailable); Richard Williams, *Public Interest Comment on Mandatory Inspection of Catfish and Catfish Products*, GEO. MASON U. MERCATUS CTR., June 20, 2011, <http://mercatus.org/publication/comment-usda-mandatory-inspection-catfish> (showcasing many of the issues with the FSIS's risk assessment, such as the unfounded assumption that the risk of the presence of *Salmonella* in catfish was equivalent to that in poultry, the problems with its probabilistic modeling, its use of conservative parameter values, the outdated and limited data used by the FSIS in its analysis, and the lack of significant risk associated with catfish).

63. See, e.g., Sean Murphy, *GAO Again Calls U.S. Catfish Inspection Program A Waste of Money*, SEAFOOD SOURCE, Feb. 12, 2015, <http://www.seafoodsource.com/news/supply-trade/27672->

of 2014,<sup>64</sup> which encompassed “all fish of the order Siluriformes” as opposed to limiting the definition to one family of catfish.<sup>65</sup> This broad definition resulted in the inclusion of all thirty-five domestic and foreign families belonging to the order Siluriformes.<sup>66</sup> Significantly, it included those species of catfish that had previously been excluded by the limited definition promulgated by the 2002 Farm Bill, like the Vietnamese *Pangasius*.<sup>67</sup>

The USDA published the final rule in the Federal Register on December 2, 2015,<sup>68</sup> nearly a year after its anticipated release, first in December 2014<sup>69</sup> and later in April 2015.<sup>70</sup> The rule, which applies to both domestically and internationally farmed fish of the order Siluriformes, will become effective in March 2016.<sup>71</sup> Once effective, the rule begins an 18-month “transitional

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gao-again-calls-u-s-catfish-inspection-program-a-waste-of-money (reporting that the GAO issued its eighth publication calling for action to stop the catfish inspection program); Hemingway, *supra* note 8 (noting that, despite the appearance of the then-proposed rule as a “protectionist racket and a waste of taxpayer money,” no one can get rid of it: “In 2012, the Senate voted by voice to eliminate the program. In 2013, the House Agriculture Committee voted 31-15 to eliminate the program.”); Letter from The Honorable John McCain, Senator, United States Senate to The Honorable Debbie Stabenow, Chairwoman, Committee on Agriculture, Nutrition & Forestry, United States Senate and The Honorable Thad Cochran, Ranking Member, Committee on Agriculture, Nutrition & Forestry, United States Senate (Jan. 8, 2014), *available at* [http://www.mccain.senate.gov/public/\\_cache/files/96c665ac-6c0b-4723-8af6-d82e3233b2fd/1-8-14-mccain-letter-on-catfish-conference-vote.pdf](http://www.mccain.senate.gov/public/_cache/files/96c665ac-6c0b-4723-8af6-d82e3233b2fd/1-8-14-mccain-letter-on-catfish-conference-vote.pdf)) (stating that during Senate consideration of the Farm Bill, McCain offered an amendment to repeal the catfish inspection program, but he was denied a vote even though the Senate approved a similar amendment by voice-vote in 2012).

64. Agric. Act of 2014, Pub. L. No. 113-79, 128 Stat. 649 (2014).

65. *Compare id.* § 12106 (broad definition) with Farm Sec. and Rural Inv. Act of 2002, Pub. L. No. 107-171, § 10806(a)(1), 116 Stat. 134, 526 (May 13, 2002) (narrow definition).

66. *Catfish*, BRITANNICA.COM, <http://www.britannica.com/EBchecked/topic/99455/catfish> (last visited June 28, 2014) (defining the order Siluriformes to include 2,900 individual species of catfish).

67. Press Release, Senator Thad Cochran, Cochran Hears Miss. Delta Views on Farm Bill Implementation (Aug. 4, 2014), *available at* <http://www.cochran.senate.gov/public/index.cfm/2014/8/cochran-hears-miss-delta-views-on-farm-bill-implementation> (“The 2014 law more clearly spells out that foreign imported catfish must undergo the same food safety requirements as domestically-produced catfish.”).

68. *See generally* Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, 80 Fed. Reg. 75590.

69. FEDERAL REGISTER, MANDATORY INSPECTION OF CERTAIN FISH, INCLUDING CATFISH AND CATFISH PRODUCTS: TIMELINE (2014), <https://www.federalregister.gov/regulations/0583-AD36/mandatory-inspection-of-certain-fish-including-catfish-and-catfish-products>.

70. *See* Philip Brasher, *Poultry Inspection Overhaul Set for Summer, Catfish Plan Coming*, AGRI-PULSE, Feb. 26, 2015, <http://www.agri-pulse.com/Poultry-catfish-inspection-on-track-02262015.asp> (quoting the USDA’s deputy undersecretary for food safety, Al Almanza, who expected the final rule to be released in April 2015).

71. Press Release, FSIS, USDA Releases Final Rule Establishing Inspection Program For Siluriformes Fish, Including Catfish (Nov. 25, 2015) (on file with FSIS).

implementation period” for both domestic and international producers.<sup>72</sup> During this time, the FSIS will conduct inspections and species and residue sampling on imported catfish shipments on a random basis.<sup>73</sup> Countries wishing to continue exporting their products must apply for an equivalency determination.<sup>74</sup>

With the rule’s finalization and the grossly inadequate timeframe,<sup>75</sup> the resulting regulatory shift will likely lead to the United States defending the rule before a WTO Panel against Vietnam’s claims that the rule is based on a flawed risk assessment and serves as a thinly veiled attempt to prevent the entry of foreign catfish into the American market.<sup>76</sup> If Vietnam is successful, the judgment against the United States could range from removal of the rule within a reasonable period of time, to WTO-approved sanctions, or to compensation.<sup>77</sup>

## II.

### WHAT’S THE CATCH?: THE FUTURE BEFORE A WTO PANEL

The WTO’s SPS Agreement reflects both the importance of global food safety measures and the recognition that such measures can be used for protectionist purposes.<sup>78</sup> For that reason, the SPS Agreement includes significant safeguards to ensure that Members’ SPS measures are genuine food safety measures addressing real health concerns rather than measures intended to provide trade protection against imports.<sup>79</sup> The SPS Agreement requires that an SPS measure is (1) supported by sufficient scientific evidence, (2) based on a risk assessment, and (3) not a disguised restriction on international trade.<sup>80</sup> Thus, in its complaint before the WTO Panel, Vietnam<sup>81</sup> would assert that the

72. *Id.*

73. *Id.*

74. *Id.*

75. See *supra* note 54 (showcasing the difficulties and time-consuming processes associated with achieving equivalence).

76. See Nixon, *supra* note 6, at A15 (reporting growing international concern over the inspection program).

77. See Robert Z. Lawrence, Council on Foreign Relations, *Council Special Report: The United States and the WTO Dispute Settlement System*, CSR No. 25 (Mar. 2007) (explaining the WTO dispute settlement process); see, e.g., Decision by the Arbitrators, *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, ¶¶ 83–84, WT/DS26/ARB (July 12, 1999) (deciding that the United States was entitled to suspend concessions on products from the E.U. in the amount of \$116.8 million because the level of impairment suffered by the United States as a result of the E.U.’s ban on hormone-treated beef was \$116.8 million).

78. See generally *WTO Agreement Series: Sanitary and Phytosanitary Measures*, 9-11 (2010), [https://www.wto.org/english/res\\_e/booksp\\_e/agrmtseries4\\_sps\\_e.pdf](https://www.wto.org/english/res_e/booksp_e/agrmtseries4_sps_e.pdf) (providing an overview of the SPS Agreement).

79. Comments of Jim Bacchus and Ira Shapiro on Proposed Rule for Mandatory Inspection of Catfish and Catfish Products (June 24, 2011) (on file with the FSIS).

80. See SPS Agreement, *supra* note 13, arts. 2.2, 5.1, 5.5.

81. See Bruce Einhorn & Chau Mai, *The Catfish Wars Could Derail U.S.-Asia Trade*, BLOOMBERG BUS. WK., July 3, 2014, <http://www.businessweek.com/articles/2014-06-30/the->

shift in regulatory oversight mandated by the 2008 Farm Bill and reaffirmed in the FSIS's rule is neither supported by scientific evidence nor based on a risk assessment, and it functions as a protectionist policy that—as finalized—would dramatically impact international trade.

A. *The FSIS's Rule Is Neither Founded on Sufficient Scientific Evidence nor Based on a Risk Assessment*

Article 5.1 of the SPS Agreement provides that Members shall ensure that their sanitary or phytosanitary measures are based on an assessment of the risks<sup>82</sup> to human, animal, or plant life or health.<sup>83</sup> Analysis under article 5.1 consists of two fundamental questions: first, whether a risk assessment appropriate to the circumstances was conducted, and second, whether the SPS measure is based on that risk assessment.<sup>84</sup>

A risk assessment, within the meaning of article 5.1, must: (1) identify the diseases whose entry, establishment, or spread a Member country wants to prevent; (2) evaluate the likelihood of entry, establishment, or spread of these diseases; and (3) evaluate the likelihood of entry, establishment, or spread of these diseases according to the SPS measures which might be applied.<sup>85</sup>

It is unlikely that a WTO Panel would find that the United States failed to meet the first of these requirements because it identified *Salmonella* as the target pathogen whose entry it sought to prevent. But under the latter two prongs, the result would turn on the Panel's interpretation of "potential."<sup>86</sup> Were the Panel

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catfish-wars-heat-up-and-u-dot-s-dot-asia-trade-hangs-in-the-balance (showcasing that Vietnam would be the most likely complainant before a WTO Panel as the Vietnam Association of Seafood Exporters and Producers have already taken action by hiring Jim Bacchus, a former chairman of the WTO's Appellate Body, to prepare a possible legal challenge to the FSIS's then-proposed rule); see also Ron Nixon, *New Catfish Inspections Are Posing a Problem for a Pacific Trade Pact*, N.Y. TIMES, Nov. 14, 2013, at A23 (explaining that of all the countries in the talks, "Vietnam is going to have to do the most in terms of changing its policies to comply with any trade agreement obligations") (internal quotations omitted).

82. See SPS Agreement, *supra* note 13, Annex 1A(4) (defining a "risk assessment" as the "evaluation of the likelihood of entry, establishment, or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences").

83. SPS Agreement, *supra* note 13, art. 5.1.

84. See Panel Report, *United States—Certain Measures Affecting Imports of Poultry from China*, ¶ 7.173, WT/DS392/R (Sept. 29, 2010) [hereinafter *U.S.—Poultry*].

85. See Appellate Body Report, *Australia—Measures Affecting Importation of Salmon*, ¶ 121, WT/DS18/AB/R (Oct. 20, 1998) [hereinafter *Australia—Salmon*] (emphasis omitted).

86. Compare *id.* ¶ 125 (claiming that it is not sufficient that a risk assessment conclude that there is a possibility of entry, establishment, or spread of diseases and that a proper risk assessment must make its evaluations based on the probability of entry, establishment, or spread of diseases), with Appellate Body Report, *European Communities—Measures Concerning Meat and Meat*

to base its decision on the probability of entry, the risk assessment would be insufficient.<sup>87</sup> However, if it were to base its decision on the possibility of entry, the risk assessment would likely stand.

Next, assuming that the Panel would find that the FSIS conducted a risk assessment, it would then need to decide whether the SPS measure implemented is “based on” that risk assessment.<sup>88</sup> To answer this question, the Panel would have to determine: (A) whether the SPS measure, in accordance with article 2.2,<sup>89</sup> is supported by scientific principles and maintained with sufficient scientific evidence,<sup>90</sup> and (B) whether the results of the risk assessment sufficiently warrant the SPS measure at issue.<sup>91</sup>

The Panel has at its disposal many possible approaches when assessing sufficiency that might be appropriate depending on the factual situation. This Article first evaluates the sufficiency of the scientific evidence in support of the SPS measure and then examines whether the science reasonably supports the risk assessment.

*1. The FSIS’s Rule Is Not Supported by Scientific Principles or Maintained with Sufficient Scientific Evidence*

Vietnam would have a strong claim that there is not sufficient scientific evidence to justify the protectionist shift in oversight of catfish imports based on (1) the lack of an established risk, (2) the theoretical nature of the risk, and (3) the expert opinions that disavow the existence of the risk.

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*Products (Hormones)*, ¶¶ 182–84, WT/DS26/AB/R (Jan. 16, 1998) [hereinafter *European Communities—Hormones*] (cautioning against using “probability” as an alternative meaning for “potential,” as the ordinary meaning of “potential” relates to possibility and is different from the ordinary meaning of “probability,” where “probability” implies a higher degree or a threshold of potentiality or possibility).

87. See, e.g., 2015 FSIS RISK ASSESSMENT, *supra* note 61, at 9; 2012 FSIS RISK ASSESSMENT, *supra* note 61, at 9 (“[L]imited information on the distribution of microbial contamination and chemical residues on catfish limit [the FSIS’s] ability to make strong statements about the baseline risk. Furthermore, the lack of experience with implementing continuous inspection programs in the context of aquaculture makes estimating the impact of such a program on risk difficult. As such, the risk assessment [the] FSIS presents . . . simply provides insight into the risk reductions that *might* accompany the implementation of the type of continuous inspection program now required for catfish under the FMIA.”) (emphasis added).

88. SPS Agreement, *supra* note 13, art. 5.1.

89. See Appellate Body Report, *European Communities—Hormones*, *supra* note 86, ¶ 180 (emphasizing that articles 2.2 and 5.1 should constantly be read together because “the elements that define the basic obligation set out in article 2.2 impart meaning to article 5.1”).

90. See SPS Agreement, *supra* note 13, art. 2.2 (requiring that Members ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal, or plant life or health, is based on scientific principles, and is not maintained without sufficient scientific evidence).

91. See Panel Report, *U.S.—Poultry*, *supra* note 84, ¶ 7.180 (explaining how the Panel determines if an SPS measure is “based on” a risk assessment).



For scientific evidence to support a measure sufficiently under article 2.2, it must first establish the existence of the risk that the SPS measure is created to address.<sup>92</sup> For example, in *U.S. – Poultry*,<sup>93</sup> the Panel determined that the scientific evidence was not sufficient within the meaning of article 2.2 because the evidence put forward by the United States did not precisely address the risks associated with China’s poultry inspection system.<sup>94</sup>

In this case, just as in *U.S. – Poultry*, the evidence promulgated by the FSIS in its risk assessment fails to establish the existence of the risk of *Salmonella* contamination in catfish and catfish products.<sup>95</sup> In fact, the risk assessment ultimately reaches the conclusion that “if Siluriformes were truly responsible for tens of thousands of *Salmonella* illnesses each year, it is expected that there would be more evidence of this food source based on epidemiological data . . . .”<sup>96</sup>

Moreover, a risk assessment must evaluate an ascertainable risk; the scientific evidence is not to be based upon hypothetical scenarios.<sup>97</sup> For example, the WTO Appellate Body in *European Communities – Hormones*<sup>98</sup> refused to accept the opinion of an expert advising the Panel because his estimate was, at best, a “rough guess” in light of the limited scientific evidence

92. See Appellate Body Report, *Japan—Measures Affecting the Importation of Apples*, ¶¶ 143–216, WT/DS245/AB/R (Nov. 26, 2003) [hereinafter *Japan—Apples*].

93. Panel Report, *U.S.—Poultry*, *supra* note 84.

94. See *id.* ¶¶ 7.200–7.202.

95. See 2015 FSIS RISK ASSESSMENT, *supra* note 61, at 95 (noting that salmonellosis from consuming a serving of fish is an “uncommon event”); 2012 FSIS RISK ASSESSMENT, *supra* note 61, at 11 (presenting evidence suggesting that the baseline risk of catfish is unknown, emphasizing that the likelihood of catfish being contaminated by *Salmonella* is low, and estimating an average probability of illness of  $1.5 \times 10^{-6}$  salmonellosis cases per serving; when, in fact, according to the risk assessment, all seafood accounts for just two percent of all *Salmonella* illnesses nationwide); Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, 80 Fed. Reg. at 75595, 75599 (reporting that the CDC lists that catfish may have been the vehicle in “at least one outbreak of salmonellosis” in 1991. It further provides an update from the CDC’s outbreak database, stating that it does not indicate that any additional outbreaks have occurred recently) (emphasis added); Mandatory Inspection of Catfish and Catfish Products, (proposed Feb. 24, 2011) 76 Fed. Reg. at 10440 (noting that since implementation of the FDA’s mandatory seafood HACCP controls in 1998, “no cases of salmonellosis linked to catfish have been reported”).

96. 2015 FSIS RISK ASSESSMENT, *supra* note 61, at 93 (emphasis added).

97. See Appellate Body Report, *Australia—Salmon*, *supra* note 85, ¶ 125 (“Theoretical uncertainty is not the kind of risk which . . . is to be assessed”) (internal quotation marks omitted); Appellate Body Report, *European Communities—Hormones*, *supra* note 86, ¶¶ 187, 207 (holding that while a theoretical framework may represent the beginning of a risk assessment, the risk must be both ascertainable in a science laboratory operating under strictly controlled conditions, and apparent in human societies as they actually exist).

98. Appellate Body Report, *European Communities—Hormones*, *supra* note 86.

available.<sup>99</sup> The Appellate Body determined that the scientific evidence was insufficient because the expert's inexperienced opinion<sup>100</sup> neither purported to be the result of his own scientific studies nor specifically focused on the risks of hormones to meat and meat products.<sup>101</sup>

Here, akin to the expert in *European Communities – Hormones*, the FSIS's lack of expertise in this area is evidenced by its hypothetical risk assessment.<sup>102</sup> The indeterminate and uncertain nature of the data concerning the presence of *Salmonella* in catfish caused the FSIS to use data from its experience with poultry as a proxy in its analysis of the possible effectiveness of an FSIS continuous inspection program for controlling *Salmonella* in catfish.<sup>103</sup> Yet nowhere in the risk assessment does the FSIS explain how poultry, a land-based bird, has any relationship to catfish, a water-based fish, in terms of predicting the risk of *Salmonella*.<sup>104</sup> In fact, the risk of *Salmonella* contamination in poultry and catfish differs substantially.<sup>105</sup> As such, the WTO Panel would find that the use of poultry data amounts to the creation of a theoretical risk.

Furthermore, while analyzing the sufficiency of the scientific evidence, the Panel would consider the views and opinions of experts.<sup>106</sup> During its

99. *See id.* ¶ 198.

100. *Id.*; *see also* Panel Report, *European Communities—Hormones*, ¶ 6.17, WT/DS26/R/USA (Aug. 18, 1997).

101. *See* Panel Report, *European Communities—Hormones*, *supra* note 100, ¶ 6.17.

102. *See* 2015 FSIS RISK ASSESSMENT, *supra* note 61, at 12 (finding substantial uncertainty regarding “the extent to which the experience associated with controlling *Salmonella* in poultry is applicable to controlling *Salmonella* in Siluriformes.”).

103. *See id.* at 10–12.

104. *See* Williams, *supra* note 62, at 6 (“FSIS inexplicably assumed that the distribution of number of *Salmonella* is exactly the same distribution as is found in poultry . . . There is no justification given for this assumption, and it seems implausible that catfish have any more relationship to chickens than they do to elephants.”) (citations omitted).

105. *See, e.g.*, 2015 FSIS RISK ASSESSMENT, *supra* note 61, at 55 (acknowledging the risks associated with using its experience with poultry as a surrogate); Michael B. Batz et al., RANKING THE RISKS: THE 10 PATHOGEN-FOOD COMBINATIONS WITH THE GREATEST BURDEN ON PUBLIC HEALTH, at 63 (2011), available at <https://folio.iupui.edu/bitstream/handle/10244/1022/72267report.pdf> (reporting that, statistically, the risks of salmonellosis in poultry and seafood are far from equivalent because, in a recent study, *Salmonella*-Poultry ranked as the number four pathogen-food combination in terms of annual disease burden, and *Salmonella*-Seafood ranked eighteenth); FSIS IMPACT ANALYSIS, *supra* note 18, at 99 (“The number of human illnesses associated with catfish and catfish products is relatively small compared to that associated with meat and poultry products”); *see also* Comments of the American Soybean Ass’n et al. on Proposed Rule for Mandatory Inspection of Catfish and Catfish Prods. 5 (June 24, 2011) (on file with FSIS) (“It is clear that the conclusions drawn by any risk assessment are only as good as the data and assumptions used. In this case, since the inputs are largely speculative, so must be the results.”).

106. *See, e.g.*, Appellate Body Report, *India—Quantitative Restrictions on Imports of Agric, Textile and Indus. Products*, ¶ 142, WT/DS90/AB/R (Aug. 23, 1999) (finding that the Panel was entitled to take into the account the view of the experts to determine if a case has been made); Appellate Body Report, *European Communities—Hormones*, *supra* note 86, ¶ 198 (analyzing the scientific evidence developed by experts on a specific topic).

consideration, the Panel enjoys discretion as the trier of fact<sup>107</sup> and is not obliged to give precedence to the importing Member's scientific evidence.<sup>108</sup> Thus, if Vietnam were to bring a complaint, the Panel would evaluate both the opinions expressed in the FSIS's risk assessment and the opinions of additional experts testifying on behalf of Vietnam.<sup>109</sup> In this case, the greater scientific community does not consider the potential risks of *Salmonella* contamination in catfish to be an identifiable, ascertainable risk requiring intensified inspection procedures.<sup>110</sup> The twelve authors of the risk assessment, moreover, seem to agree.<sup>111</sup>

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107. See Appellate Body Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, ¶ 161, WT/DS135/AB/R (Mar. 12, 2001) (finding that the Panel was entitled, in the exercise of its discretion, to determine that certain elements of evidence should be accorded more weight than other elements).

108. See Appellate Body Report, *Japan—Apples*, *supra* note 92, ¶¶ 165–67 (holding that a Panel is not obliged to give precedence to the importing Member's approach to scientific evidence when analyzing and assessing scientific evidence to determine whether a complainant established a case under article 2.2).

109. See *supra* notes 107–108 (concerning how the Panel is under no obligation to hear only evidence from the importing member and that it may use its discretion to afford weight to that evidence).

110. See Mandatory Inspection of Catfish and Catfish Products, 76 Fed. Reg. at 10438 (proposed Feb. 24, 2011) (acknowledging that the CDC finds commercially raised catfish to be a low-risk food); Food and Agric. Org. [FAO], *Report of the FAO Expert Workshop on Application of Biosecurity Measures to Control Salmonella Contamination in Sustainable Aquaculture*, FIPM/R937, at 2 (Jan. 19–21 2010) (“Although *Salmonella* is a major foodborne pathogen, products of aquaculture are rarely involved in outbreaks of salmonellosis. Very low level prevalence of *Salmonella* can be seen in raw products from aquaculture systems in developed countries, but this has not led to any particular public health problems in these countries”); Erica McCoy et al., *Foodborne Agents Associated with the Consumption of Aquaculture Catfish*, 74 J. OF FOOD PROTECTION 352, 500, 502 (2011) (finding the results unclear about whether catfish served as the primary vehicle of illness for reported outbreaks of *Salmonella* or whether other foods played a role); Tom McCasky et al., *Safe and Delicious: Study Shows Catfish is Low Risk for Foodborne Illness*, 45 HIGHLIGHTS OF AGRIC. RESEARCH, 1998, at 2–3 (concluding that health hazards from *Salmonella* and other bacteria in catfish were practically zero); Marcia Wood, *In-Demand Fish: Making Sure They're Safe to Eat*, AGRIC. RESEARCH MAGAZINE, Oct. 2010, at 19 (explaining that foodborne illnesses are not commonly associated with catfish); see generally GAO REPORT, *supra* note 30, at 10–14 (2012) (showcasing that the FSIS used outdated and limited information as its scientific basis for implementing a catfish inspection program).

111. See 2015 FSIS RISK ASSESSMENT, *supra* note 61, at 70 (finding that “*Salmonella* illnesses attributable to Siluriformes are rare”); 2012 FSIS RISK ASSESSMENT, *supra* note 61, at 11, 36, 40 (concluding consumption of catfish does not pose a substantial risk of *Salmonella*, because of the lack of illnesses reported by public health agencies and because public health data, when plugged into models used to predict future outbreaks, yield extremely low results). See also, RISK ASSESSMENT PEER REVIEW COMMENTS, *supra* note 61, at 14 (disagreeing with the conclusion: “Our analyses indicate that the implementation of an FSIS inspection based program will have a beneficial public health impact by decreasing the number of such adverse effects experienced by [U.S.] consumers.” This disagreement, according to one author, is due to the lack of sufficient current data.).

Given the United States' failure to prove a risk of *Salmonella* contamination in catfish and catfish products, the theoretical nature of the scientific assessment, and the overwhelming opinion of the scientific community,<sup>112</sup> Vietnam would assert that this regulatory shift in oversight is neither supported by scientific principles nor maintained with sufficient scientific evidence and thus violates article 2.2.

2. *The FSIS's Risk Assessment Does Not Sufficiently Warrant the Rule and Therefore the Rule Is Not "Based on" a Risk Assessment*

In conjunction with the determination that the rule is not founded on sufficient scientific evidence, Vietnam could allege that the rule fails to fulfill article 5.1 because the rule is not sufficiently warranted by the risk assessment.<sup>113</sup> In examining claims under article 5.1, WTO Panels have explained that SPS measures must be "based on" a risk assessment; in other words, there is a substantive requirement that there be a rational, objective, proportionate relationship between the SPS measure and the risk assessment.<sup>114</sup> In short, the scientific conclusions reached in the risk assessment must conform to and reflect the scientific conclusions implicit in the SPS measure.<sup>115</sup>

Therefore, to justify the regulatory shift in this case, there must be a legitimate food safety threat that the current FDA regulations cannot handle. Although the risk assessment purports to establish that *Salmonella* is one such food safety threat, Vietnam would argue that the scientific evidence promulgated in the risk assessment and the level of oversight required by the rule are disproportionate to the actual risk of *Salmonella* contamination in catfish and catfish products.<sup>116</sup>

This disproportionality is particularly apparent when considering the uncertainty of the success of the USDA's inspection program in preventing *Salmonella* from adulterating catfish and catfish products.<sup>117</sup> The risk

112. See Connelly, *supra* note 35, at 29 (arguing that the justification for the proposed rule is unpersuasive, which is why so many of the expert conclusions in the risk assessment are either "unsupportive of aggressive FSIS regulation or studiously neutral").

113. See *supra* note 91 and accompanying text.

114. See Appellate Body Report, *Japan—Apples*, *supra* note 92, ¶ 163 (concluding that the overall risk of fire blight presented in the risk assessment was negligible and disproportionate to the severity of the SPS measure proposed and therefore the measure was not "based on" a risk assessment within the meaning of article 5.1); Appellate Body Report, *Japan—Measures Affecting Agric. Products*, ¶ 73, WT/DS76/AB/R (Feb. 22, 1999) (explaining that there must be a sufficient or adequate relationship between the SPS measure and the scientific evidence); Appellate Body Report, *European Communities—Hormones*, *supra* note 86, ¶¶ 193–94 ("[T]he results of the risk assessment must sufficiently warrant . . . the SPS measure at stake.").

115. See Appellate Body Report, *European Communities—Hormones*, *supra* note 86, ¶¶ 192–94.

116. See *supra* note 95 and accompanying text (showing that the risk of *Salmonella* contamination in catfish is uncommon).

117. See 2015 FSIS RISK ASSESSMENT, *supra* note 61, at 74; 2012 FSIS RISK ASSESSMENT,

assessment presented the estimates of the inspection program's potential effectiveness relative to the number of *Salmonella* illnesses estimated to be associated with catfish.<sup>118</sup> However, given the substantial uncertainty regarding the number of *Salmonella*-related illnesses attributable to catfish,<sup>119</sup> the determination concerning the effectiveness of the FSIS's catfish inspection program is similarly plagued with uncertainty.<sup>120</sup> Despite this uncertainty, the rule, in line with the statute, requires the shifting of jurisdiction over catfish from the FDA to the USDA's FSIS.<sup>121</sup> If the rule was truly "based on" the FSIS's risk assessment, it would be clear that there is no need for such a burdensome regulatory shift, particularly because the risk of contamination is unknown and unsupported by available data.

Given the uncertainty of both the risk and the effectiveness of the program, the lack of scientific data, and the absence of any expert testimony expressing significant concern about the risks of *Salmonella*, it would be difficult for the United States to contend before a WTO Panel that an SPS measure implementing such a dramatic shift is founded on scientific principles, maintained with sufficient scientific evidence, and sufficiently warranted by the risk assessment in accordance with articles 2.2 and 5.1.

#### *B. The FSIS's Rule Amounts to a Disguised Barrier to Trade*

Beyond asserting the invalidity of the risk assessment, Vietnam would claim that the rule amounts to a disguised barrier to trade in violation of article 5.5 of the SPS Agreement.<sup>122</sup> In an attempt to maintain balance between the competing interests of promoting international trade and protecting human life

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*supra* note 61, at 40 ("The true effectiveness of FSIS inspection for reducing catfish-associated human illnesses is unknown. Also, the rate at which FSIS inspection will achieve its ultimate reductions is unknown. Consequently, the model incorporates substantial uncertainty about program effectiveness. A plausible range [of effectiveness] might be from more than 90% effective to less than 10% effective.").

118. See 2012 FSIS RISK ASSESSMENT, *supra* note 61, at 33.

119. See *id.* at 12 ("This risk assessment's outputs are subject to substantial uncertainty regarding . . . the estimated baseline number of salmonellosis cases attributable to catfish consumption.").

120. See *id.* at 41 ("Predicting the effectiveness of [the] FSIS inspection for the reduction of illness from catfish consumption is uncertain because data are . . . unavailable.").

121. See *id.* ("The role of daily FSIS inspection of catfish processing establishments in reducing potential contamination events is expected to be important.").

122. See SPS Agreement, *supra* note 13, art. 5.5.; see also SPS Agreement, *supra* note 13, art. 2.3; Panel Report, *Australia—Salmon*, ¶ 8.52 WT/DS18/R (June 12, 1998) (holding that articles 2.3 and 5.5 "may be seen to be marking out and elaborating a particular route leading to the same destination").

and health,<sup>123</sup> article 5.5 requires WTO Panels to make a searching analysis of whether a measure is a disguised form of protectionism.<sup>124</sup>

WTO Panels have identified three conditions that must be satisfied in order to establish a violation of article 5.5: (1) the Member country has different levels of protection in comparable situations; (2) the levels of protection show arbitrary and unjustifiable differences in their treatment of different situations; and (3) these arbitrary or unjustifiable differences lead to discrimination or disguised restrictions on trade.<sup>125</sup> These three elements are to be distinguished and addressed separately, but all must be present.<sup>126</sup> Each is addressed here in turn.

### 1. *Element #1: Different Levels of Protection in Comparable Situations*

With regard to the first element, there are two closely related sub-elements: first, the existence of different products that can be compared to the SPS measure at issue; and second, the existence of different levels of protection associated with such comparable products.<sup>127</sup> For example, Canada, the complainant in *Australia – Salmon*,<sup>128</sup> alleged that Australia's restriction on the importation of salmon was a disguised barrier to trade.<sup>129</sup> Arguing that the different products to be compared under article 5.5 are those that involve some of the same disease agents at issue,<sup>130</sup> Canada submitted four non-salmonid seafood products that are also at risk of the same or similar diseases as those mentioned in Australia's risk assessment pertaining to salmon.<sup>131</sup> The Panel,

123. See SPS Agreement, *supra* note 13, art. 5.5 (“With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health . . . each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.”).

124. See Jan Bohanes, *Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle*, 40 COLUM. J. TRANSNAT'L L. 323, 383 (2002) (explaining that although WTO Members enjoy discretion in the level of protection they set for themselves, they may not establish widely differing levels of protection in comparable situations because widely differing levels of protection may indicate protectionist intent).

125. Appellate Body Report, *European Communities—Hormones*, *supra* note 86, ¶ 214.

126. See *id.* ¶ 215 (stating that the Panel considers these three elements to be cumulative in nature; all of them must be present if a violation of article 5.5 is to be found).

127. See Panel Report, *U.S.—Poultry*, *supra* note 84, ¶ 7.225 (enumerating the sub-elements).

128. Appellate Body Report, *Australia—Salmon*, *supra* note 85.

129. See Panel Report, *Australia—Salmon*, *supra* note 122, ¶¶ 4.180–4.216.

130. See *id.* ¶ 8.117 (finding the Panel can compare situations under article 5.5 if the situations involve either a risk of entry, establishment, or spread of the same or similar disease).

131. See *id.* ¶ 8.113 (holding that Australia's import ban on salmon can be compared with the treatment it provides to non-salmonids (1-2) uncooked Pacific herring, cod, haddock, Japanese eel, and plaice for human consumption; (3) herring in whole, frozen form for use as bait; and (4) live ornamental finfish, which represent a risk of entry, establishment, or spread of the same or a similar disease).

and later the Appellate Body, upheld these products as comparable because each had at least one disease agent in common.<sup>132</sup>

Similarly, Vietnam would present different seafood products with a risk of *Salmonella* contamination comparable to that of catfish and catfish products.<sup>133</sup> Although there is not much epidemiological data on the presence of *Salmonella* in catfish, there is a considerable amount of information available regarding the presence of *Salmonella* in seafood generally.<sup>134</sup> In fact, mollusks, shrimp,<sup>135</sup> and finfish (such as tuna)<sup>136</sup> are all at risk for *Salmonella* contamination.<sup>137</sup> Therefore, a Panel would uphold these as comparable products because they all have the same risk of *Salmonella* in common.<sup>138</sup>

The Panel would next determine whether there is a distinction in the levels of protection associated with each of these comparable products by examining the current laws and regulations imposed upon them.<sup>139</sup> It is the duty of the Panel to assess the sanitary regimes and the corresponding level of protection imposed on the comparable seafood products in contrast to the sanitary regime and level of protection for the SPS measure at issue.<sup>140</sup> For example, in *Australia – Salmon*, where Australia banned the importation of salmon, imports of the four comparable seafood products exported by Canada continued to reach Australian markets despite the fact that all of the products, including salmon, were at risk for similar diseases.<sup>141</sup> Based on this difference, the Panel found a distinction in levels of protection.<sup>142</sup>

In this case, Vietnam would argue that the heightened regulatory requirement mandated by the FSIS indicates that the level of protection deemed

132. See *id.* ¶ 8.121 (stating the Panel’s finding); Appellate Body Report, *Australia—Salmon*, *supra* note 85, ¶ 153 (upholding the Panel’s finding).

133. Cf. *supra* note 131 and accompanying text (listing Canada’s comparable products).

134. See generally G. Amagliani et al., *Incidence and Role of Salmonella in Seafood Safety*, 45 *FOOD SERV. INT’L* 780, 780 (2011).

135. See, e.g., M.N. Wan Norhana et al., *Prevalence, Persistence, and Control of Salmonella and Listeria in Shrimp and Shrimp Products: A Review*, 21 *FOOD CONTROL* 344, 354 (2010) (acknowledging the widespread prevalence of *Salmonella* in shrimp production chains).

136. See, e.g., Bill Tomson, *Tuna Blamed in Salmonella Outbreaks is Recalled*, *WALL ST. J.*, Apr. 16, 2012, <http://online.wsj.com/news/articles/SB10001424052702304299304577348030392954406> (highlighting a recent example of a *Salmonella* outbreak due to contaminated tuna).

137. See generally Amagliani, *supra* note 134, at 780–82.

138. Cf. *supra* note 132 and accompanying text (upholding Canada’s proposed comparisons as they all had the same or similar diseases in common).

139. See Panel Report, *Australia—Salmon*, *supra* note 122, ¶¶ 8.123–8.124.

140. See *id.* ¶¶ 8.123–8.124.

141. See *id.* ¶ 8.129.

142. See *id.*

appropriate for these catfish and catfish products is very high. This is particularly apparent given that catfish would be singled out as the only seafood product subject to the FSIS's mandatory and continuous inspection regime.<sup>143</sup> Moreover, the unique treatment of catfish does not coincide with the level of protection deemed appropriate for comparable seafood products also at risk of *Salmonella* contamination, such as mollusks, shrimp, and finfish, which are all overseen (and will remain overseen) by the FDA's seafood HACCP program.<sup>144</sup> Thus, there is a substantial difference between the level of protection for catfish in the FSIS's rule and the levels of protection deemed appropriate for similar seafood products also at risk of *Salmonella* contamination.

2. *Element #2: Arbitrary or Unjustifiable Differences in Levels of Protection*

Having found that the risks associated with catfish are comparable to those of other seafood products, and having found that the United States is applying different levels of protection to these types of products, the Panel would proceed with the second element of its analysis and determine whether this disparity in the level of protection for the products is arbitrary or unjustifiable.<sup>145</sup>

There are two ways to accomplish this analysis; the Panel could either examine the justification for increased regulatory oversight by verifying whether it is based on scientific evidence,<sup>146</sup> or it could look to the comparable products to determine if a justification for the disparity in regulatory measures and corresponding levels of protection exists, such as a scientifically higher-risk product.<sup>147</sup> If the Panel were to evaluate the rule based on the former method, it would likely conclude that the appropriate level of protection for catfish and catfish products is arbitrary and unjustifiable within the meaning of article 5.5. This is true given that the rule is neither maintained with sufficient scientific evidence, nor is it proportional to the risk assessed, as set forth above.<sup>148</sup>

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143. See Senator John McCain, Floor Statement (Feb. 3, 2014) (transcript available at <http://www.mccain.senate.gov/public/index.cfm/2014/2/statement-by-senator-john-mccain-on-farm-bill-conference-report>) (emphasizing that catfish would be the only seafood product singled out for inspection by the FSIS).

144. See Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65096, 65109 (Dec. 18, 1995) (codified in 21 C.F.R. Pts. 123 and 1240) (requiring fish (fresh or saltwater finfish, molluscan shellfish, crustaceans) and fishery products (any edible human food derived in whole or in part from fish) be produced in accordance with HACCP-type control procedures).

145. See Panel Report, *U.S.—Poultry*, *supra* note 84, ¶¶ 7.255, 7.259.

146. See *id.* ¶ 7.267 (finding the United States' SPS measure was arbitrary or unjustifiable based on the lack of scientific evidence and the lack of a risk assessment).

147. See Panel Report, *Australia—Salmon*, *supra* note 122, ¶ 8.134 (analyzing the comparable situations put forth by Canada, from which the Panel found that there is no scientific explanation for treating salmon as a higher risk product).

148. Cf. *supra* note 146 (finding the United States' SPS measure arbitrary or unjustifiable because it did not comport with articles 2.2 and 5.1).



However, if the Panel were to consider the treatment of the comparable seafood products under the latter method, the result would be the same. The Panel would recall that the rule imposes on catfish and catfish products heightened inspection requirements due to the risk of *Salmonella* contamination.<sup>149</sup> It might, therefore, be expected that some justification for this distinction in comparable products and corresponding levels of protection exists, such as a higher risk related to the imports of catfish and catfish products.<sup>150</sup>

As the Panel stated in *Australia – Salmon*, if one comparison put forward by a complainant involved arbitrary or unjustifiable distinctions in levels of protection, no further findings or analyses would be necessary.<sup>151</sup> Under this standard, Vietnam could propose comparisons between the presence and risk of *Salmonella* in catfish to the presence and risk of *Salmonella* in mollusks, finfish, or, most persuasively, shrimp.<sup>152</sup> Americans consume more shrimp than any other seafood product,<sup>153</sup> and ninety percent of shrimp is imported.<sup>154</sup> Further, the risk of *Salmonella* contamination in shrimp is well documented,<sup>155</sup> and unlike the low-risk nature of catfish,<sup>156</sup> the research concerning shrimp indicates that it is at high-risk for *Salmonella* contamination.<sup>157</sup>

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149. See 2015 FSIS RISK ASSESSMENT, *supra* note 61, at 10; 2012 FSIS RISK ASSESSMENT, *supra* note 61, at 9 (explaining that the risk assessment focused on “*Salmonella* because a broad hazard identification study found *Salmonella* as a potential concern in catfish”).

150. Cf. Panel Report, *Australia—Salmon*, *supra* note 122, ¶ 8.133 (expecting salmon to be a higher risk product based on this distinction in sanitary measures and corresponding levels of protection).

151. See *id.* ¶ 8.143.

152. See *id.*

153. Paul Greenberg, *Why Are We Importing Our Own Fish?*, N.Y. TIMES, June 20, 2014, at Sunday Review Desk 6 (“Americans eat nearly as much [shrimp] as the next two most popular seafoods (canned tuna and salmon) combined.”).

154. See *The Surprising Sources of Your Favorite Seafoods: Shrimp*, FISHWATCH.GOV (2011), [http://www.fishwatch.gov/features/top10seafoods\\_and\\_sources\\_10\\_10\\_12.html](http://www.fishwatch.gov/features/top10seafoods_and_sources_10_10_12.html) (last visited Aug. 4, 2014) (finding that although shrimp fisheries are among the largest and highest valued in the United States, over 90 percent of it is farmed overseas).

155. See, e.g., N. Bhaskar, *Incidence of Salmonella in Cultured Shrimp Penaeus Monodon*, 138 AQUACULTURE 257, 263–64 (1995) (concluding that *Salmonella* is a part of the natural flora of the shrimp culture environment); P.J.A. Reilly & D.R. Twiddy, *Salmonella and Vibrio Cholerae in Brackish Water Cultured Tropical Prawns*, 16 INT’L J. OF FOOD MICROBIOLOGY 293, 293 (1992) (displaying results that indicate that *Salmonella* can be found in shrimp farms irrespective of the culture methods); see generally Norhana, *supra* note 135, at 348 (discussing several authors’ findings on the prevalence of *Salmonella* in the shrimp production chain).

156. See *supra* note 110 (identifying catfish as a low-risk food).

157. See JANE ALLSHOUSE ET AL., INT’L TRADE AND SEAFOOD SAFETY: ECONOMIC THEORY AND CASE STUDIES, 109, 116 (J. Buzby ed. 2003), available at [www.ers.usda.gov/publications/aer828/](http://www.ers.usda.gov/publications/aer828/) (demonstrating that most *Salmonella* contamination in fish and fishery products is with shrimp, as is showcased by the 2001 data where fifty-eight percent of the FDA’s *Salmonella*-

The FDA has been very concerned about combating the entry of contaminated shrimp. The agency initiated a procedure under which shrimp processing facilities, or even entire countries, with a history of *Salmonella*-positive products are placed on a list for “detention without physical examination.”<sup>158</sup> Interestingly, this solution was pursued instead of legislatively mandating a shift in oversight to the FSIS, as was done with catfish.

Considering the popularity of shrimp, its high rate of importation, and the well-documented risk of *Salmonella* contamination, particularly when compared to the unknown risks of catfish, the United States would not be able to justify a more stringent and scrutinized inspection of catfish. This indicates that the rule establishes an arbitrary and unjustifiable level of protection.<sup>159</sup>

3. *Element #3: Distinctions in Levels of Protection That Result in a Disguised Restriction on International Trade*

Vietnam’s final assertion would be that the rule constitutes a disguised restriction on international trade.<sup>160</sup> While considerations pertinent to deciding whether the application of a particular SPS measure amounts to arbitrary or unjustifiable discrimination may be taken into account during this evaluation,<sup>161</sup> a separate analysis is required to determine if the measure itself results in discrimination or a disguised restriction on trade.<sup>162</sup>

In examining the rule, the Panel will consider “warning signals,” including: (1) the arbitrary or unjustifiable character of the differences in levels of protection, (2) the rather substantial difference in levels of protection between the previously identified comparable situations, and (3) the inconsistency of the SPS measure with articles 5.1 and 2.2.<sup>163</sup> These warning signals are further

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related detentions were for shrimp and only two percent were for catfish or catfish products).

158. FDA, *Import Alert 16-18: “Detention Without Physical Examination of Shrimp,”* June 25, 2014, [http://www.accessdata.fda.gov/cms\\_ia/importalert\\_35.html](http://www.accessdata.fda.gov/cms_ia/importalert_35.html); see Norhana, *supra* note 135, at 345 (explaining that this means every shipment of shrimp from these countries or their subsidiary facilities will be detained automatically and denied entry into the United States unless evidence is provided that the shipment is free of *Salmonella*).

159. Cf. Panel Report, *Australia—Salmon*, *supra* note 122, ¶ 8.143 (finding the distinctions in levels of protection reflected in Australia’s treatment of salmon products, as compared to herring as bait and live ornamental finfish, are “arbitrary or unjustifiable” because the latter products present a higher risk).

160. See Appellate Body Report, *European Communities—Hormones*, *supra* note 86, ¶¶ 214–15 (explaining that the last element refers to the SPS measure resulting in a disguised restriction on international trade).

161. See *id.* (stating that the presence of the an arbitrary or unjustifiable difference in levels of protection “may in practical effect operate as a ‘warning’ signal that the implementing measure . . . might be a discriminatory measure or might be a restriction on international trade disguised as an SPS measure for the protection of human life or health”) (emphasis omitted).

162. See *id.* ¶ 215.

163. Appellate Body Report, *Australia—Salmon*, *supra* note 85, ¶¶ 161–65.

informed by additional factors, such as an abrupt change in conclusions or an evaluation of a country's internal policies.<sup>164</sup>

Utilizing these warning signals and additional factors, Vietnam would allege that requiring increased oversight for catfish qualifies as a disguised restriction on international trade. Looking to the first warning signal, the Panel would recall the arbitrary or unjustifiable distinctions in levels of protection imposed by the United States for comparable seafood products.<sup>165</sup> In this case, the evidence shows that imports of shrimp, rather than posing less risk and thus warranting a less stringent SPS measure, actually represent a higher risk than the uncertain risks related to *Salmonella* in catfish imports. Yet it is catfish that will be subject to more stringent inspection procedures under the FSIS.<sup>166</sup>

Second, the Panel would recall that this arbitrary difference in levels of protection imposed by the United States for comparable seafood products is substantial.<sup>167</sup> Namely, the Panel would find that catfish, and catfish alone, would be subject to heightened regulatory inspection under the FSIS, unlike comparable products that will continue to be subject to inspection by the FDA.<sup>168</sup> The fact that the United States applies substantially different inspection measures for products that represent the same or greater risk suggests that it is effectively discriminating against other seafood products by requiring additional and increased oversight for catfish absent a logical, scientific explanation.<sup>169</sup>

Finally, with respect to the third warning signal, the Panel would consider the rule's inconsistencies with article 2.2 (requiring sufficient scientific evidence) and article 5.1 (requiring the measure be "based on" a risk assessment).<sup>170</sup> In this case, Vietnam would again assert that the rule was neither founded on sufficient scientific evidence nor based on a risk assessment. This is indicative of the fact that the rule is protectionism masquerading as a legitimate food safety regulation.<sup>171</sup>

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164. See, e.g., *id.* ¶¶ 170, 174 (considering the "substantial, but unexplained" change in conclusion which resulted in the import prohibition and the absence of controls on the internal movement of salmon products within Australia as additional factors).

165. See Panel Report, *Australia—Salmon*, *supra* note 122, ¶ 8.149.

166. See *supra* notes 155–157 and accompanying text.

167. See *supra* note 144 and accompanying text.

168. See generally Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, 80 Fed. Reg. at 75590.

169. Cf. Panel Report, *Australia—Salmon*, *supra* note 122, ¶ 8.150 (finding the substantial difference between Australia's import prohibition on salmon and its simultaneous tolerance of imports of herring for use as bait and of live ornamental finfish despite comparable risks).

170. See *id.* ¶ 8.151 (stating that an analysis under articles 5.1 and 2.2 may, together with other facts, lead to the conclusion that the measure at issue results in a disguised restriction on international trade).

171. Cf. Appellate Body Report, *Australia—Salmon*, *supra* note 85, ¶¶ 161–65 ("[F]inding an

In conjunction with these warning signs, the Panel would consider additional factors proposed by Vietnam, provided they constitute new evidence.<sup>172</sup> At this point, Vietnam would raise the United States' abrupt legislative change to catfish policy,<sup>173</sup> which suggests elements of domestic protectionism.<sup>174</sup>

For the past decade, catfish have been a constant source of trade friction between the United States and Vietnam.<sup>175</sup> This friction is best seen through the enactment of the 2008 Farm Bill, for which there was no scientific explanation indicating that catfish posed a food safety threat substantiating the need for heightened regulatory oversight.<sup>176</sup> In light of this history, Vietnam would argue that the United States catfish industry is once again seeking a roadblock to oppose imports from Vietnam, not heightened oversight.<sup>177</sup> In fact, many supporters of the domestic catfish industry have made statements urging the implementation of the FSIS's inspection program and the broadening of the definition of catfish, emphasizing the need to provide commercial comfort to a struggling industry rather than the need to improve food safety.<sup>178</sup>

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SPS measure is not based on an assessment of the risks to human, animal or plant life or health . . . is a strong indication that this measure is not really concerned with the protection of human, animal or plant life or health but is instead a trade-restrictive measure taken in the guise of an SPS measure.”)

172. See *id.* ¶ 168 (requiring that the additional factors be differentiated from the warning signals in the determination of whether an SPS measure results in a disguised restriction on international trade).

173. Compare Farm Sec. and Rural Inv. Act of 2002, Pub. L. No. 107-171, § 10806(a)(1), 116 Stat. 134, 526 (May 13, 2002) (defining “catfish” as only those of the species *Ictaluridae*), with Agricultural Act of 2014, Pub. L. No. 113-79, § 12106, 128 Stat. 649, 981 (2014) (defining “catfish” as encompassing all species of the order Siluriformes); see also Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, § 11016(b), 112 Stat. 1651 (June 18, 2008) (shifting regulatory oversight from the FDA to the USDA).

174. Compare Panel Report, *Australia—Salmon*, *supra* note 122, ¶ 8.154 (determining that the change in recommendations between the 1995 Draft Report and the 1996 Final Report, which went from allowing fresh, chilled or frozen salmon under specified conditions to prohibiting its importation or requiring heat treatment, was not sufficiently explained and thus might have been inspired by domestic pressures to protect the Australian salmon industry against import competition), with *A Fish By Any Other Name*, *supra* note 11 (explaining that the “linguistic backflip” of the United States emphasizes the protectionist nature of the legislation).

175. See MICHAEL F. MARTIN, CONG. RESEARCH SERV. R40755, U.S.-VIETNAM ECONOMIC TRADE RELATIONS: ISSUES FOR THE 111TH CONGRESS 11 (2009).

176. See *id.*

177. Ben Evans & Mary Clare Jalonick, *Catfish Wars Heat Up Over Inspection Feud*, ASSOCIATED PRESS (Mar. 23, 2011), <https://sg.news.yahoo.com/catfish-wars-heat-over-inspection-feud-20110323-001136-340.html>; see also GEOFFREY S. BECKER, CONG. RESEARCH SERV., RS228s86, FOOD SAFETY PROVISIONS OF THE 2008 FARM BILL, at 3 (2008) (reporting that the inspection program was urged by the U.S. catfish industry, which has faced strong opposition from foreign catfish producers in Vietnam).

178. See Press Release, Senator Thad Cochran, Cochran Hears Miss. Delta Views on Farm Bill Implementation (Aug. 4, 2014), available at <http://www.cochran.senate.gov/public/index.cfm/2014/8/cochran-hears-miss-delta-views-on-farm-bill-implementation> (“The U.S. catfish industry has taken hits from unfair foreign competition.”); Press Release, Senator Jeff Sessions, Sessions Sends Letter to OMB On Catfish Inspection Program, Urges Fairness For Domestic Producers (July 17,

Moreover, throughout the rulemaking process, the United States had countless opportunities to ensure the rule's compliance with the SPS Agreement. Particularly given the millions of dollars already spent in creating the catfish inspection program and its corresponding office within the USDA,<sup>179</sup> one could conclude that a reasonable course of action would be to ensure that the rule included a lengthy transition period to equivalence in which parties compliant with the FDA's HACCP program should remain unaffected.<sup>180</sup> This lengthy transition period would have provided foreign catfish producers, such as Vietnam, with the time necessary to accomplish the historically difficult task of achieving equivalence with the inspection procedures of the United States.<sup>181</sup> However, by providing a mere 18-month transition period, during which foreign governments would have to fundamentally alter their respective nation's food safety procedures and processes through legislation, rulemaking, or otherwise, the United States made it nearly impossible for foreign exporters of catfish to be deemed equivalent.

Individually, these warning signals and additional factors may not constitute evidence of a disguised restriction on international trade. However, when taken together, a Panel would find the rule requiring mandatory and continuous inspection of catfish to be a disguised restriction, therefore fulfilling the third element under article 5.5.<sup>182</sup>

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2014), available at <http://www.sessions.senate.gov/public/index.cfm/2014/7/sessions-sends-letter-to-omb-on-catfish-inspection-program-urges-fairness-for-domestic-producers> ("The catfish industry is critical to many of our rural communities and important to our state's economy"); Townsend Kyser, Address at the Pub. Meeting Concerning the USDA Proposed Rule for Mandatory Inspection of Catfish and Catfish Products (May 26, 2011) (on file with FSIS) ("Catfish is about the only money being pumped into [the] economy; it's the economic engine that drives the black belt in west Alabama."); Dr. Lester Spell, Address at the Pub. Meeting Concerning the USDA Proposed Rule for Mandatory Inspection of Catfish and Catfish Products (May 26, 2011) (on file with FSIS) ("This is a big industry in our state; it [is] important to our state."); Congressman Bennie Thompson, Address at the Pub. Meeting Concerning the USDA Proposed Rule for Mandatory Inspection of Catfish and Catfish Products (May 24, 2011) (on file with FSIS) ("[T]he rule will have tremendous impact on jobs in . . . Mississippi.").

179. Ron Nixon, *Number of Catfish Inspectors Drive Debate on Spending*, N.Y. TIMES, July 27, 2013, at A11 ("Since 2009 the [USDA] said that it has spent \$20 million to set up the catfish inspection office . . . The department said that it expects to spend about \$14 million a year to run it.").

180. *Contra* Letter from Jeff Sessions, U.S. Senator, to Brian Deese, Acting Director, Office of Mgmt. and Budget (July 17, 2014), [http://www.sessions.senate.gov/public/\\_cache/files/10f78c55-d92f-4868-b2f2-e9f93615ff50/catfish-inspection-letter-7.17.14.pdf](http://www.sessions.senate.gov/public/_cache/files/10f78c55-d92f-4868-b2f2-e9f93615ff50/catfish-inspection-letter-7.17.14.pdf) ("Once the final regulations are issued, [Congress] look[s] forward to seeing . . . that the transition to the inspection program occurs concurrently for both domestic and foreign catfish.").

181. *See, e.g.*, Engle *supra* note 54 (exemplifying the never-ending nature of the equivalency process). China has been attempting to develop an equivalent system for its poultry processing since 2004 and the methods, according to FSIS, are still not equivalent.

182. *See* Appellate Body Report, *European Communities—Hormones*, *supra* note 86, ¶ 240

## III.

## “DEEP FRY” THE RULE: THE NECESSITY OF REPEAL

Ultimately, the rule will likely prompt a costly response from one or more of the United States’ trade partners.<sup>183</sup> To eliminate the possibility of a WTO sanction, to enhance the effectiveness of food safety, and to avoid duplication of effort and cost, Congress should repeal section 11016 of the 2008 Farm Bill that assigned the USDA responsibility for inspecting catfish and catfish products. Though it has already been tried,<sup>184</sup> the enactment of new legislation containing language repealing section 11016 would allow those foreign countries and their subsidiary companies to continue to be inspected under the FDA’s HACCP program as opposed to having to attempt to develop an equivalent system to that of the FSIS.

The United States will soon begin experiencing the negative impacts, economic and otherwise, associated with implementing this rule. For example, amidst the negotiations for the Trans-Pacific Partnership (TPP), Vietnam pressed its opposition to the new inspections. The trade deal, which awaits congressional approval, notably contained an assurance from the Office of the United States Trade Representative that the new catfish inspection program would be “consistent with its obligations” under the WTO’s rules.<sup>185</sup> However, implementing the program as written will likely violate that promise by singling out one product for uniquely difficult regulatory treatment without a compelling scientific reason.<sup>186</sup> Moreover, the rule raises serious questions and concerns about the United States’ commitment to fair play and fair trade on the international stage, potentially opening up the United States to retaliation from other TPP member nations.<sup>187</sup>

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(“[T]he degree of difference . . . in the levels of protection, is only one kind of factor which, along with others, may cumulatively lead to the conclusion that . . . a disguised restriction on international trade in fact results from the application of a measure.”).

183. See Nixon, *supra* note 6, at A15 (“[Ten Asian and Pacific nations] say that the inspection program is a trade barrier erected under the guise of a food safety measure and that it violates the United States’ obligations under World Trade Organization agreements.”).

184. Ron Nixon, *New Inspections for Catfish Stoke Debate Over Safety vs. Trade*, N.Y. TIMES, Nov. 26, 2015, at A24 (explaining that the Obama administration opposed the new inspection program and tried to eliminate it in numerous budgets); Press Release, Senator Jeanne Shaheen, *Shaheen, McCain to Introduce Amendment to Repeal Duplicative Catfish Inspection Program* (May 21, 2013), available at <http://www.shaheen.senate.gov/news/press/release/?id=c23e7d0e-ba91-4c48-849d-e6fcbac8a32e> (announcing that Senators Shaheen and McCain were introducing an amendment to eliminate the catfish inspection program as created by the 2008 Farm Bill).

185. Letter from Michael B.G. Froman, Ambassador, Office of the United States Trade Representative to Vu Huy Hoang, Minister of Industry and Trade, Vietnam (on file at <https://ustr.gov/sites/default/files/TPP-Final-Text-US-VN-Letter-Exchange-on-Catfish.pdf>).

186. *A Catfish Trade Ambush*, WALL ST. J. (Nov. 26, 2015), <http://www.wsj.com/articles/a-catfish-trade-ambush-1448575357?alg=y>.

187. See *id.* (illustrating that a loss before a WTO Panel would give any exporter of Asian catfish the right to retaliate against a range of exports such as beef and soybeans); see also Nixon, *supra* note 184 (quoting James Bacchus, the former chief judge at the court for the World Trade

Concerns such as these will have much broader implications than whatever good may be done by propping up a small number of domestic catfish farmers.<sup>188</sup> As John McCain warned, “[i]f we do not repeal the USDA Catfish Inspection Program, hardworking farmers and ranchers across the United States may find themselves reeling from the effects of a multi-billion dollar trade war.”<sup>189</sup> However, if the sentiment held by the domestic catfish industry is truly based on a deep concern for food safety, the repeal of section 11016 of the 2008 Farm Bill could be accompanied by a statutory effort to replace that intention within the confines of the FDA. This would involve providing the FDA with additional funding to bolster inspections of catfish and ensure their sanitary safety.

Absent a decision to repeal the rule through enacting new legislation, there is a timely alternative that may take shape. Under the Congressional Review Act,<sup>190</sup> Congress is granted the authority to disapprove of “major” rules issued by federal agencies within sixty days of Congress having received the rule.<sup>191</sup> If a resolution of disapproval is enacted by both chambers of Congress within that timeframe and signed by the President, the rule may not take effect and the agency may not issue a substantially similar rule without subsequent statutory authorization.<sup>192</sup> This would be an efficient and effective means for Congress to eliminate this wasteful program.<sup>193</sup> However, given the intense partisanship in Washington, such an outcome seems difficult to achieve.

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Organization, who said that the new catfish inspection office “will not only be inviting a [WTO] challenge to the rule; it will be giving other nations an opening to enact ‘copycat legislation’ which will further disadvantage our exports.”).

188. Nixon, *supra* note 6, at A23 (stating that Vietnamese trade officials wrote to Secretary of State John Kerry and threatened trade retaliation if the program was not repealed).

189. Press Release, Senator John McCain, McCain Requests Vote on Repeal of Wasteful Catfish Program (Jan. 8, 2014), *available at* <http://www.mccain.senate.gov/public/index.cfm/2014/1/senator-john-mccain-requests-farm-bill-conference-vote-on-repealing-wasteful-and-duplicative-catfish-inspection-program>; *see also* Letter from The Honorable Jeff Merkley, Senator, United States Senate and The Honorable Ron Wyden, Senator, United States Senate, to The Honorable Debbie Stabenow, Chairman, Committee on Agriculture, Nutrition & Forestry, United States Senate (Oct. 16, 2013), <https://repealcatfish.files.wordpress.com/2013/10/usda-catfish-letter.pdf> (noting that choking off the supply of imported catfish will “pave the way for retaliation against U.S. agricultural exports, including \$1.3 billion worth of Oregon fruits, vegetables, seeds, greenhouse and nursery products, and beef”).

190. 5 U.S.C. §§ 801–808 (2012).

191. *Id.* § 801(a)(2)(A).

192. *Id.* § 801(b).

193. On December 7, 2015, Republican Senators John McCain and Kelly Ayotte introduced a resolution disapproving of the rule. The resolution would nullify the USDA’s final rules should it pass through both chambers and be signed by President Obama. *See* S.J. Res. 28, 114th Cong. (2015).

In the meantime, Vietnam and other nations that are being unduly burdened by this unnecessary regulatory switch are likely to take action. While an effort to bolster catfish inspections at the FDA may address the food safety concerns, there is little evidence to suggest that additional oversight is necessary, and although a lengthy transition period would be helpful, the process is exceedingly difficult and additional time can only go so far. The rule's lack of necessity, its invalid risk assessment, and its effect as a disguised trade barrier still stand in both of these instances. Therefore, WTO proceedings may still be a viable remedy for foreign catfish exporters who feel they have been disenfranchised. The only path forward that is guaranteed not to result in a United States appearance before a WTO Panel requires the repeal, through either the enactment of new legislation or a resolution of disapproval, of section 11016 of the 2008 Farm Bill.

#### CONCLUSION

The rule requiring the continuous and mandatory inspection of catfish and catfish products unmistakably violates the WTO SPS Agreement and contradicts recent public policy efforts to engage with Asian nations, many of which would face significant setbacks now that the rule has become a reality. There is no scientific evidence supporting this regulatory shift and its arbitrary and unjustifiable nature. Inspecting catfish should not be assigned to the USDA. In order to avoid a dispute before the WTO Panel, section 11016 of the 2008 Farm Bill, which mandated the rule, must be repealed.